

Operating Instructions

**ENGLISH**

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1 Introduction

1.1 Preface

First of all we would like to thank you for purchasing the sealing device.

In these instructions you will find information about using the device, servicing and care as well as process validation.

The sealing device is a microprocessor controlled rotary sealer with printer for packaging sealable pouches and reels (SBS¹).

The sealing device meets the requirements of DIN 58953-7, DIN EN ISO 11607-2 and the resulting DGSV² guideline for validating the sealing process.



Please read these operating instructions carefully before commissioning so that you are familiar with the capabilities of the device and you can make optimum use of its functions.



Always keep these instructions close to the device.

1.2 Legend

	The exclamation mark in the triangle draws your attention to important notes in the operating instructions, which must absolutely be observed.
	This warning sign refers to measures that could result in danger to human health if they are not observed. It is compulsory to observe it.
	Tips with a hand symbol next to them, which relate to daily practice.

¹ Steril-Barriere-System

² Deutsche Gesellschaft für Sterilgutversorgung e.V.

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1.3 Important notice



In accordance with the intended use, the CE marking is displayed based on the following EU directives:

2006/42/CE, 2006/95CE and 2004/108/CE.

Medical device directive 93/42/CE is not applicable to sealing devices.

The limit values of IEC 60601-1 may not be applied in repeated electrical inspections.

The manufacturer accepts no liability whatsoever for damage caused by tests in accordance with standards not listed in the Conformity Declaration.

Note

Because we are constantly improving our products, we reserve the right to modify these operating instructions and the functions described in them.

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1.4 Safety instructions



1. Our products left the plant in perfect safety condition.
2. To maintain this condition, the content of these safety instructions as well as type plates, labeling and safety instructions attached to the device must be observed while handling the device (transport, storage, installation, commissioning, operation and maintenance).
3. This device is suitable for processing laminated films in the heat-sealing process. See also chapter 2.1 "Designated use".
4. Please check the packaging and lodge a complaint for any damage with the carrier or parcel service immediately before installing the device.
5. Before commissioning, ensure that the device does not show any evidence of damage. In case of doubt, contact the manufacturer or a service partner authorized by the manufacturer.
6. Do not operate the device if the power cable or the power plug is damaged. Do not use the device if it does not operate correctly or it is damaged in any way. If the mains cable or the device have been damaged, the device must be repaired by the manufacturer or by one of the manufacturer's authorized service partners.
7. The device must be connected using the mains cable included in shipment to a protective contact socket with a stable voltage. Operation on IT networks is not permitted.
8. Please place the device on a stable base.
9. The device must not be installed and operated in explosive areas.
10. If the sealing device is brought directly from a cold environment into a hot environment, bedewing may occur. Wait until temperature equalization has taken place.
Starting up the device when it is bedewed causes danger to life!
11. Fuse changes and repairs must only be performed by the manufacturer or by one of the manufacturer's authorized service partners.
12. Switch off the device when it is not in use or remove the power plug from the socket.

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13. **Before cleaning: Disconnect from the mains!** Clean the device only with a dry or damp soft cloth and a mild cleaning agent. Do not allow any water to find its way into the device. **Caution!** Never wet clean the device!!
14. Do not insert pointed or flat items into the import slot of the device. This can result in damage to the device and instruments.
15. Do not insert items into the louvers of the device. You may receive an electric shock or the device could be damaged.
16. Do not use the device if you have any doubts about device safety.
17. The device must not be installed or operated by persons under 16 years of age.
18. The device must not be operated unsupervised.
19. It is forbidden to operate the device under the influence of drugs or alcohol.

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2 Before starting Up

2.1 Intended use

The device is intended only for commercial and industrial use and may only be used for the intended use and with following materials.

Sealable materials

Pouches and reels in accordance with EN 868-5 and EN ISO 11607-1*

Paper pouches in accordance with EN 868-4*

HDPE (e.g. Tyvek™, 1059B, 1073B and 2FS)*

Aluminum laminate film

* also with side gusset

The correct sealing temperature must be identified by means of test sealings.

The device output depends on the condition of the sealing material used.

Non-sealable materials

Polyethylene film

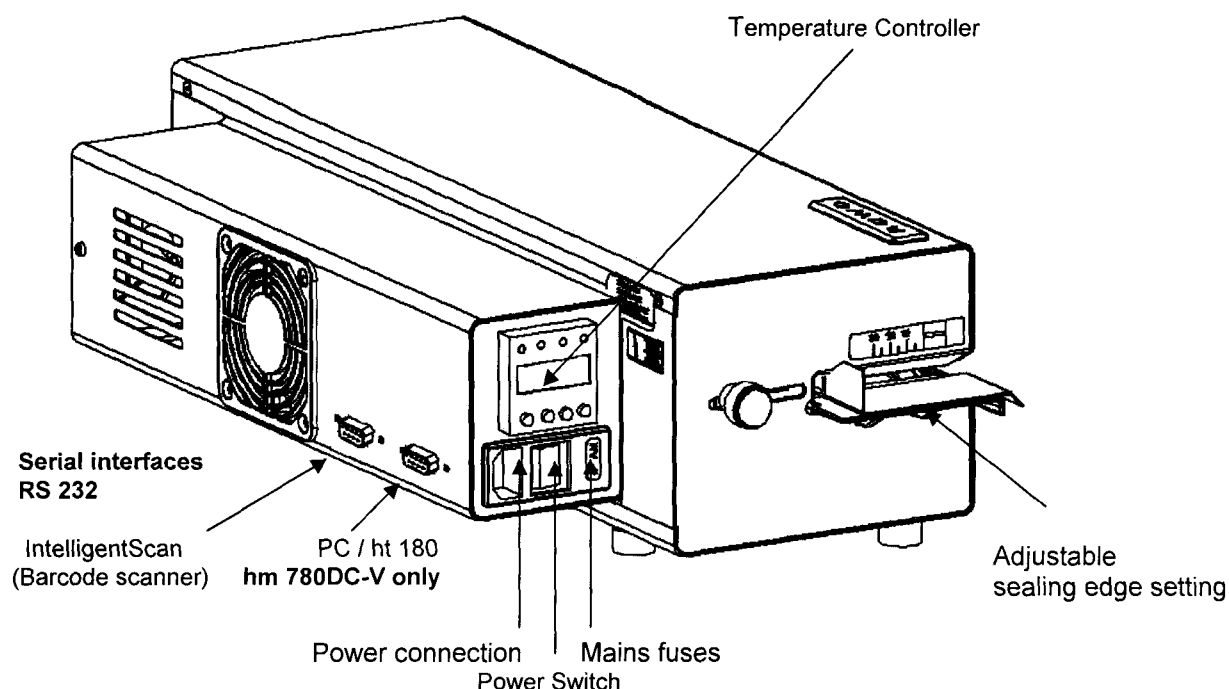
Soft PVC film

Hard PVC foils

Polyamide film

Polypropylene film

2.2 Composition and function



Sealing and printing process sequence

1. After the sterilization packaging has been inserted, the feed process is started automatically by means of photoelectric cell.
2. The sterilization packaging is now fed and the sealing seam area is heated up to the set sealing temperature by the heating units located at the top and bottom. The sealing temperature is monitored.
3. The sealing seam, which is now heated, is pressed together by the sealing roller and sealed.
With the hm 780 DC-V device, besides temperature, contact pressure and sealing speed are monitored as well.
4. The printing process is triggered by means of a photoelectric cell when the pressure is switched on and the activated print data is printed onto the sealed packaging.
5. The finished sterilization packaging is transported to the extraction side.
6. If no item to be sealed is fed in, the feed switches off after approximately 30 seconds.
7. The set parameters remain saved after the device is switched on or off, or after a power failure. The date and time are updated automatically (auto safe).

2.3 Installation instructions and commissioning

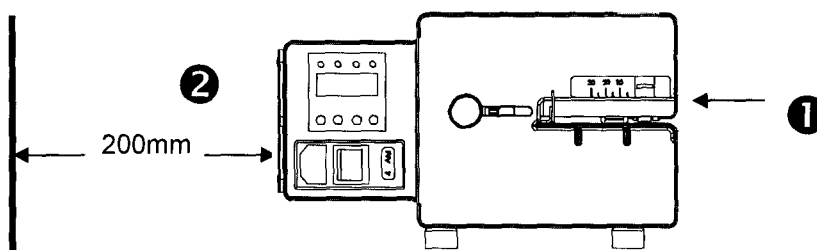


Prior to installation, read the safety notices in chapter 1.4

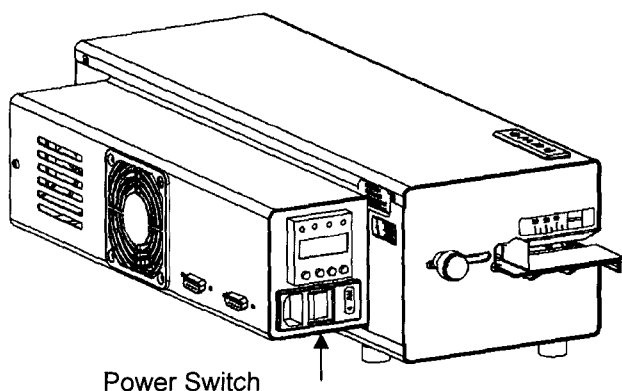
2.3.1 Installation

Place the device on a horizontal surface.

- ❶ Please do not lift the device by the in feed section.
- ❷ The distance from the device to a wall must be at least 200 mm.



2.3.2 Commissioning

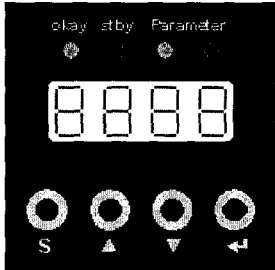
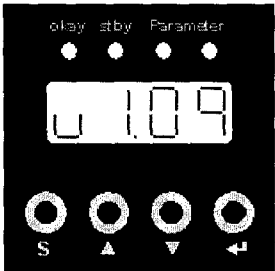
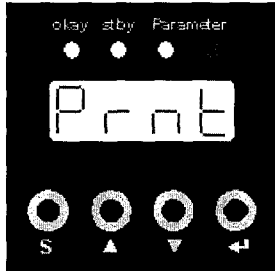
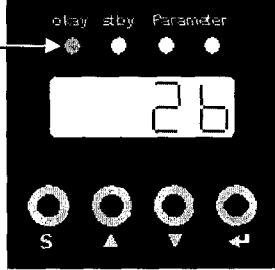
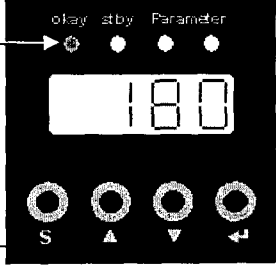


To switch on the device, press the power switch on the left-hand side.

After a short self-test and after the selected sealing temperature has been reached, the device is operational. You will see this when the "okay" indicator light has stopped flashing (see chapter 3.1).

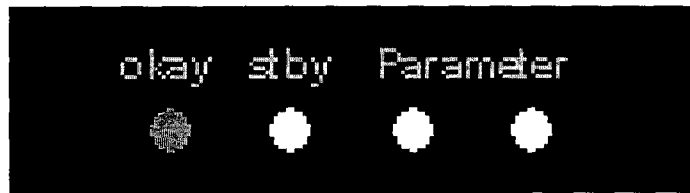
3 Configuration of device

3.1 Basic functions

Switch on the device The self test runs for approx. 5 seconds (see Chapter 2.3)	Indicator lights and display test	
	Software version indicator	
	Configuration test	
The "okay" indicator light flashes until the set temperature is reached, after about 3 - 4 minutes	"okay" inspection light flashes Current actual temperature display	
After reaching the set temperature, the indicator light remains permanently on	"okay" inspection light on Selected actual temperature is reached The device is ready for use	

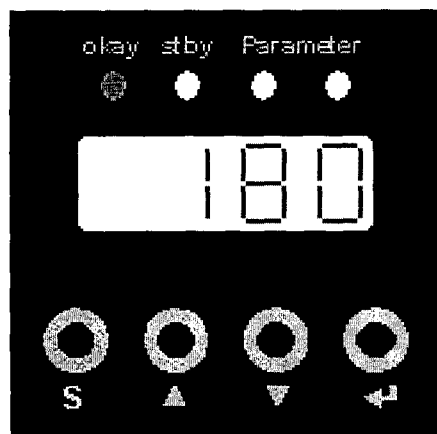
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
3.2 Inspection light functions



Function				
Device switched on Warm-up phase	flashes	off	off	off
Sealing temperature = $\pm 5^\circ$ hm 780 DC-V Contact pressure = $\pm 20\%$ Sealing speed = $\pm 10\%$	on	off	on	off
Sealing temperature <> $\pm 5^\circ$ hm 780 DC-V Contact pressure <> $\pm 20\%$ Sealing speed <> $\pm 10\%$	off	on	off	on
Standby	off	on	off	on
warming up after standby or change in set temperature	flashes	off	off	on

3.3 Button functions



			
Menu level 1 Menu level 2 activation Press for 3 s Menu level 3 activation Press for 7 s	Switch printer off/on	Personal identification input	"Seal check" activation
Menu level 2 Sealing temperature input	Temperature value + 1	Temperature value -1	Confirm input
Menu level 3 3.1 Sealing parameters view 3.2 Print data configuration 3.3 Data input	Switchover 3.1 - 3.2 - 3.3 on Input value +1	Switchover 3.1 - 3.2 - 3.3 off Input value -1	Confirm input

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3.4 Device settings

3.4.1 Sealing temperature input

<div data-bbox="175 369 279 481"></div> <p>Press button for 3s</p> <p>Change set value</p> <div data-bbox="167 828 391 940"> </div>	<p>Display for 1s</p> <div data-bbox="630 436 901 548"></div> <p>Current temperature set value display</p> <div data-bbox="630 672 901 784"></div> <div data-bbox="630 817 901 929"></div>	<div data-bbox="1029 817 1141 929"></div> <p>Confirm input</p>
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3.4.2 Switch printer off and on

<div data-bbox="175 1131 279 1243"></div> <p>Press button</p> <p>Switch printer off or on</p> <div data-bbox="167 1556 391 1668"> </div>	<p>Display for 1s</p> <div data-bbox="630 1187 901 1299"></div> <p>Current setting display</p> <p>Printer switched on</p> <div data-bbox="630 1422 901 1534"></div> <p>Printer switched off</p> <div data-bbox="630 1579 901 1691"></div>	<div data-bbox="1013 1590 1125 1702"></div> <p>Confirm input</p>
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3.4.3 Personal code input

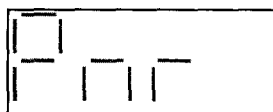


Press button

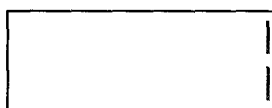
Select new code



Display for 1s



Current personal code display












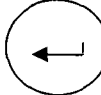


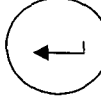
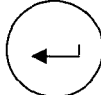
☞ In this display
an alphanumeric code has been
input by barcode scanner




















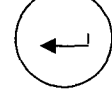


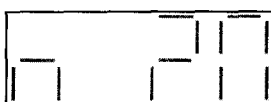
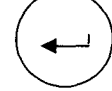
Confirm input










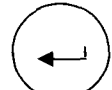




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3.4.4 Data input



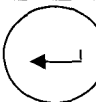

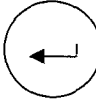
<p>Activate</p> <p></p> <p>Press button for 7s</p> <p>Switchover to data input</p> <p> </p> <p>Keylock</p> <p>active Input 1 - 9999</p> <p>inactive Input 0</p> <p> </p>	   	<p> Confirm selection</p> <p>Select data</p> <p> </p> <p> Confirm selection</p> <p> Confirm input</p>
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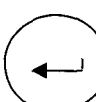
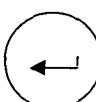
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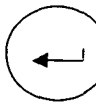
<p>Date and time</p>		 Confirm selection
<p>Day input</p> <div data-bbox="175 414 399 515">   </div>		 Confirm input
<p>Month input</p> <div data-bbox="175 560 399 660">   </div>		 Confirm input
<p>Year input</p> <div data-bbox="175 694 399 795">   </div>		 Confirm input
<p>Hour input</p> <div data-bbox="175 862 399 963">   </div>		 Confirm input
<p>Minute input</p> <div data-bbox="175 1008 399 1108">   </div>		 Confirm input






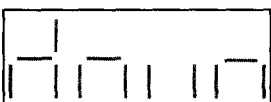

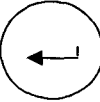
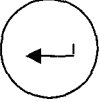
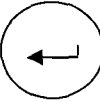

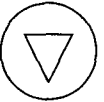


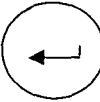
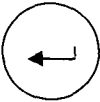




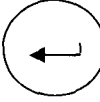
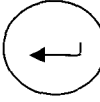
<p>Expiry date</p>		 Confirm selection
<p>Day input</p> <div data-bbox="175 1377 399 1478">   </div>		 Confirm input
<p>Month input</p> <div data-bbox="175 1523 399 1624">   </div>		 Confirm input
<p>Year input</p> <div data-bbox="175 1657 399 1758">   </div>		 Confirm input

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<p>Batch Input 0000 - 9999</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <div style="display: flex; justify-content: space-around;"> L 0 0 0 </div> </div> <div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-around;"> 0 0 0 0 </div> </div>	<div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm selection</div> </div> <p style="margin-top: 20px;">  In this display an alphanumeric code has been input by barcode scanner </p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 150px;"> <div style="display: flex; justify-content: space-around;"> _ _ _ _ </div> </div> <div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm input</div> </div>
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<p>Pack content quantity Input 0 - 99</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <div style="display: flex; justify-content: space-around;"> P 0 0 </div> </div> <div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-around;"> </div> </div>	<div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm selection</div> </div> <div style="display: flex; align-items: center; margin-top: 20px;">  <div style="margin-left: 10px;">Confirm input</div> </div>
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<p>Sterilization type</p> <p>Sterilization type selection</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>	<div style="margin-bottom: 10px;"> <p>Steam</p> <div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-around;"> S T E A </div> </div> </div> <div style="margin-bottom: 10px;"> <p>Ethylene oxide</p> <div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-around;"> E O </div> </div> </div> <div style="margin-bottom: 10px;"> <p>Formaldehyde</p> <div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-around;"> F O </div> </div> </div> <div> <p>Plasma</p> <div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-around;"> P L A S </div> </div> </div>	<div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm selection</div> </div> <div style="display: flex; align-items: center; margin-top: 100px;">  <div style="margin-left: 10px;">Confirm selection</div> </div>
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<p>Batch counter Input 0 - 9999</p> <div data-bbox="177 360 400 461">   </div> <p>Counting direction selection</p> <p>If counting direction down has been selected, an alarm sounds when the value 0 is reached</p> <p>Switch off batch counter</p>	<div data-bbox="632 219 903 320">  </div> <div data-bbox="632 365 903 465">  </div> <p>Counting direction up</p> <div data-bbox="632 521 903 622">  </div> <p>Counting direction down</p> <div data-bbox="632 678 903 779">  </div> <p>Switch off batch counter</p> <div data-bbox="632 835 903 936">  </div>	<div data-bbox="1015 226 1115 327">  </div> <p>Confirm selection</p> <div data-bbox="1015 360 1115 461">  </div> <p>Confirm input</p> <div data-bbox="1015 707 1115 808">  </div> <p>Confirm selection</p>
<p>Standby Input 0 – 60min</p> <div data-bbox="177 1155 400 1256">   </div> <p>If the motor was not started before reaching the set time, then the temperature is set automatically to 50°C / 122°F.</p>	<div data-bbox="632 1010 903 1111">  </div> <div data-bbox="632 1155 903 1256">  </div> <p>The brief insertion of a package causes the temperature to reset to its previous set value. Once this has been reached, the device is again ready for use</p>	<div data-bbox="1015 1016 1115 1117">  </div> <p>Confirm selection</p> <div data-bbox="1015 1155 1115 1256">  </div> <p>Confirm input</p>
<p>Operating data View of the operating hours and the absolute batch counter</p> <p>View selection</p> <div data-bbox="177 1659 400 1760">   </div>	<p>Operating hours</p> <div data-bbox="632 1496 903 1597">  </div> <p>Absolute batch counter</p> <div data-bbox="632 1832 903 1933">  </div>	<div data-bbox="1015 1496 1115 1597">  </div> <p>Confirm selection</p> <div data-bbox="1015 1731 1115 1832">  </div> <p>Confirm selection</p>

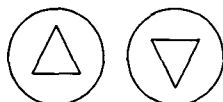
hm 780DC
hm 780DC-V

Configuration

Section 3

Units of measurement

Units of measurement selection



Europe

Temperature in °C

hm 780 DC-V

Contact pressure in N

Sealing speed in m/min

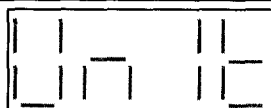
USA

Temperature in °F

hm 780 DC-V

Contact pressure in lbf

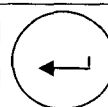
Sealing speed in in inch/mm



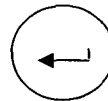
Units of measurement Europe



Units of measurement USA



Confirm selection



Confirm selection

Character width



Input 0 - 2

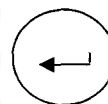
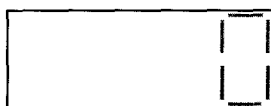
In accordance with the setting selected, the characters are printed in various widths

Input A

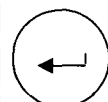
Automatic setting of the character width, depending on the width of the packaging and the length of the print line.

PNR

PNR

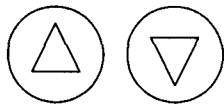


Confirm selection



Confirm input

Monitoring
Personal number
Input 0 – 60min

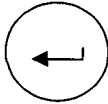
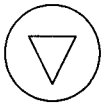
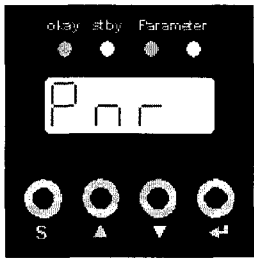
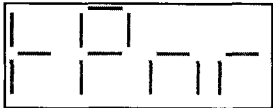


When inputting a time > 0
monitoring of the personal number is
active and the motor can only be
started if the value of the
personal number is 1-9999

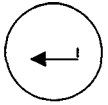
Once the set time is reached, the
personal number is automatically set
to 0

If the personal number is 0000 and a
package is inserted, a command
prompt appears

By inputting a personal number of
1-9999, the lock of the drive motor is
disabled and the command prompt
disappears





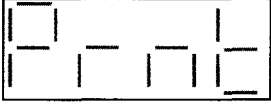
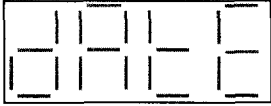

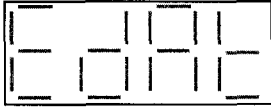

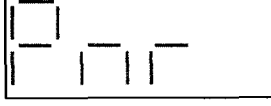


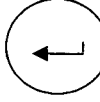

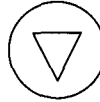












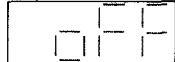

















Confirm selection



Confirm input

3.4.5 Print data selection

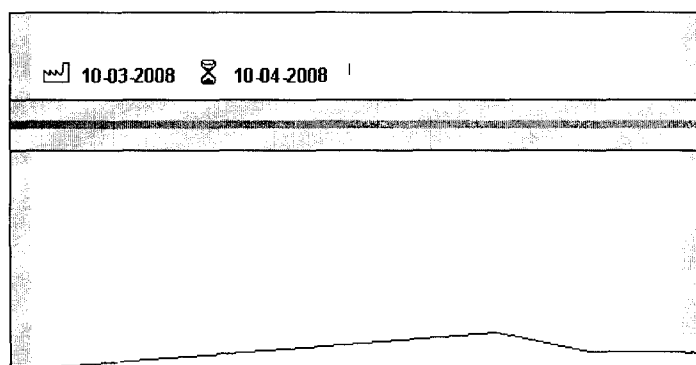
<p>Activate</p> <p></p> <p>Press button for 7s</p> <p>Switchover to print data</p> <p> </p> <p>The print sequence is predefined. Activated print data is always printed in this sequence</p> <p>Sterilization date Time Expiry date Batch counter Personal identification Batch counter Sterilization type Pack content quantity Text (with barcode list and attached barcode scanner)</p>	<p></p> <p></p> <p>Sterilization date</p> <p></p> <p>Time</p> <p></p> <p>Expiry date</p> <p></p> <p>Batch number</p> <p></p> <p>Personal identification</p> <p></p> <p>Batch counter</p> <p></p> <p>Sterilization type</p> <p></p>	<p> Confirm selection</p> <p>Select data to be printed</p> <p> </p> <p>   </p> <p>   </p> <p>   </p> <p>   </p> <p>   </p> <p>   </p> <p>   </p>
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	Pack content quantity		
	Text		

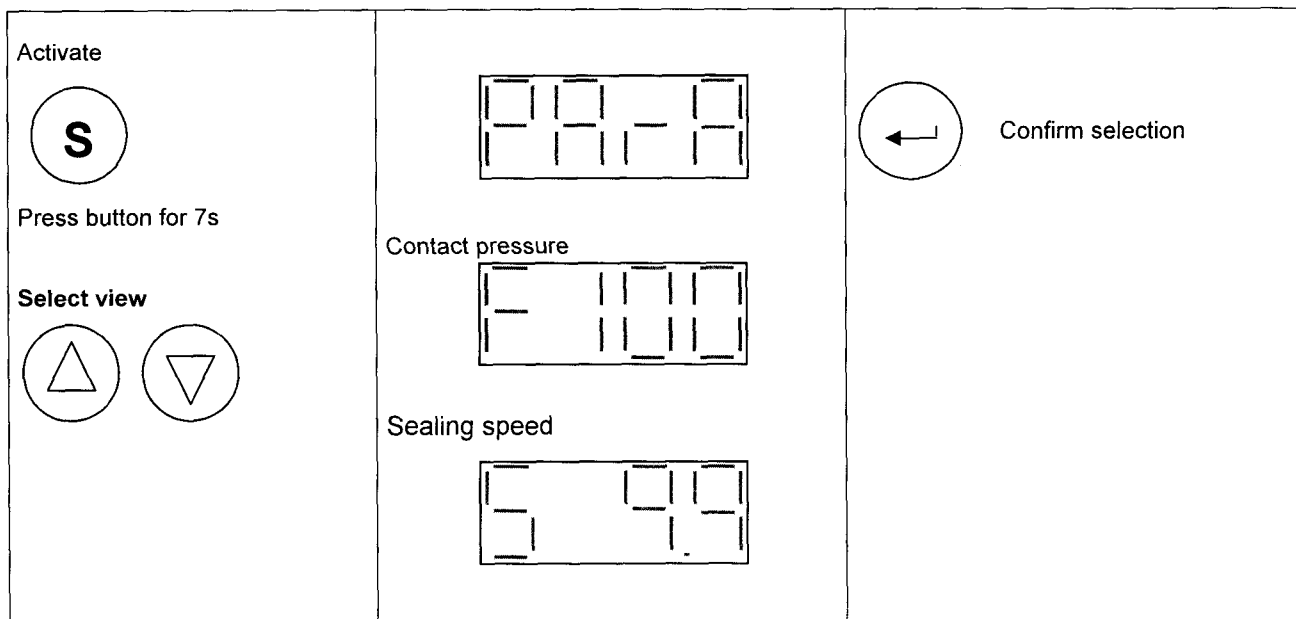
Example

Printing the sterilization date and the expiry date



hm 780DC hm 780DC-V	Configuration	Chapter 3
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3.4.6 View of sealing parameters contact pressure and sealing speed only hm 780DC-V device



hm 780DC hm 780DC-V	Configuration	Chapter 3
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3.4.7 IntelligentScan, connection of a barcode scanner

The following inputs and functions can be implemented using a hm 780 BR barcode scanner (item number 1.421.006) connected to the "IntelligentScan" interface (see page 9), and relevant barcode lists:

Inputs and functions via the controller or using the barcode scanner

Inputs

Sealing temperature input	Page 14
Personal code input	Page 15
Batch number input	Page 18
Pack content quantity input	Page 18
Sterilization type selection	Page 18
Batch counter preset	Page 19
Character width selection	Page 20
Print data selection	Page 22

Functions

Switching the printer off or on	Page 14
Activating/deactivating standby function	Page 19
Switching personal number monitoring off or on	Page 21
Seal check activation	Page 26

Inputs and functions only with the barcode scanner

Inputs

- Input of a 10-digit alphanumeric personal code
- Input of a 10-digit alphanumeric batch designation
- Input of an alphanumeric text
- Expiry dates in 1, 3, 6, 9, 12, 24 and 60 months

Functions

- Switching the batch counter off or on



The hm 780 BR barcode scanner (item number 1.421.006) is supplied with a CD (item number 1.490.016) enclosed, facilitating the generation and recording of the barcode lists on a PC.

For further information, please contact your authorized service partner or the hawo service line: +49 (0) 6261 9770 0

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3.5 Operation and sealing process

- The material to be sealed must be sealed according to the manufacturer's instructions.
- Set the peel edge width:
After the locking device has been loosened, the peel edge can be set by shifting the in feed section variably between 0 mm and 35 mm. A sufficient protrusion must be available between the sealing seam and the reel interface given on the extraction side (in accordance with DIN 58953-7 min. 10 mm).
- Sterilization packaging must be inserted from the left-hand side, always with the side to be printed face down.
The drive is switched on automatically.
- Remove the sealed sterilization packaging and leave briefly to cool.



Sealable pouches and reels must only be filled to $\frac{3}{4}$ full (DIN 58953-7). The limited filling prevents a load that is too large from being placed on the sealing seams.



The correct sealing temperature must be identified by means of sealing tests. Sealing must be performed in such a way that the sealing seam meets the quality characteristics requirements of EN ISO 11607-2, even with varying material thicknesses. The following quality characteristics must be met:

- Intact sealing across the entire sealing seam width
- No channels or open seals
- No punctures or tears
- No delamination or material separation

hawotest SEAL CHECK is considered suitable for checking these quality characteristics.* The hawotest SEAL CHECK seal indicators are available separately.

* see the DGSV guideline for validation of the sealing process

hm 780DC hm 780DC-V	Configuration	Chapter 3
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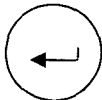
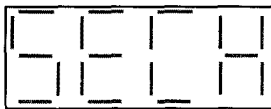
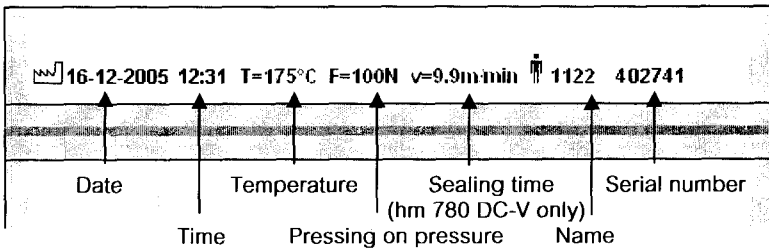
3.6 Sealing seam test – "Seal Check"

Testing of the critical process parameters temperature, contact pressure and sealing time with "SEAL CHECK".

This test should be performed before and after the daily working process and/or before/after each load and can be documented by routinely filing the printout (DIN EN ISO 11607-2).

The additional use of the SEAL CHECK sealing indicator in combination with the SEAL CHECK function of the sealing device is recommended.

Before the test, the device must be ready for use and the set temperature must have been reached.

<p>Device ready for use Specified set temperature has been reached</p>  <p>Press button</p>	
<p>Sterilization packaging, minimum width 200 mm and insert SEAL CHECK indicator strips if necessary</p>	

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4 Troubleshooting and servicing

4.1 Troubleshooting checklist



The trouble shooting suggestion marked with a * may only be carried out by a service partner authorised by the manufacturer.

Malfunction	Possible cause	Troubleshooting
Device does not switch on No data in the display	Mains connection - Mains cable not plugged in	Check mains connection and connect to another socket if necessary
	- Mains cable defective	Replace mains cable
	Mains fuse	Replace mains fuse* ! In case of repeated failure you must have the device fuse checked
	Temperature controller defective	Replace Temperature controller*
Device not heating up	Set temperature too low	Increase set temperature (see page 13)
	Temperature limitation active	Reset the temperature limiter by pushing down the pin ! In case of repeated activation you must have the device checked
	Temperature sensor	Replace temperature sensor*
	Heating element	Check heating element and replace if necessary*
	Temperature controller defective	Replace Temperature controller
No feed	SST Module defective	Replace SST Module*
	Conveyor belt - damaged - no feed	Replace conveyor belt Check belt tension
	Front flap not closed	Close front flap
	Motor - sensor	Replace light barrier*
	Front flaps - sensor	Replace front flap sensor*
	Motor	Replace motor*
	Temperature controller defect	Replace Temperature controller*

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Malfunction	Possible cause	Troubleshooting
Uneven material feed or loud running noise	Conveyor belt guide Conveyor belt - damaged - no feed Motor	Replace PTFE belt on guide unit (see pages 25-26) Replace conveyor belt Check belt tension Replace motor*
Sealing seam does not hold	Temperature too low Contact pressure too low Sealing unit - Distance between sealing units too large	Increase temperature Adjust the contact pressure of the sealing roller or replace the sealing roller* Set sealing unit clearance to 0.5 mm*
Sealing seam distorted	Contact pressure too high	Adjust sealing seal roller contact pressure or replace sealing roller*
Paper side of the packaging discolored or side gusset shrunk	Temperature too high	Reduce temperature (see page 13)
No imprint or imprint incomplete	Programming - Printing start margin incorrectly set Ribbon Printer control Switched – mode power supply defective	Program the printing start margin again (see page 12) Ribbon not inserted correctly Replace ribbon. (see page 24) Replace printer control* Replace power supply*
Imprint too weak	Ribbon Print head Paper - pressure roller	Replace ribbon. Adjust print head again Paper - adjust pressure roller

4.2 Customer service

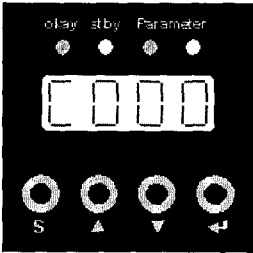


Your hawo customer service is at your disposal Monday through Friday 8:00 AM through 5:00 PM and by phone on +49 (0)6261-9770-31. Please also feel free to send any questions you may have to the following e-mail address: service@hawo.com

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4.3 Alarm functions and error displays

4.3.1 Alarm functions

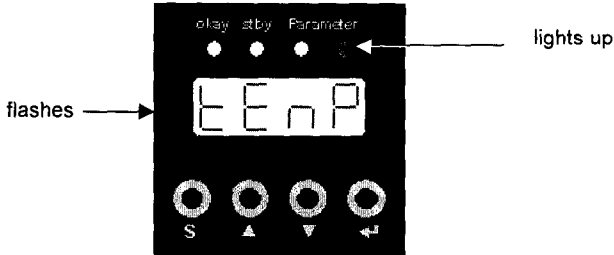
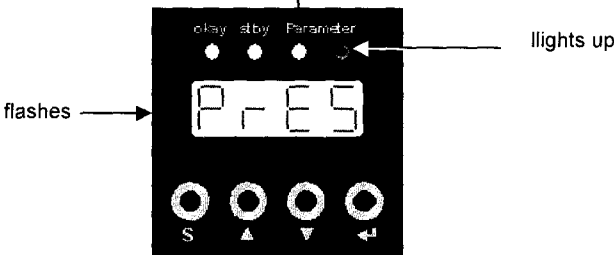
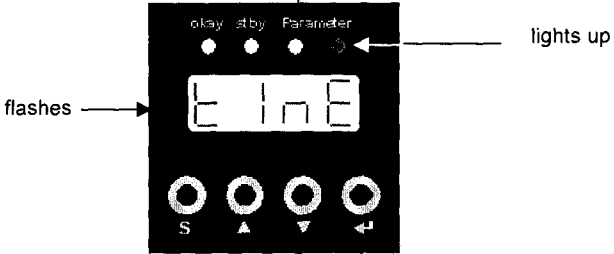
Batch counter, set to count down, has reached the value 0	flashes →	
		Canceling the Alarm Set batch counter to a value > 0 or Set batch counter direction to up see page 19

hm 780DC hm 780DC-V	Troubleshooting and servicing	Section 4
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4.3.2 Error displays



The trouble shooting suggestion marked with a * may only be carried out by a service partner authorised by the manufacturer.

Sealing temperature outside tolerance	
Possible cause Temperature sensor defective Temperature Controller defective SST module defective	Troubleshooting Replace temperature sensor* Replace controller* Replace SST module*
Only hm 780 DC-V Contact pressure outside tolerance	
Possible cause DMS module not adjusted / calibrated DMS module defective	Troubleshooting Adjust / calibrate DMS module again* Replace DMS module*
Only hm 780 DC-V Sealing speed outside tolerance	
Possible cause Motor defective	Troubleshooting Replace motor*

hm 780DC hm 780DC-V	Troubleshooting and servicing	Section 4
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4.4 Servicing / calibration



Like all technical devices, your device is also subject to technical wear. In order to guarantee continuous operational readiness, your device should be inspected regularly by a competent person and serviced and calibrated at least once per year by the manufacturer or by one of the manufacturer's authorized service partners.

Maintenance chart	Ink ribbon	PTFE strip for guide die	Pressure roller	Toothed belt	Sealing die interval	Critical process parameters calibration
At least every 3 months						
Depending on use, at least once annually						

Legend:



4.5 Parts Service



Simply order parts by fax:

- Please copy the following pages according to the parts required.
Page 31: Parts required for maintenance and wear
Page 32: Replacement parts

- Enter machine number. _____
- Enter machine model _____
- Enter name, address, fax number and order number.
- Mark items required
- Enter quantity required.
- Sign order.
- Fax order.

No.: 123456 Type: hm 780 DC-V <small>Bitte diese Daten bei Ersatzteilbestellung angeben. Please state this data when ordering spares. Veuillez indiquer ces données en cas de commande des pièces de rechange.</small>	

To:

Sender:

Fax No.

Your order no.: _____		Date _____	
Machine model _____		Seral number _____	
<input checked="checked" type="checkbox"/>	Designation	Part No	qty
<input type="checkbox"/>	Ink ribbon black	6.813.104	
<input type="checkbox"/>	Ink ribbon red	6.813.224	
<input type="checkbox"/>	PTFE strip for upper guide rail	6.105.178	
<input type="checkbox"/>	PTFE strip for lower guide rail	6.105.177	
<input type="checkbox"/>	Pressure roller plastic	2.230.008	
<input type="checkbox"/>	Toothed belt drive	6.271.018	
<input type="checkbox"/>	Toothed belt, material transport	6.271.019	
<input type="checkbox"/>	Heating cartridge	6.536.024	
<input type="checkbox"/>	Upper sealing die complete	1.616.049	
<input type="checkbox"/>	Lower sealing die complete	1.616.050	
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>	Print head	1.653.002	
<input type="checkbox"/>	Reed Contact	6.543.011	

Signature _____

To:

Sender:

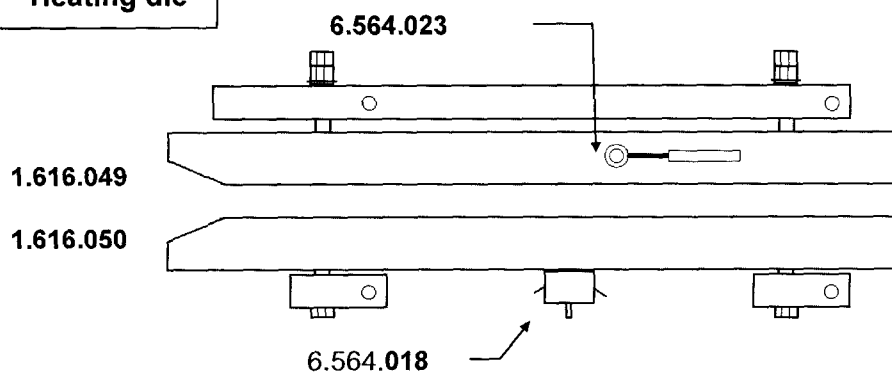
Fax No.

Your order no.: _____		Date _____	
Machine Model _____		Serial number _____	
<input checked="" type="checkbox"/>	Designation	Part No	qty
<input type="checkbox"/>	Temperature control 100 - 245V	6.564.042	
<input type="checkbox"/>	Printer control	1.461.013	
<input type="checkbox"/>	DMS Module Only hm 780 DC-V	1.410.018	
<input type="checkbox"/>	SST Module	1.461.014	
<input type="checkbox"/>	Switched –mode power supply	6.533.001	
<input type="checkbox"/>	Light barrier	1.561.003	
<input type="checkbox"/>	hm 780 DC		
<input type="checkbox"/>	Gear motor 230V	1.212.026	
<input type="checkbox"/>	Gear motor 115V	1.212.027	
<input type="checkbox"/>	Gear motor 100V	1.212.028	
<input type="checkbox"/>	hm 780 DC-V		
<input type="checkbox"/>	Gear motor 230V	1.212.020	
<input type="checkbox"/>	Gear motor 115V	1.212.021	
<input type="checkbox"/>	Gear motor 100V	1.212.022	
<input type="checkbox"/>	Motor ink ribbon	1.212.012	
<input type="checkbox"/>	Temperature limit switch	6.564.018	
<input type="checkbox"/>	Thermocouple	6.564.023	
<input type="checkbox"/>	Fan 24V	6.212.028	

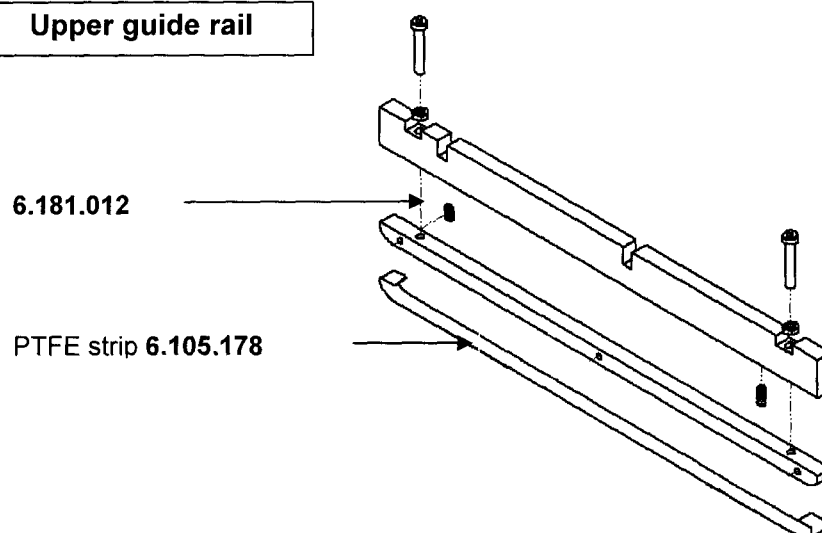
Signature _____

4.6 Replacement part orders- allocation of article numbers

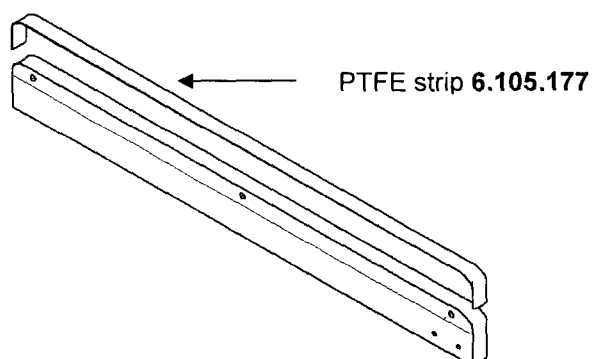
Heating die



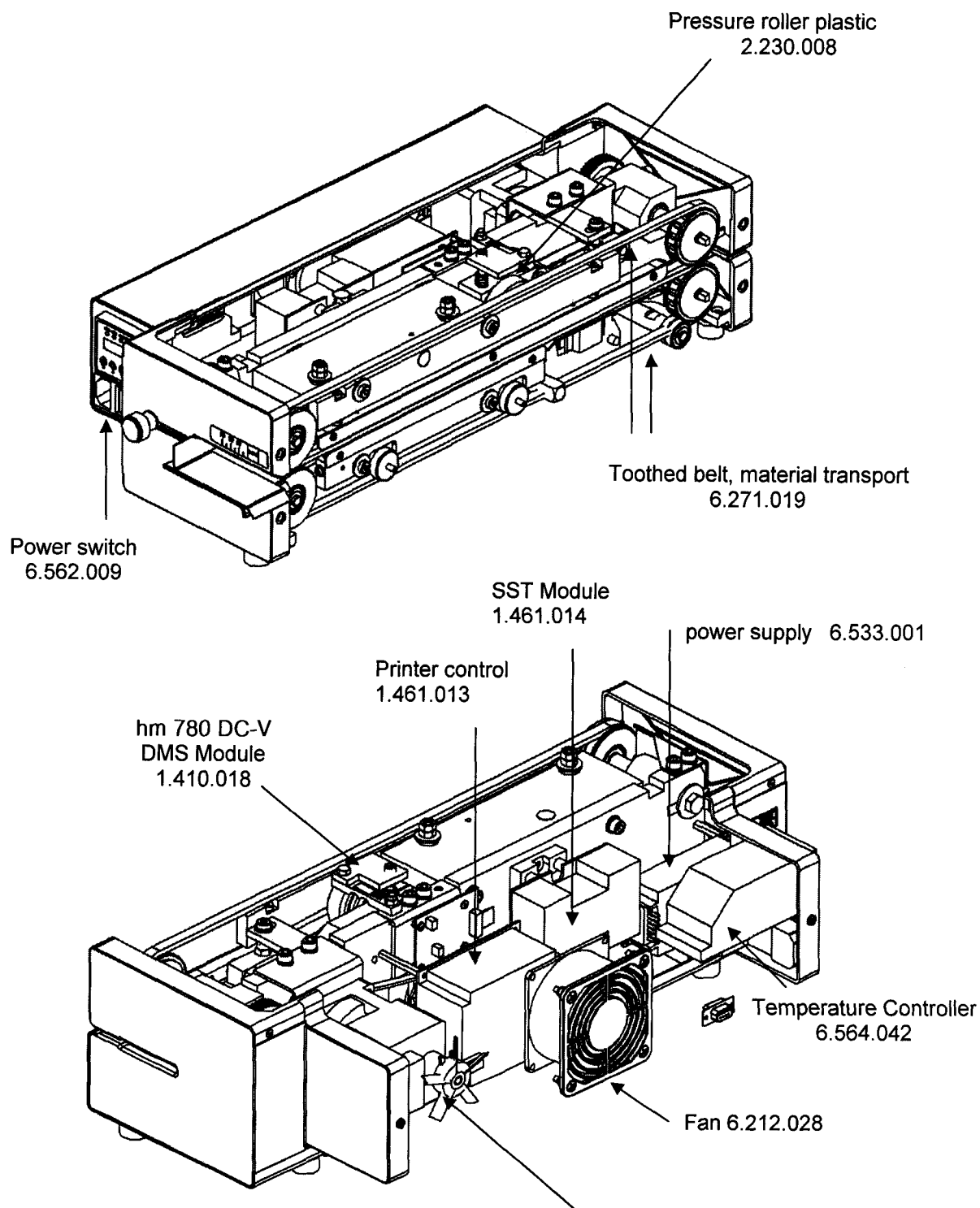
Upper guide rail



lower guide rail



4.7 Spare part ordering – Complete overview



hm 780 DC	Gear motor 230V	1.212.026
	Gear motor 115V	1.212.027
	Gear motor 100V	1.212.028
hm 780 DC-V	Gear motor 230V	1.212.020
	Gear motor 115V	1.212.021
	Gear motor 100V	1.212.022

4.8 Information about replacing wearing and spare parts

! Please use only genuine replacement parts

Replacing ink ribbon

→ Switch off machine

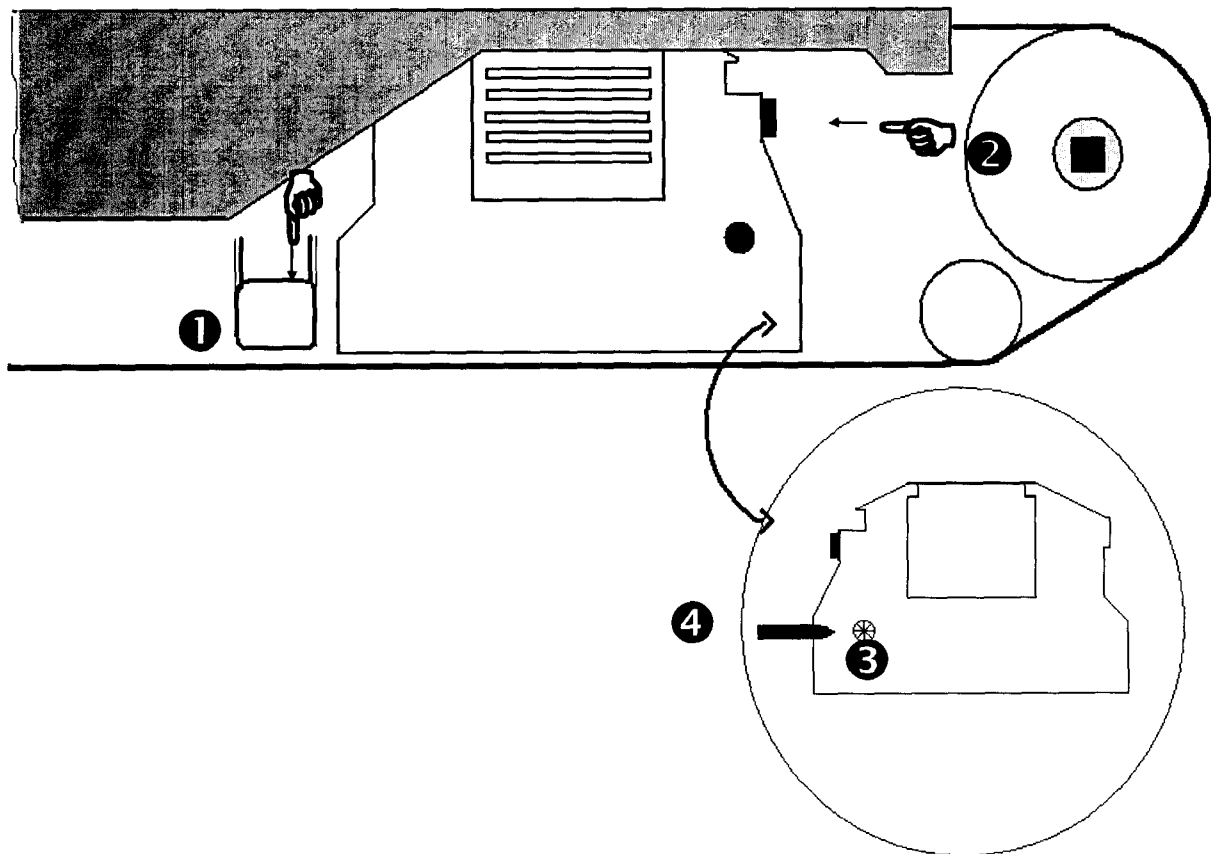
- Open front flap, set in feed section to 0 if appropriate
- Press lever for ink ribbon holder ❶ down with left hand.
- Press holder for ink ribbon cassette ❷ to side and remove cassette.
- Insert new ink ribbon cassette



Always ensure that the transport opening ❸ in the cassette is attached to the transport shaft ❹.

- Press ink ribbon cassette toward rear until holder ❷ catches
- Close front flap

→ Switch on machine and check printing function after reaching nominal temperature



Maintenance Information

! Please use only genuine replacement parts

Replacing PTFE strip on guide rail

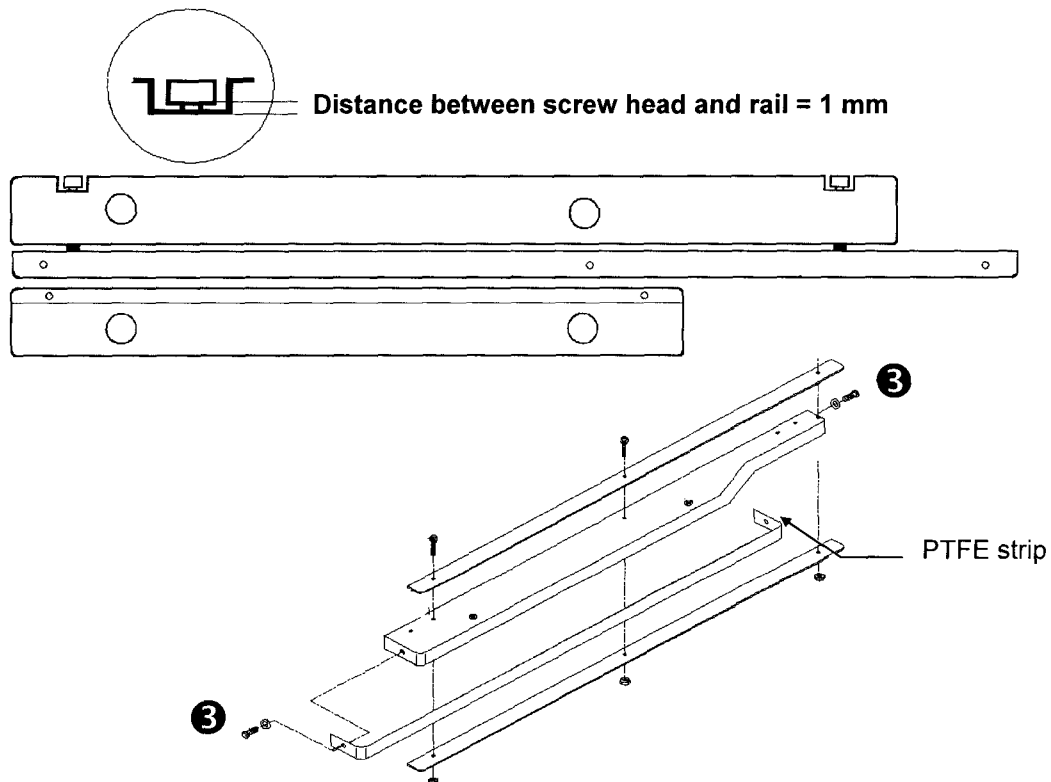
→ Switch off machine and DISCONNECT POWER PLUG !

- Open housing
- Remove mounting screws **1** for upper guide rail and remove guide rail or
- Remove mounting screws **2** for lower guide rail and remove guide rail
- Remove mounting screws **3** and detach PTFE strip
- Pull backing foil off of new PTFE strip and glue new PTFE strip on straight and without wrinkles
- Fasten PTFE strip with screws **3**
- Install guide rail



When installing the upper guide rail before fastening, push the die down so that the interval between the screw head and rail is 1 mm on both sides. This ensures the correct contact pressure for the guide rail.

- Close housing



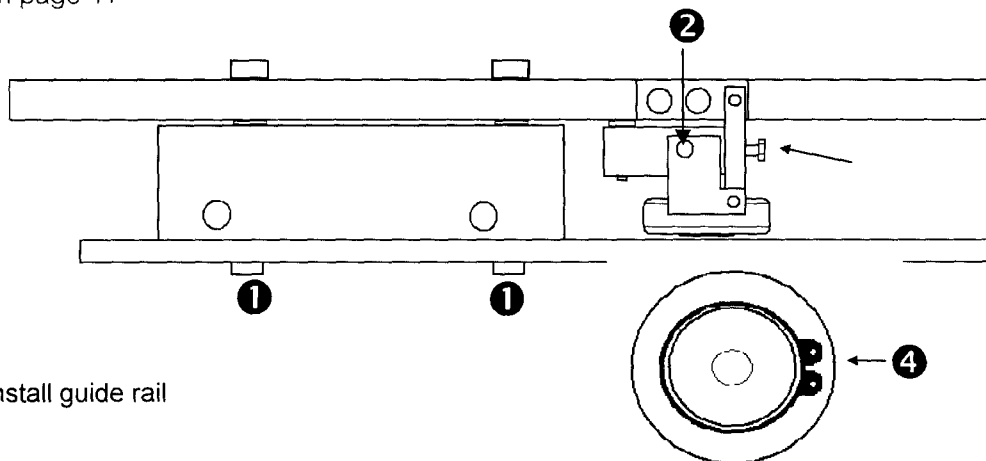
Maintenance Information

! Please use only genuine replacement parts

Replacing pressure roller

→ Switch off machine and DISCONNECT POWER PLUG !

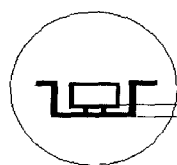
- Open housing
- Remove mounting screws **1** for upper guide rail and remove guide rail.
- Unscrew pressure adjustment screw **2** approx. 5 mm
- Loosen mounting screw **3** and pull pressure roller completely out of holder
- Detach snap ring **4** and remove pressure roller
- Install new pressure roller and fasten with snap ring **4**
- Position complete pressure roller in holder, center in relation to bottom roller and tighten mounting screw **3**
- Adjust contact pressure by screwing in adjustment screw **2** according to calibration instructions on page 41



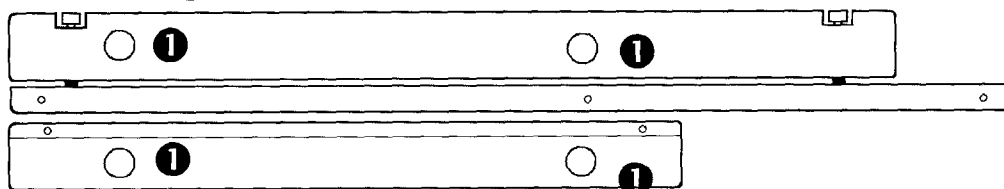
- Install guide rail



When installing the upper guide rail before fastening screws **1**, push the die down so that the interval between the screw head and rail is 1mm on both sides. This ensures the correct contact pressure for the guide rail



Distance between screw head and rail = 1mm



- Close housing

4.9 Process parameters adjustment



After adjustment, the device should remain switched on for a further 10 seconds!

4.9.1 Temperature control



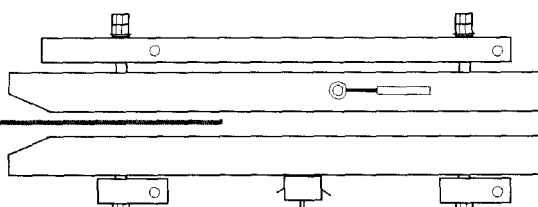
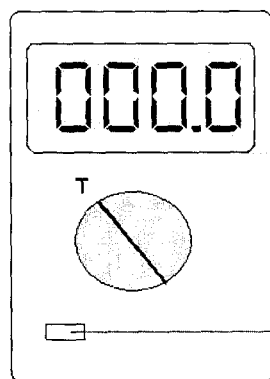
The temperature control adjustment should always be carried out after replacing a heating element, after replacing the temperature sensor and after replacing the temperature control

The temperatures **120 °C** and **200 °C** are measured consecutively and the difference between set and actual value corrected.

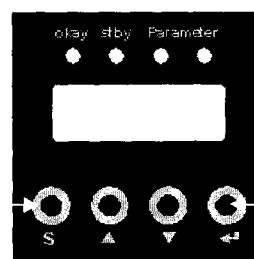
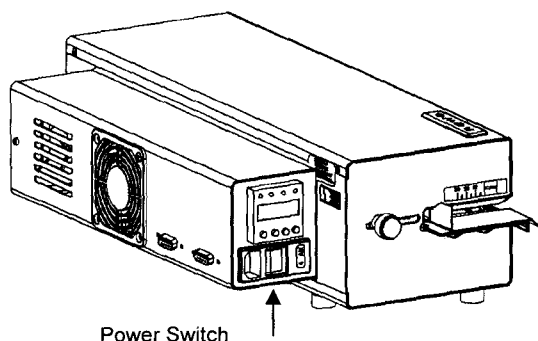
After reaching the set temperature, this is stabilized for 120 s. At the end of 120 s, the temperature value measured with the temperature gauge is input

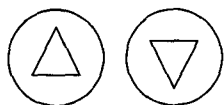
Process

Insert the temperature sensor of a temperature measuring device from the inflow side on the left, between the sealing units



Press both buttons simultaneously and switch on the device.



**Select temperature
adjustment**

The set temperature of the
device is set automatically to
120 °C

After reaching that temperature
the stabilizing time starts

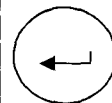
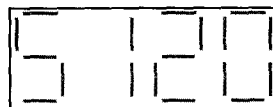
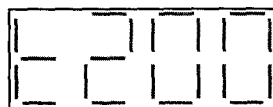
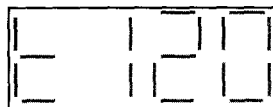
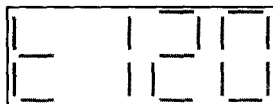
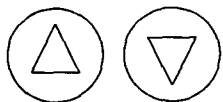
After expiry of that time
input the temperature measured
with the measuring device



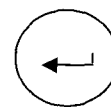
The set temperature of the
device is set automatically to
200 °C

After reaching that temperature
the stabilizing time starts

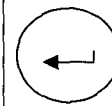
After expiry of that time
input the temperature measured
with the measuring device



Confirm selection



Confirm input



Confirm input

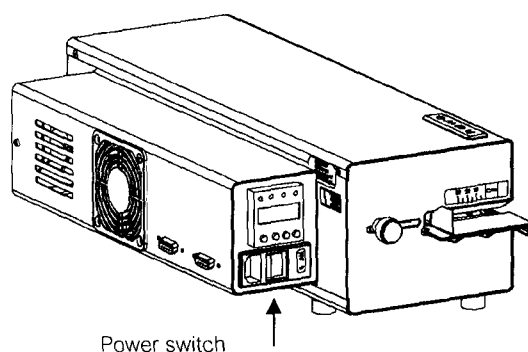
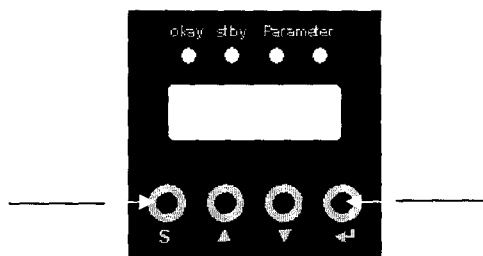
4.9.2 Contact pressure ONLY hm 780 DC-V device



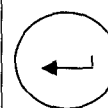
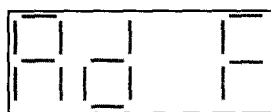
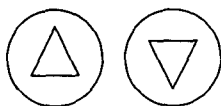
Setting of the contact pressure should always be done after replacing the temperature control, after replacing the DMS module and after replacing the pressure roller.

Only then is the contact pressure monitoring active

Press both buttons simultaneously and switch on the device



Select contact pressure setting



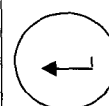
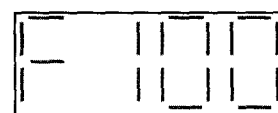
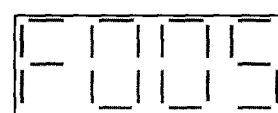
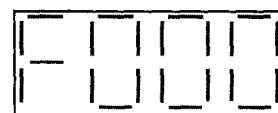
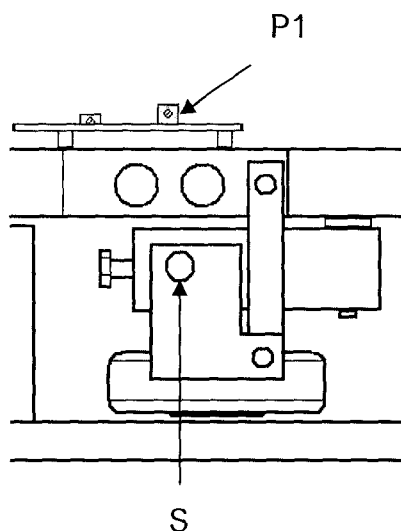
Confirm selection

Process

Turn screw **S** to the left until the value displayed does not change any more

Using the potentiometer **P1**, set the zero point of the DMS module to 005

By turning the screw **S** clockwise, set the contact pressure to 100N



Confirm input

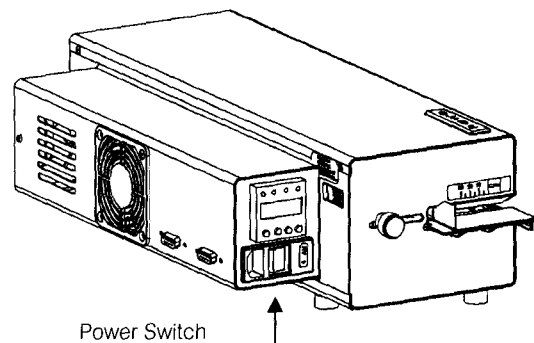
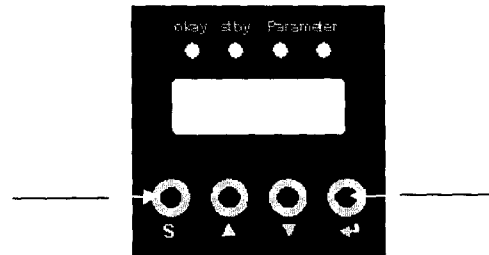
4.9.3 Motor monitoring configuration ONLY hm 780 DC-V device



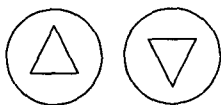
Motor monitoring configuration should always be done after replacing the temperature control, after replacing the motor and after replacing the tachogenerator

Only then is the motor monitoring active

Press both buttons simultaneously and switch on the device



Select motor monitoring configuration

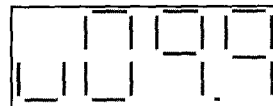


Process

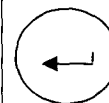
The motor is started and for 5s the measured sealing speed is displayed



Display motor hm 780 DC-V



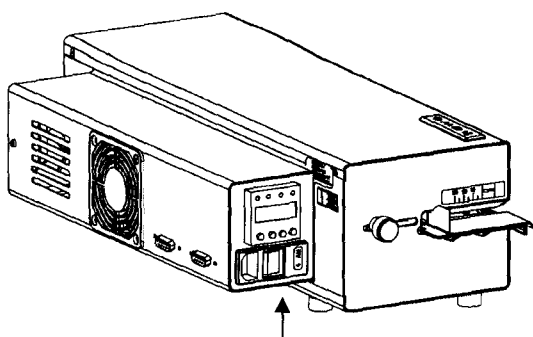
Display motor hm 780 DC



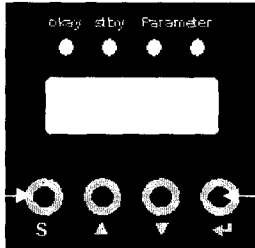
Confirm selection

4.9.4 Setting the transmission rate (baud rate) of the serial interface

Press both buttons simultaneously and switch on the device



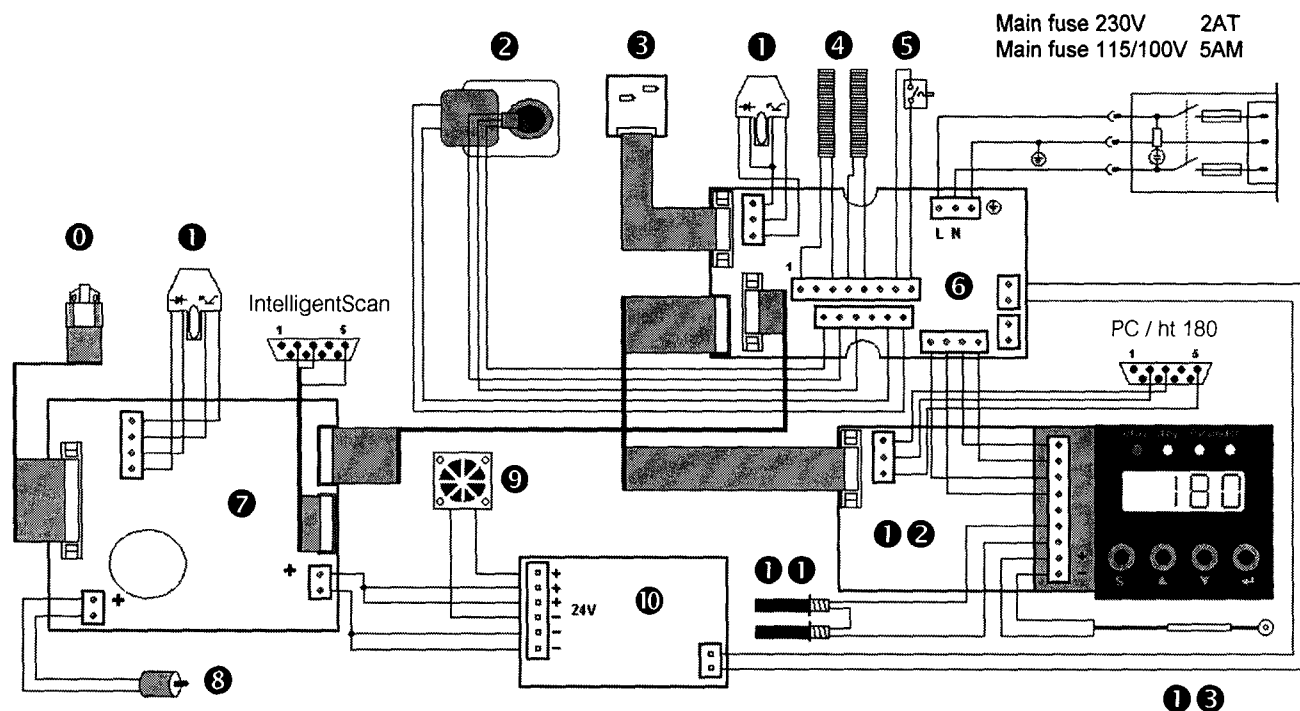
Power Switch



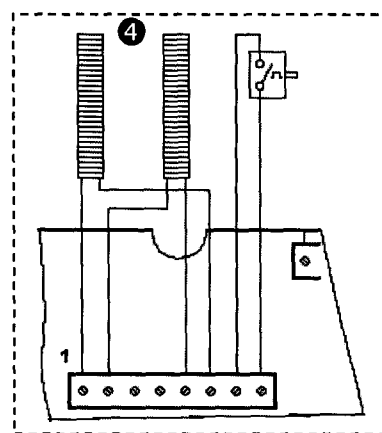
Select baud rate setting			Confirm selection
Select baud rate			Confirm selection
1200Bd – 57600Bd	Example: Baud rate 57600Bd		

5 Technical Data

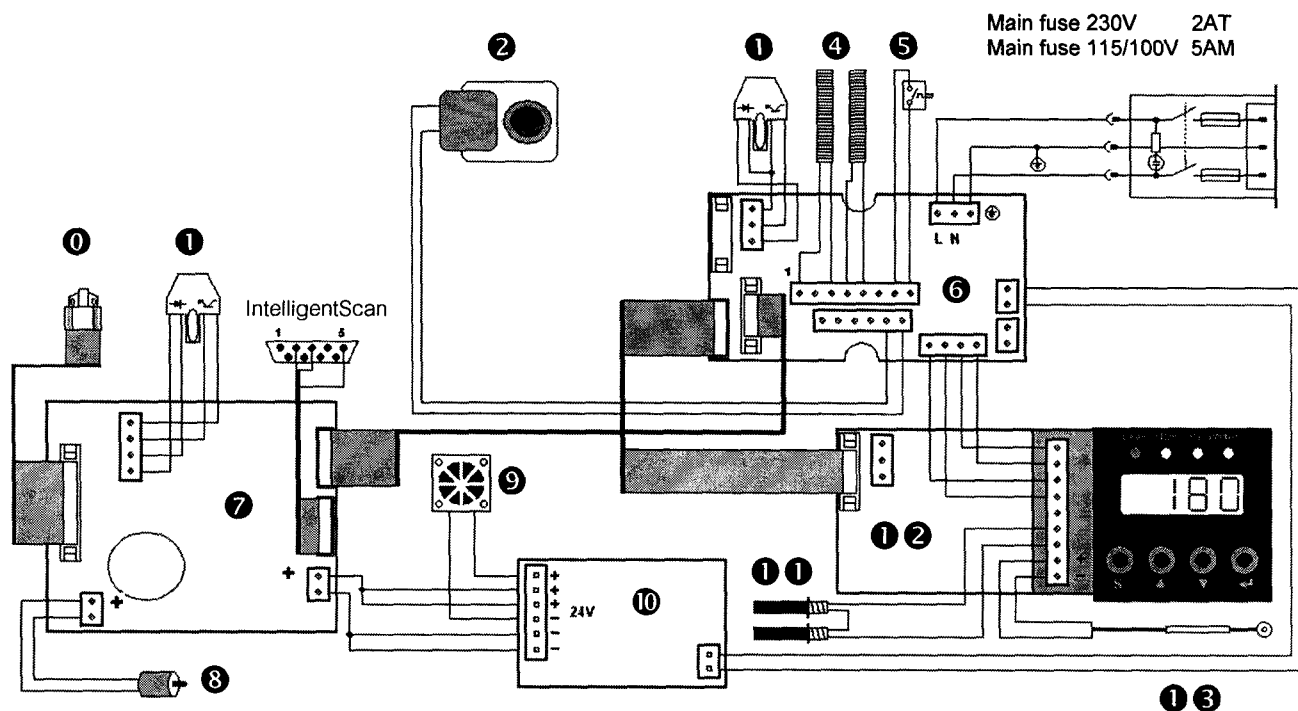
5.1 Circuit and Wiring Diagram hm 780 DC-V



0	Print head	1.653.002
1	Light barrier	1.561.003
2	Gear motor 230V Gear motor 115V Gear motor 100V	1.212.020 1.212.021 1.212.022
3	DMS-Module	1.410.018
4	Heating cartridge	6.536.024
5	Temperature limit switch	6.564.018
6	SST Module	1.461.014
7	Printer control	1.461.013
8	Motor ink ribbon	1.212.012
9	Fan	6.212.028
10	Switched-mode power supply	6.533.001
11	Reed contact	6.543.011
12	Temperature control	6.564.042
13	Thermocouple	6.564.023

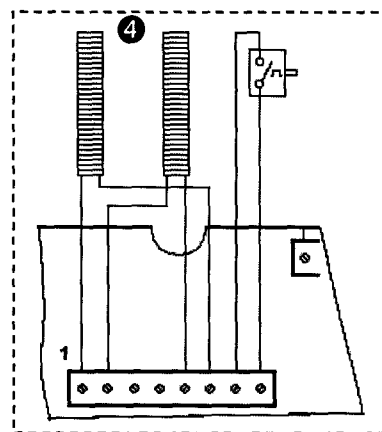


5.2 Circuit and Wiring Diagram hm 780 DC



Heating elements connection at 115/100 V

0	Print head	1.653.002
1	Light barrier	1.561.003
2	Gear motor 230V	1.212.026
	Gear motor 115V	1.212.027
	Gear motor 100V	1.212.028
3		
4	Heating cartridge	6.536.024
5	Temperature limit swswitch	6.564.018
6	SST Module	1.461.014
7	Printer control	1.461.013
8	Motor ink ribbon	1.212.012
9	Fan	6.212.028
10	Switched-mode power supply	6.533.001
11	Reed contact	6.543.011
12	Temperature control	6.564.042
13	Thermocouple	6.564.023



hm 780DC hm 780DC-V	Technical Data	Section 5
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5.3 Specifications

Connection data

Power connection	[V]	230 / 115 / 100
Power frequency	[Hz]	50 / 60
Power consumption standard	[W]	390
Power consumption max.	[W]	500
Main fuse 230V (110V / 115V)	[A]	2 T (5 M)

Mechanic

Dimension	Length [mm]	555
	Width	250
	Height	145
Housing cover		Steel AISI 304
Housing bottom		Steel AISI 304
Weight	[kg]	14
Sealed edge infinitely adjustable	[mm]	0 – 35
Sealing seam width	[mm]	12
sealing system		hawoflex™
Length of sealing seam	[mm]	unlimited
Sealing seam distance from pack content	[mm]	>30 (DIN 58953-7:2003)

Process parameter / Sealing parameter

Sealing temperature max.	[°C]	220
Tolerance limit motor stop temperature	[°C]	± 5
Temperature ranges		1
Temperature-tolerance	[%]	±2
hm 780DC-V		
Pressure applied	[N]	100
Tolerance limit motor stop pressure	[%]	±20
Throughput rate	[m / min]	10
Tolerance Throughput rate	[%]	±10

Electronic and Communication

System		Microprozessor
Serial Interfaces:	RS-232 connector for PC RS-232 connector for bar code scanner USB with adapter Ethernet (LAN) with adapter	hm 780 DC-V only yes optional available (Art.-Nr.: 1.596.024) optional available
Datea rate (Baudrate)	[Bd]	RS 232 PC 1200 – 57600 RS 232 Bar Code Scanner 9600
Protection class		1

Environmental parameter

Heat dissipation	[kJ/s]	0,1
Noise intensity	[dB/ A]	<70



hm 780DC
hm 780DC-V

Declarations of Conformity



Section 6

6 Declarations of Conformity


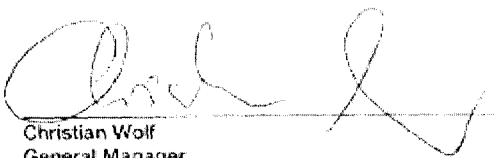
6.1 CE Declaration of Conformity

 <small>10047 Oberheim / Germany</small>	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaración de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade		9.694.026C																																																																								
Seite 1/1 Version 1.0.1																																																																											
<p>Hiermit erklären wir, dass die Folienschweißmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastiques: Por la presente certificamos que las máquinas embolsadoras modelos: Dichiarando con la presente che le macchine per saldatura di fogli: Per este meio se declara que as máquinas de selar em folhas de plástico:</p> <p style="text-align: center;">hm 780 DC, hm 780 DC-V</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: correspondre aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <table border="0"> <tr> <td>EG - Maschinenrichtlinie</td> <td></td> <td>2006/42/EG</td> <td></td> </tr> <tr> <td>Machinery directive</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Directive "CE" rel. aux machines</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Directiva de Maquinaria de la CE</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Direttiva CE sulle macchine nella versione</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Directiva da UE relativa a maquinaria</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Niederspannungsrichtlinie</td> <td>Low voltage directive</td> <td>2006/95/EG</td> <td></td> </tr> <tr> <td>Directive à basse tension</td> <td>Directive de Basse tension</td> <td></td> <td></td> </tr> <tr> <td>Directiva sulla bassa tensione</td> <td>Directiva relativa a baixa tensão</td> <td></td> <td></td> </tr> <tr> <td>EMV-Richtlinie</td> <td>EMC directive</td> <td>2004/108/EG</td> <td></td> </tr> <tr> <td>Directive CEM</td> <td>Directive de CEM</td> <td></td> <td></td> </tr> <tr> <td>Direttiva CEM</td> <td>Directiva CEM</td> <td></td> <td></td> </tr> <tr> <td>RoHS-Richtlinie</td> <td>RoHS-directive</td> <td>2002/95/EG</td> <td></td> </tr> <tr> <td>Directive RoHS</td> <td>Directive de RoHS</td> <td></td> <td></td> </tr> <tr> <td>Direttiva RoHS</td> <td>Directiva RoHS</td> <td></td> <td></td> </tr> <tr> <td>Harmonisierte Normen</td> <td>Harmonized standards</td> <td>EN ISO 12100-1</td> <td>EN 60204-1</td> </tr> <tr> <td>Standard harmonisé</td> <td>Las normas armonizadas</td> <td>EN ISO 12100-2</td> <td>LN 61000-6-1</td> </tr> <tr> <td>Norme armonizzate</td> <td>Normas harmonizadas</td> <td>EN ISO 13857</td> <td>EN 61000-6-3</td> </tr> </table> <p>Verantwortliche Person für die Technischen Unterlagen siehe unten Responsible person for technical documentation see below La personne responsable pour la documentation technique est mentionnée au-dessous</p> <div style="text-align: center;">  Christian Wolf General Manager </div> <p>hawa GmbH, Obere Au 2, D-74847 Obargheim, Germany</p>				EG - Maschinenrichtlinie		2006/42/EG		Machinery directive				Directive "CE" rel. aux machines				Directiva de Maquinaria de la CE				Direttiva CE sulle macchine nella versione				Directiva da UE relativa a maquinaria				Niederspannungsrichtlinie	Low voltage directive	2006/95/EG		Directive à basse tension	Directive de Basse tension			Directiva sulla bassa tensione	Directiva relativa a baixa tensão			EMV-Richtlinie	EMC directive	2004/108/EG		Directive CEM	Directive de CEM			Direttiva CEM	Directiva CEM			RoHS-Richtlinie	RoHS-directive	2002/95/EG		Directive RoHS	Directive de RoHS			Direttiva RoHS	Directiva RoHS			Harmonisierte Normen	Harmonized standards	EN ISO 12100-1	EN 60204-1	Standard harmonisé	Las normas armonizadas	EN ISO 12100-2	LN 61000-6-1	Norme armonizzate	Normas harmonizadas	EN ISO 13857	EN 61000-6-3
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Norme armonizzate	Normas harmonizadas	EN ISO 13857	EN 61000-6-3																																																																								
hawa GmbH Obere Au 2/4 74847 Obargheim / Germany	T +49 (0) 714 61 78 77 0 F +49 (0) 714 61 82 0 15 info@hawa.com www.hawa.com	Assignment Manager: 91-RE 44 121 Geschäftsführer: Hans-Wilfried Christian Wolf Christian Wolf GmbH	This document is the property of hawa GmbH and its contents are confidential. It is not to be distributed outside the company without the written consent of hawa GmbH. If you are not an authorized recipient, please inform us immediately.																																																																								

6.2 EN ISO 11607-2 / DIN 58953-7 Conformity Declaration hm 780 DC-V

 <small>78847 Oberghem / Germany</small>	Konformitätserklärung – Declaration of Conformity Déclaration de Conformité Declaración de conformidad Dichiarazione di conformità – Certificação de conformidade	9.694.026D
		Seite 1/1 Version 1.01
<p>Hiermit erklären wir, daß die Folienschweißmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas empujadoras modelos: Dichiaro con la presente che le macchine per saldatura di fogli: Por este meio se declara que as máquinas de selagem de folhas de plástico:</p> <p style="text-align: center;">hm 780 DC-V</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: correspondre aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem as seguintes determinações e normas harmonizadas.</p> <p>Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens Packaging for terminally sterilized medical devices – Part 2 Validation requirements for forming, sealing and assembly processes Emballages des dispositifs médicaux stérilisés au stade terminal – Partie 2 Exigences relatives aux procédés de mise en forme, de fermeture et d'assemblage</p> <p style="text-align: right;">DIN EN ISO 11607-2:2006 ANSI/AAMI/ISO 11607-1:2006</p> <p>Sterilisation – Sterilgutversorgung – Teil 7: Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und –schläuchen Sterilization – Sterile supply – Part 7: Use of sterilization paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels Stérilisation – Approvisionnement en produits stériles – Partie 7: Utilisation de papier pour stérilisation, de matériaux d'enveloppe en non-tissé, matériaux textiles tissés, de sacs en papier, de sachets et gaines scellables</p> <p style="text-align: right;">DIN 58953-7:2008</p> <p> Christian Wolf General Manager</p> <p>hawa GmbH, Opere Art 2, D-78847 Oberghem, Germany</p>		
hawa GmbH Opere Art 2 78847 Oberghem / Germany	Tel.: +49 (0) 780 52 27 00 Fax: +49 (0) 780 52 27 15 eMail: info@hawa.de www.hawa.de	Ansprechpartner: Herrmann, HBS, HBS 11 GbR, 78847 Oberghem Herr Wolf und Christian Wolf hawa GmbH, Oberghem

hm 780DC
hm 780DC-V
Declarations of Conformity
Section 6
6.3 DIN 58953-7 Conformity Declaration hm 780 DC

 <small>74847 Oberrhein / Germany</small>	Konformitätserklärung – Declaration of Conformity Déclaration de Conformité Declaración de conformidad Dichiarazione di conformità - Declaração de conformidade	9.694.026D
Gültig ab: 01.01.2010 Valid from:	Seite 1/1 Version 1.01	
<p>Hiermit erklären wir, daß die Folienschweißmaschinen: Herewith we declare that the Foil sealing unit: Par la présente nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: Dichiaramo con la presente che le macchine per saldatura di foglio: Por este meio se declara que as máquinas de selagem de folhas de plástico:</p> <p style="text-align: center;">hm 780 DC</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonized standards: correspondre aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <p>Sterilisation – Sterilgutversorgung – Teil 7: DIN 58953-7:2008 Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und -schläuchen Sterilization – Sterile supply – Part 7: Use of sterilization paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels Stérilisation – Approvisionnement en produits stériles – Partie 7: Utilisation de papier pour stérilisation, de matériaux d'enveloppe en non-tissé, matériaux textiles tissés, de sacs en papier, de sachets et gaines scellables</p> <div style="text-align: center;">  Christian Wolf General Manager hawa GmbH, Obere Au 2, D-74847 Oberrhein, Germany </div>		
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7 Validation

7.1 General

Main purpose of every packaging system for medical products, which are sterilized during the final packaging, is maintaining the sterility until use or until aseptic preparation at the patient. 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.

Within the scope of the preparation of medical products, the sealing process is considered to be part of the process chain. This process is also to be validated in accordance with the Law on Medical Products and with the Medical Devices Operator Ordinance.

The international standard EN ISO 11607 – Part 2 requires and describes the validation of packaging processes. In order to implement it, the German Society for Sterile Supply (Deutsche Gesellschaft für Sterilgutversorgung) issued a Guideline for the Validation of Sealing Processes according to EN ISO 11607-2.

The sealing device meets the requirements of EN ISO 11607-2 and the resulting DGSV guideline for sealing process validation.

The guideline can be downloaded from the www.dgsv-leitlinie.de website, or it can be requested from the hawo Service Line on +49 (0) 6261 9770 0 (keyword: DGSV guideline).

Validation must always be performed by the user at the installation site.

7.2 Preparation

Your sealing device has already been calibrated before delivery (see test report).
The sealing device should be re-calibrated before each re-validation

The manufacturer's calibration of hawo sealing devices may only be performed by hawo GmbH or by one of hawo's authorized service partners. For further information, please contact your authorized service partner or the hawo Service Hotline: +49 (0) 6261 9770 0 (keyword: servicing and calibration).

The manufacturer's calibration must be ordered separately (order number 9.079.035) and is **not** included in shipment!

Furthermore, for the operational qualification you need the hawotest SEAL CHECK indicators. You can obtain these from your supplier or directly from hawo (online at www.seal-check.de).

Using the original hawotest SEAL CHECK is recommended.

7.3 Validation

We recommend that you perform validation in accordance with the DGSV* guideline for validation (available from www.dgsv-leitlinie.de). In the following section you will find useful information, which you will need to implement the DGSV guideline.

German Society for Sterile Supply DGSV

7.3.1 Validation schedule information

7.3.1.1 Description of the sealing device

Your sealing device is a rotary sealer. The precise name and the serial number are written on the type plate attached on a side of the machine.

The required sealing temperature tolerance is $\pm 5^{\circ}\text{C}$ ($\pm 9^{\circ}\text{F}$) according to DIN 58953-7.

The temperature range of the packaging material will be required again later in the process. You can get this information from your material supplier. If you do not succeed in getting this information, you can take as a rule the following ranges:

Transparent packages according to EN 868-5:	170 – 190 °C (338 – 374 °F)
HDPE (Tyvek™):	130 – 140 °C (266 – 284 °F)

7.3.1.2 Installation qualification information (IQ)

7.3.1.2.1 QM-system

You can get from hawo free of charge the necessary certificate for the quality management system ISO 9001:2000.

Ask for it from info@hawo.com or call us on: +49 (0) 6261 9770 0 (keyword: QM certificate)

7.3.1.2.2 Type of device: Rotary sealer

The device has CE marking and complies with the EN ISO 11607-2 and DIN 58953-7 standards. The corresponding conformity declarations can be found in chapter 6 and serve as certifying proof.

7.3.1.2.3 Service authorization

The service partner must be authorized by hawo in writing. Ask your service team for the certificate.

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7.3.1.2.4 Safety features

Parameter	required	existing
Sealing seam width	6 mm*	12mm
Distance from medical product	30 mm*	30 mm
Process cycle	automatic	automatic

* required in DIN 58953-7:2003

7.3.1.2.5 Process parameters

Parameter	Disconnection tolerance preset	adjustable
Sealing temperature	+/- 5°C (+/- 9°F) *	not possible
contact pressure hm 780 DC-V only	+/- 20% of the set value**	not possible

* required in DIN 58953-7:2003

These are controlled and monitored by the microprocessor system.

Systems have been integrated which, in case of deviation of the predetermined limit values from the critical process parameters, display warnings and stop the device.

This prevents further working.

The process parameters must be routinely monitored. For this hawo offers the following possibilities:

1. **SEAL CHECK function**
Daily printout of the sealing parameters with the SEAL CHECK function (see also Section 3.10).
2. **ht 180 PT-USB (order number 0.712.005) hm 780 DC-V only**
The new hawotest ht 180 PT-USB is a mobile process documentation system. This system automatically receives data about the process parameters and additional relevant protocol data (machine number, staff number, etc.). The data is stored on a USB stick and transferred to a PC. Storage occurs by means of digitally signed PDF documents directly on the PC.
3. **Batch documentation systems**
The devices can be connected through an interface directly to the batch documentation system. Ask the producer for the exact compatibilities.

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7.3.1.3 Operational qualification information (OQ)

According to standard EN ISO 11607-2, section 5.3.2 b, the quality characteristics of the sealing are the following:

- Intact sealing across the entire sealing seam width
- No channels or open seals
- No punctures or tears
- No delamination or material separation

These quality characteristics must be checked and documented with a suitable method. Quality characteristics can be checked in the best way using the hawotest SEAL CHECK indicators.

The free of charge SEAL CHECK reference card from hawo gives clear statements about their implementation.

For this purpose, a sealing must be made at the lower and upper limit value of the sealing temperature. Quality characteristics are to be fulfilled in both sealings.

After that the sealing temperature is to be determined for daily practice. It is recommended to form these from middle of the ACTUAL temperatures (during the test; e.g. a lower limit according to the manufacturer of 170 °C (338 °F) and an upper limit according to the manufacturer of 190 °C (374 °F), mean value = sealing value 180 °C (356 °F).

7.3.1.4 Performance qualification information (PQ)

With the performance qualification it is to be furnished proof of a good understanding of the process and of delivering of optimal closed sterile barrier systems - also after the sterilization. The test is carried out using a seal seam resistance check according to DIN EN 868-5, Appendix D. Packages must be sterilized before testing. Records (batch documentation) of sterilization processes are part of the validation.

For the combinations determined in the validation schedule (see also Appendix E of the DGSV guideline) 3 pouches of the same material must be sealed each time at the defined temperature (T) and subsequently sterilized using the predefined sterilization program (reels must be sealed on both sides). Each pouch is to be attributed to a different sterilization batch (if available) in order to consider all influencing variables in the sterilization batches.

Seal seam resistance must be determined by a qualified validator (e.g. directly by hawo GmbH or by an authorized service partner). Contact us now to ask us for the necessary documents and checklists (order number 9.079.036).

You can easily perform this test yourself using our sealing seam resistance testing device ht 150 SCD.

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7.3.1.5 Revalidation

Since even small changes can frequently compromise the validation status, the processes must be revalidated periodically if changes have been made to the sealing device or if the packaging material has been changed.

As the manufacturer, we recommend annual periodic revalidation. If no changes have been made to the sealing device and the material has not been modified, a repetition of the performance qualification (repeat of seal seam resistance determination) is sufficient for revalidation.

Seal seam resistance must be determined by a qualified validator (e.g. directly by hawo GmbH or by an authorized service partner). Contact us now to ask us for the necessary documents and checklists (order number 9.079.036).

You can easily perform this test yourself using our sealing seam resistance testing device ht 150 SCD.

The sealing device must be serviced and demonstrably calibrated before periodic revalidation. (see DIN EN ISO 11607-2 5.2.5)

Servicing and calibration of hawo sealing devices may only be performed by hawo GmbH or by one of hawo's authorized service partners. For further information, please contact your authorized service partner or the hawo Service Hotline: +49 (0) 6261 9770 0 (keyword: servicing and calibration)

