Translation Original - Instruction for use

ENGLISH

1 Introduction

1.1 Preface

First of all we would like to thank you for purchasing the sealing machine.
In these instructions you will find information about using the machine, servicing and care as well as process validation.

The sealing machine is a microprocessor controlled rotary sealer with printer for packaging sealable pouches and
reels (SBS[1]).
The sealing machine meets the requirements of DIN 58953-7, EN ISO 11607-2 and the resulting DGSV[2] guideline for validating the sealing process.

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

Always keep these instructions close to the machine.

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.

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 machine directive 93/42/CE is not applicable to sealing machines.

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.

In the event of conversion work or interventions to the machine undertaken without the express written permission of the manufacturer, the warranty shall be deemed void and any liability for physical or material damage shall be transferred to the operator.

Note
Because we are constantly improving our products, we reserve the right to modify these operating instructions and the functions described in them.
These operating instructions apply to products from software version V1.36 onwards.

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 machine must be observed while handling the machine (transport, storage, installation, commissioning, operation and maintenance).

3. This machine 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 machine.

5. Before commissioning, ensure that the machine 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 machine if the power cable or the power plug is damaged. Do not use the machine if it does not operate correctly or it is damaged in any way. If the mains cable or the machine have been damaged, the machine must be repaired by the manufacturer or by one of the manufacturer's authorized service partners.

7. The machine 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 machine on a stable base.

9. The machine e must not be installed and operated in explosive areas.

10. If the sealing machine is brought directly from a cold environment into a hot environment, bedewing may occur. Wait until temperature equalization has taken place.
Starting up the machine 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 machine when it is not in use or remove the power plug from the socket.

13. **Before cleaning: Disconnect from the mains!** Clean the machine only with a dry or damp soft cloth and a mild cleaning agent. Do not allow any water to find its way into the machine. **Caution!** Never wet clean the machine!!

14. Do not insert pointed or flat items into the import slot of the machine. This can result in damage to the machine and instruments.

15. Do not insert items into the louvers of the machine. You may receive an electric shock or the machine could be damaged.

16. Do not use the machine if you have any doubts about machine safety.

17. The machine must not be installed or operated by persons under 16 years of age.

18. The machine must not be operated unsupervised.

19. It is forbidden to operate the machine under the influence of drugs or alcohol.

20. Keep hair, clothing and gloves away from moving parts.
Loose clothing, jewellery or long hair can be caught by moving parts.

21. Your appliance contains valuable materials which can be recovered or recycled. Leave it at a local civic waste collection point. This appliance is labeled in accordance with European Directive 2002/96 EC concerning used electrical and electronic appliances equipment-WEEE).
The directive determines the framework for the return and recycling of used appliances as applicable throughout the EU.

1.5 Notes on the operation of the device

Checking the sealing seam[3]

Each sealing seam must be subjected to a visual inspection after the sealing process and after sterilisation.

The sealing seam must be intact across the entire width and length and must be fully sealed.
There must be no channels, kinks, folds, air pockets or indents.
There must be no visible signs of scorching or melting.

1.5.1 Sealing seam integrity test (hawo InkTest)

for assessing the function (OQ) according to standard EN ISO 11607 – Part 1

The sealing seam integrity test according to EN ISO 11607-1 is particularly recommended for checking sealing seams after sterilisation. Complete test packages can be obtained from hawo (article number: 6.061.035)

[3] The ASTM F1886 test method listed in EN 11607-1 Appendix B, "Standard test method for determining integrity of seals for medical packaging by visual inspection" can be used for routine visual inspections.

2 Before starting Up

2.1 Intended use

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

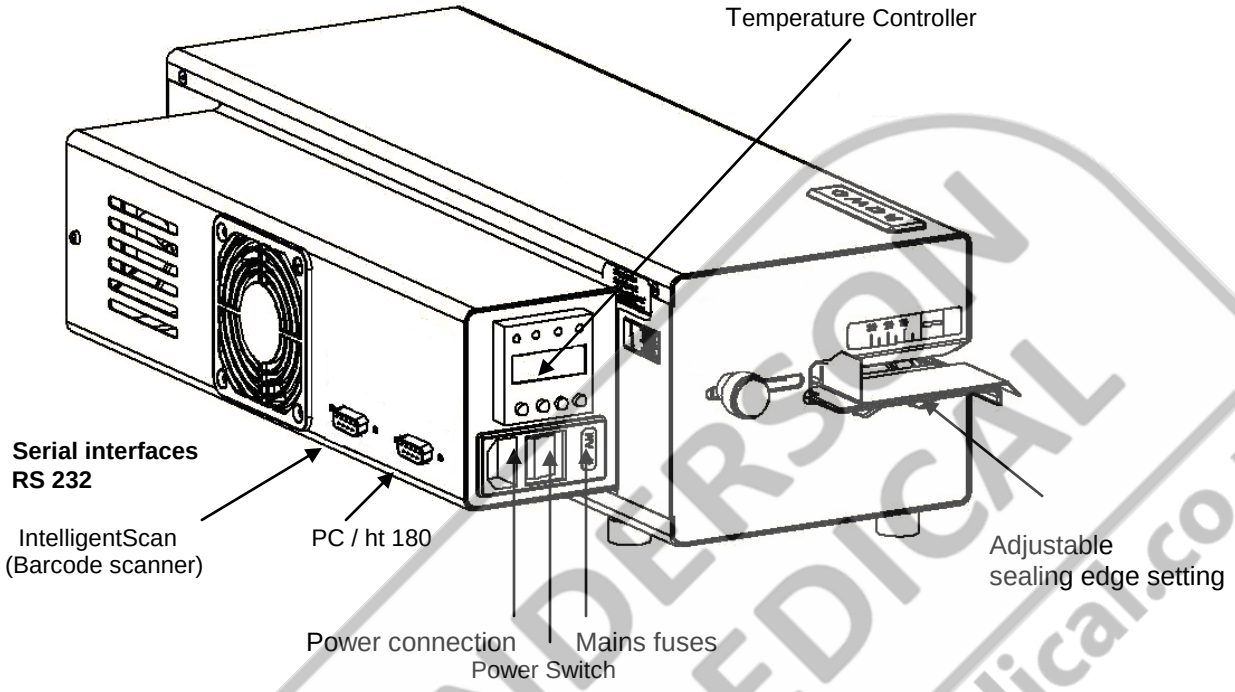
Sealable materials
Pouches and reels in accordance with EN 868-5 and EN ISO 11607-1*
Paper pouches in accordance with EN 868-4*
Uncoated HDPE *
Aluminum laminate film

* also with side gusset

The correct sealing temperature must be identified by means of test sealings (DIN 58953-7).
The machine 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 machine, 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 machine 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

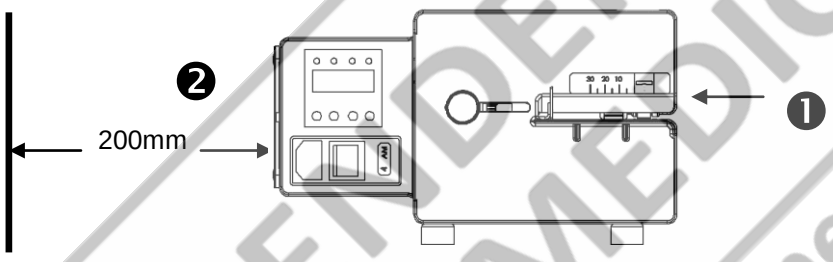
Prior to installation, read the safety notices in chapter 1.4

2.3.1 Installation

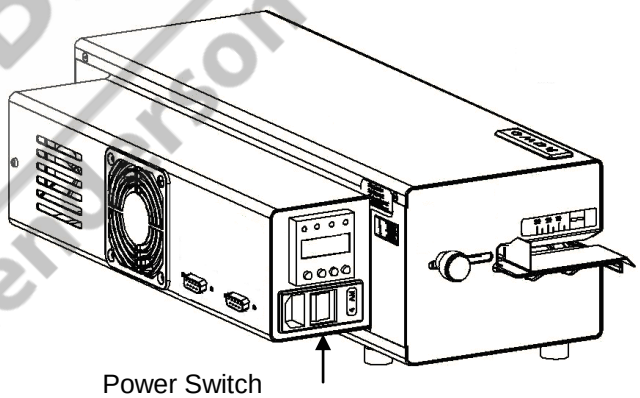
Place the machine on a horizontal surface.

❶ Please do not lift the machine by the in feed section.

❷ The distance from the machine to a wall must be at least 200 mm.



2.3.2 Commissioning

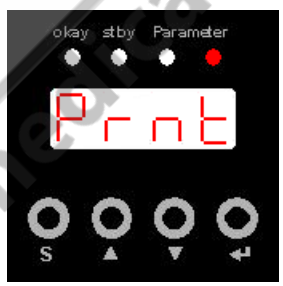
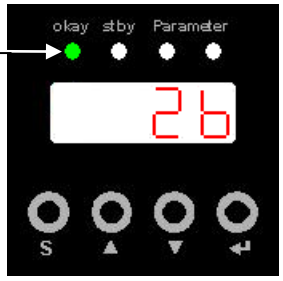
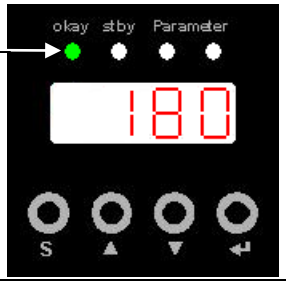


To switch on the machine, press the power switch on the left-hand side.

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

3 Configuration of machine

3.1 Basicf functions

Switch on the machine 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 machine is ready for use**	

3.2 Inspection light functions

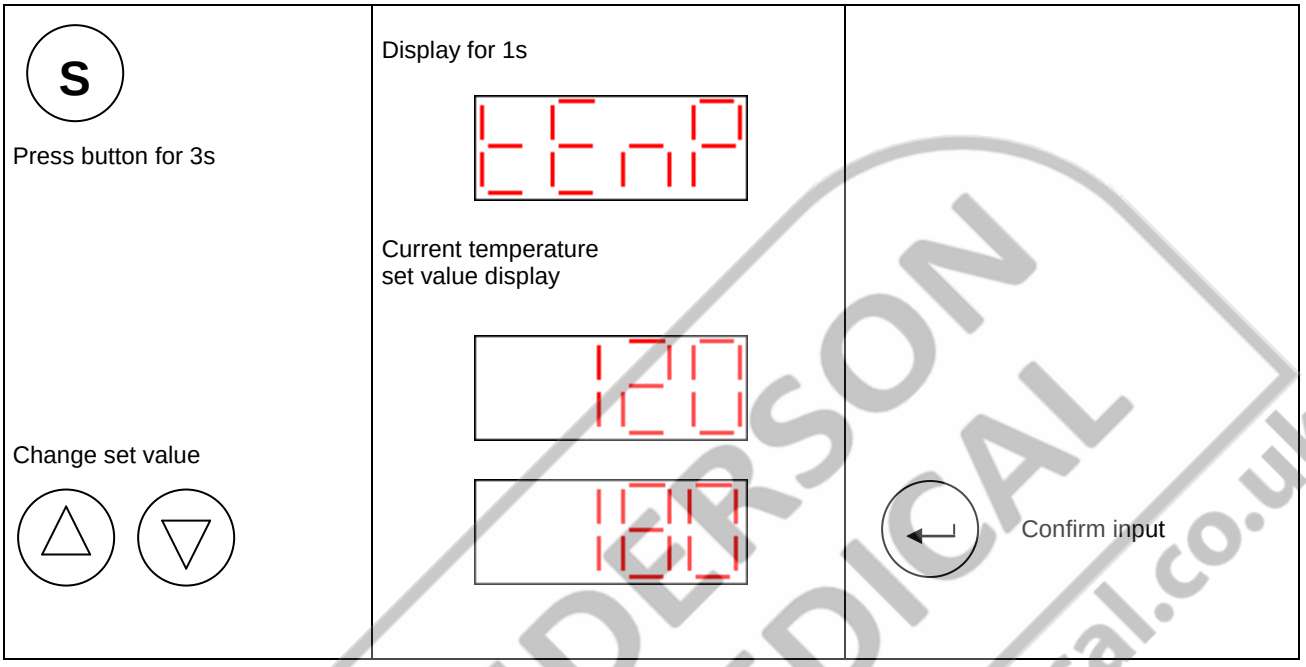
Function				
Machine switched on Warm-up phase	**flashes**	off	off	off
Sealing temperature = ± 5° **hm 780 DC-V** Contact pressure = ± 20% Sealing speed = ± 10%	on	off	**on**	off
Sealing temperature <> ± 5° **hm 780 DC-V** Contact pressure <> ± 20% Sealing speed <> ± 10%	off	on	off	**on**
Standby	off	**on**	off	on
warming up after standby or change in set temperature	**flashes**	off	off	**on**

3.3 Button functions

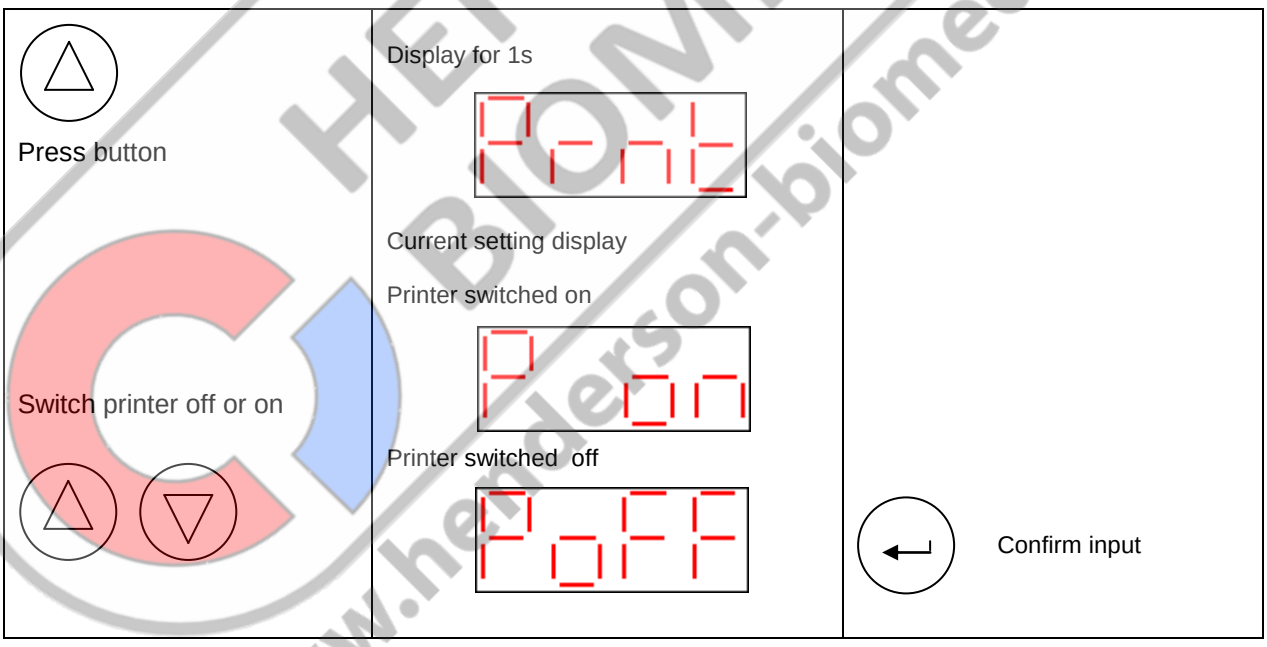
S	△	▽	↵
Menu level 1 Menu level 2 activation **Press for 3 s** Menu level 3 activation **Press for 7 s**	Switch printer off/on	Personal identification input	"Seal check" activation
Menu level 2 Sealing temperature input	Temperature value + 1	Temperature value -1	Confirm input
Menu level 3 **3.1** Sealing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

3.4 Machine settings

3.4.1 Sealing temperature input



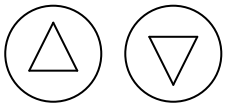
3.4.2 Switch printer off and on



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

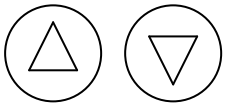
Confirm input

3.4.4 Data input

Activate

Press button for 7s

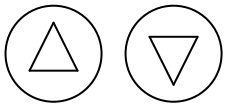
Switchover to data input

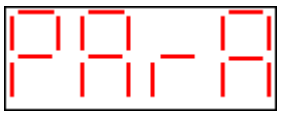


Keylock

active
Input 1 - 9999

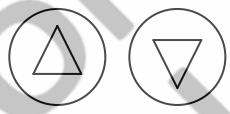
inactive
Input 0





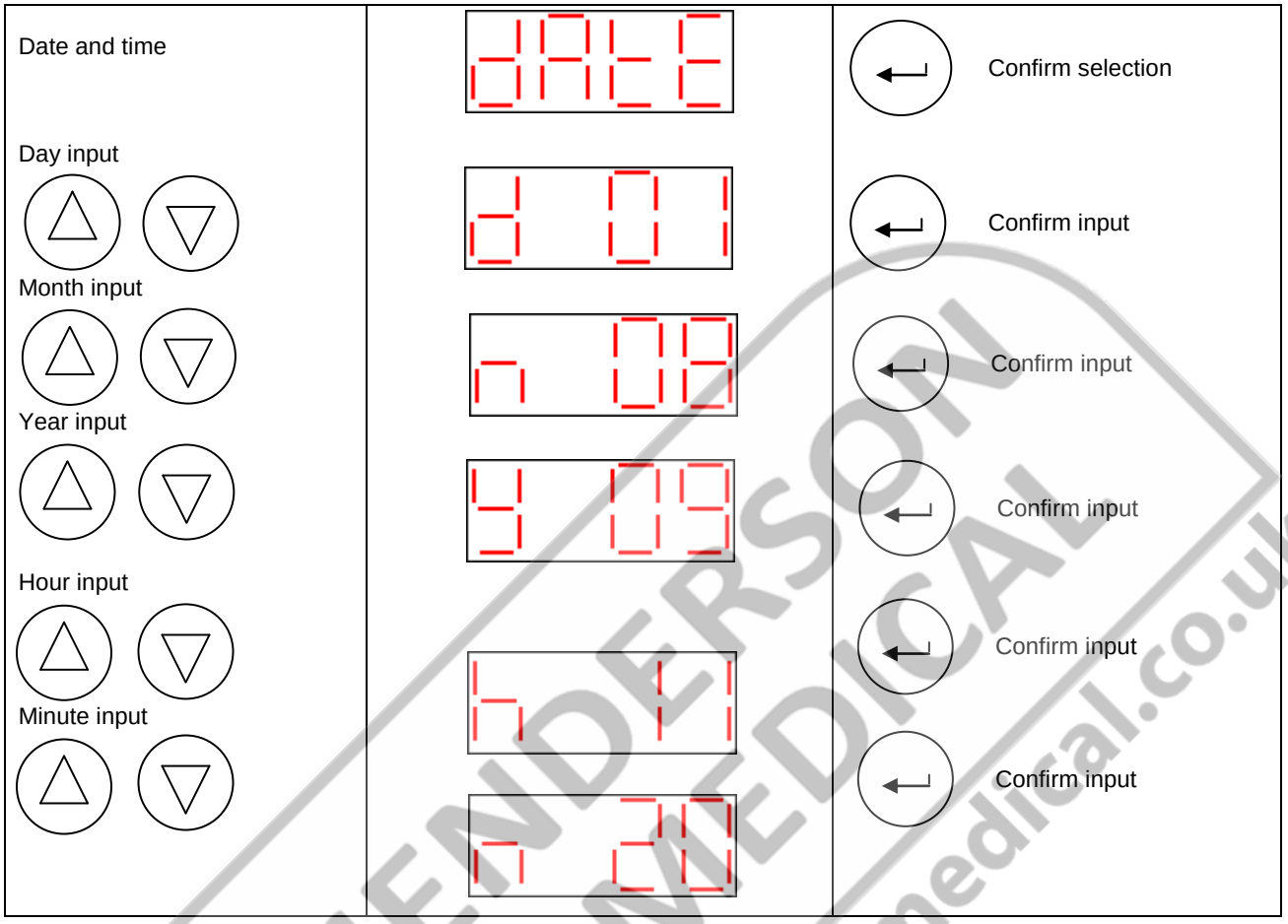
Confirm selection

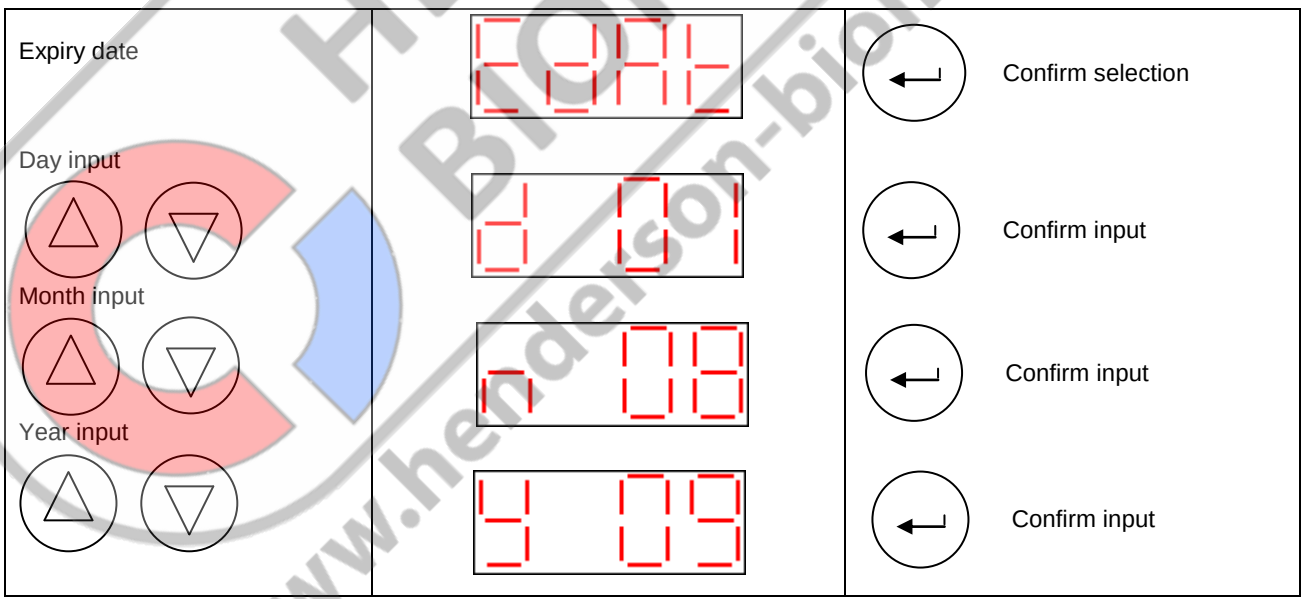
Select data



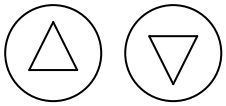
Confirm selection

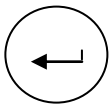
Confirm input





Batch
Input 0000 - 9999



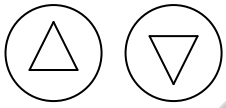


Confirm selection

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

Confirm input

Pack content quantity
Input 0 - 99

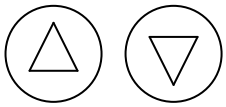


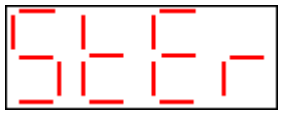
Confirm selection

Confirm input

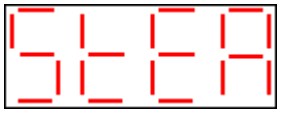
Sterilization type

Sterilization type selection

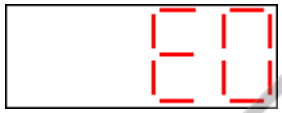




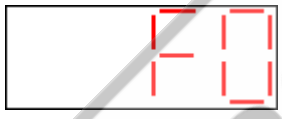
Steam



Ethylene oxide



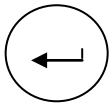
Formaldehyde



Plasma

Dry heat

Ionising radiation

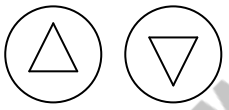


Confirm selection

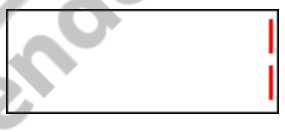
Confirm selection

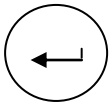
Personal code input

Select new code

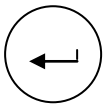


Current personal code display



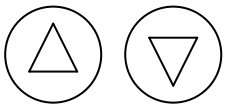


Confirm selection



Confirm input

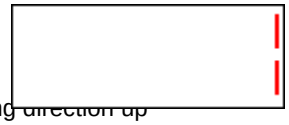
Batch counter
Input 0 - 9999



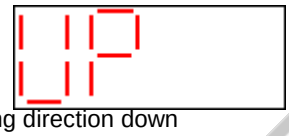
Counting direction selection

If counting direction down has been selected, an alarm sounds when the value 0 is reached

Switch off batch counter

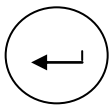


Counting direction up

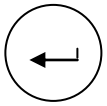


Counting direction down

Switch off batch counter



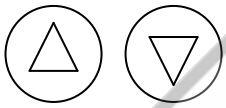
Confirm selection



Confirm input

Confirm selection

Standby
Input 0 – 60min



If the motor was not started before reaching the set time, then the temperature is set automatically to 50°C / 122°F.

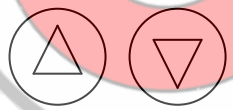
The brief insertion of a package causes the temperature to reset to its previous set value. Once this has been reached, the machine is again ready for use

Confirm selection

Confirm input

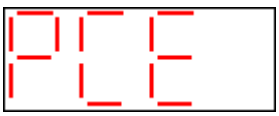
Operating data
View of the operating hours and the absolute batch counter

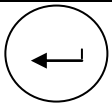
View selection



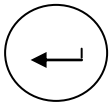
Operating hours

Absolute batch counter





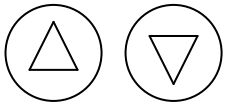
Confirm selection



Confirm selection

Units of measurement

Units of measurement selection



Europe
Temperature in **°C**

hm 780 DC-V
Contact pressure in N

Sealing speed in **m/min**

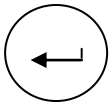
USA
Temperature in **°F**

hm 780 DC-V
Contact pressure in **lbf**

Sealing speed in in **inch/mm**

Units of measurement Europe

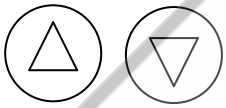
Units of measurement USA



Confirm selection

Confirm selection

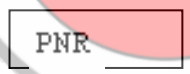
Character width

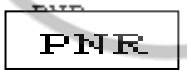


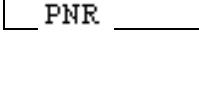
Input 0 - 2

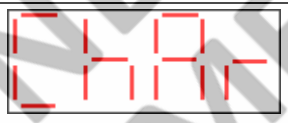
In accordance with the setting selected, the characters are printed in various widths

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





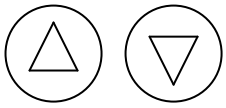




Confirm selection

Confirm input

Monitoring
Personal number
Input 0 – 60min

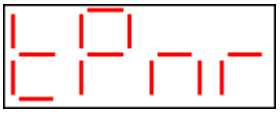


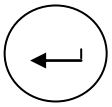
When inputting a time > 0 monitoring of the personal number is active and the motor can only be started if the value of the personal number is 1-9999

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

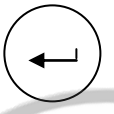
If the personal number is 0000 and a package is inserted, a command prompt appears

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





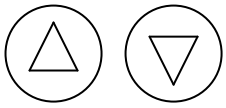
Confirm selection



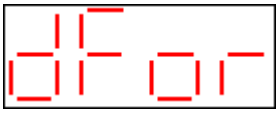
Confirm input

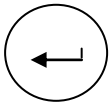
Date format

Date format selection



1	DD.MM.YYYY
2	MM.DD.YYYY
3	YYYY.MM.DD
4	YYYY.MM
5	DD.MM.YY
6	MM.DD.YY
7	YY.MM.DD



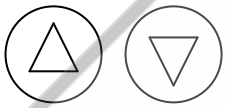


Confirm selection

Confirm selection

Time format

Time format selection



24	13:26
12	01:26 PM

Time format 24h

Time format 12h

Confirm selection

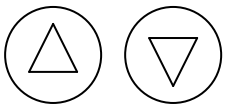
Confirm selection

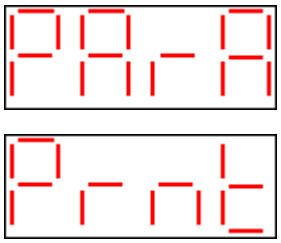
3.4.5 Print data selection

Activate

Press button for **7s**

Switchover to print data





Confirm selection

Select data to be printed

The print sequence is predefined.
Activated print data is always printed in this sequence

Sterilization date
Time
Expiry date
Batch counter
Personal identification
Batch counter
Sterilization type
Pack content quantity
Text
(with barcode list and attached barcode scanner)

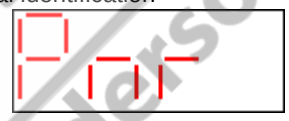
Sterilization date

Time

Expiry date

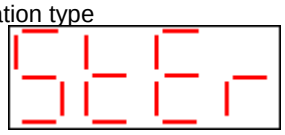
Batch number

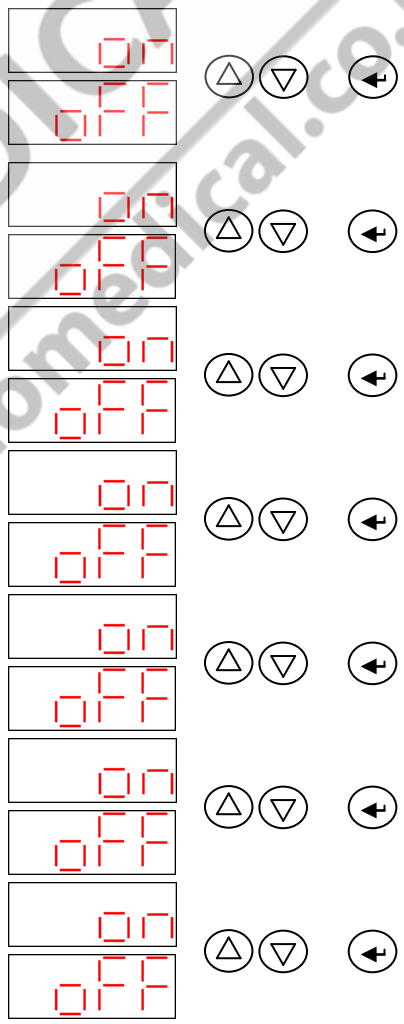
Personal identification

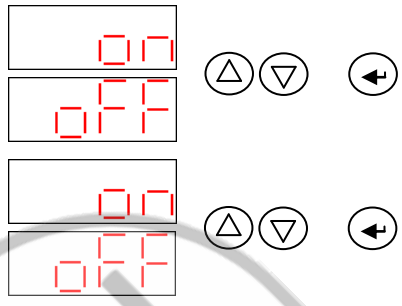


Batch counter

Sterilization type

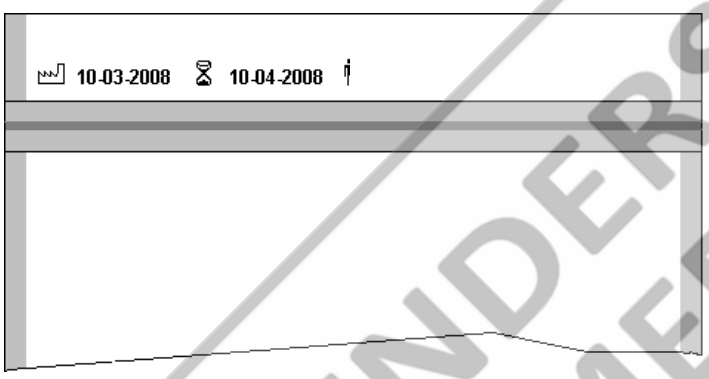




	Pack content quantity  Text 	

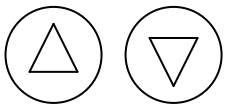
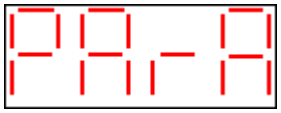
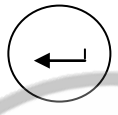
Example

Printing the sterilization date and the expiry date



3.4.6 View of sealing parameters contact pressure and sealing speed

only hm 780DC-V machine

Activate  Press button for 7s **Select view** 	 Contact pressure  Sealing speed 	 Confirm selection

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

Functions

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.

⚠ Please only use barcode scanners approved by hawo.
hawo accepts no liability for any damaged caused by the connection and use of other barcode scanners.

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

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 machine 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 ¾ 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

3.6 Sealing seam test – "Seal Check"

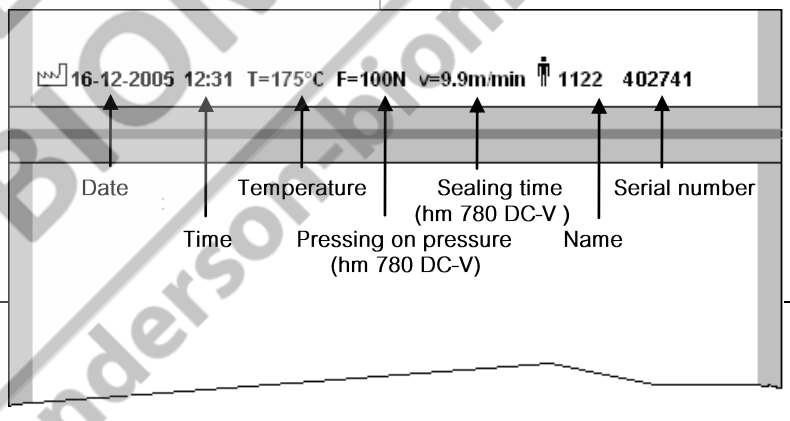
Testing of the critical process parameters temperature, contact pressure and sealing time with "SEAL CHECK".

Seal Check seal indicators are not suitable for packaging with side folds

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 (EN ISO 11607-2).

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

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

Machine ready for use **Specified set temperature has been reached** Press button	
Sterilization packaging, minimum width 200 mm and insert SEAL CHECK indicator strips if necessary	

4 Troubleshooting and servicing

4.1 Troubleshooting checklist

The trouble shooting suggestion marced with a * may only be carried of a service partner authorised by the manucaftuer.

Malfunction	Possible cause	Troubleshooting
Machine 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 machine fuse checked
	Temperature controller defective	Replace Temperature controller*
Machine not heating up	Set temperature too low	Increase set temperature (see page 14)
	Temperature limitation active	Reset the temperature limiter by pushing down the pin ! In case of repeated activation you must have the machine checked
	Temperature sensor	Replace temperature sensor*
	Heating element	Check heating element and replace if necessary*
	Temperature controller defective	Replace Temperature controller
	SST Module defective	Replace SST Module*
No feed	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*

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

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**

4.3.2 Error displays

> ⚠ The trouble shooting suggestion marced with a * may only be carried of a service partner authorised by the manucaftuer.

Sealing temperature outside tolerance

Possible cause	Troubleshooting
Temperature sensor defective	Replace temperature sensor*
Temperature Controller defective	Replace controller*
SST module defective	Replace SST module*

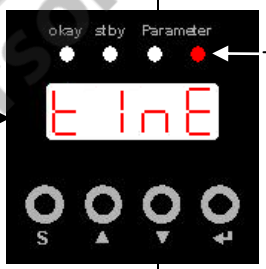
Only hm 780 DC-V

Contact pressure outside tolerance

Possible cause	Troubleshooting
DMS module not adjusted / calibrated	Adjust / calibrate DMS module again*
DMS module defective	Replace DMS module*

Only hm 780 DC-V

Sealing speed outside tolerance



Possible cause	Troubleshooting
Motor defective	Replace motor*

4.4 Servicing / calibration

Like all technical machines, your machine is also subject to technical wear.
In order to guarantee continuous operational readiness, your machine 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 annualy						

Legend:

Check Replace Adjust Measure

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

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.

To: _____ **Sender:** _____

Fax No. _____

Your order no.: _____		**Date** _____	
Machine model _____		**Seral number** _____	
☑	**Designation**	**Part No**	**qty**
☐	Ink ribbon black	6.813.104	
☐	Ink ribbon red	6.813.224	
☐	PTFE strip for upper guide rail	6.105.178	
☐	PTFE strip for lower guide rail	6.105.177	
☐	PTFE strip for heating die	6.105.125	
☐	Pressure roller plastic	2.230.008	
☐	Toothed belt drive	6.271.018	
☐	Toothed belt, material transport	6.271.019	
☐	Heating cartridge	6.536.024	
☐	Upper sealing die complete	1.616.049	
☐	Lower sealing die complete	1.616.050	
☐			
☐	Print head	1.653.002	
☐	Reed Contact	6.543.011	

Signature _____

To: **Sender:**

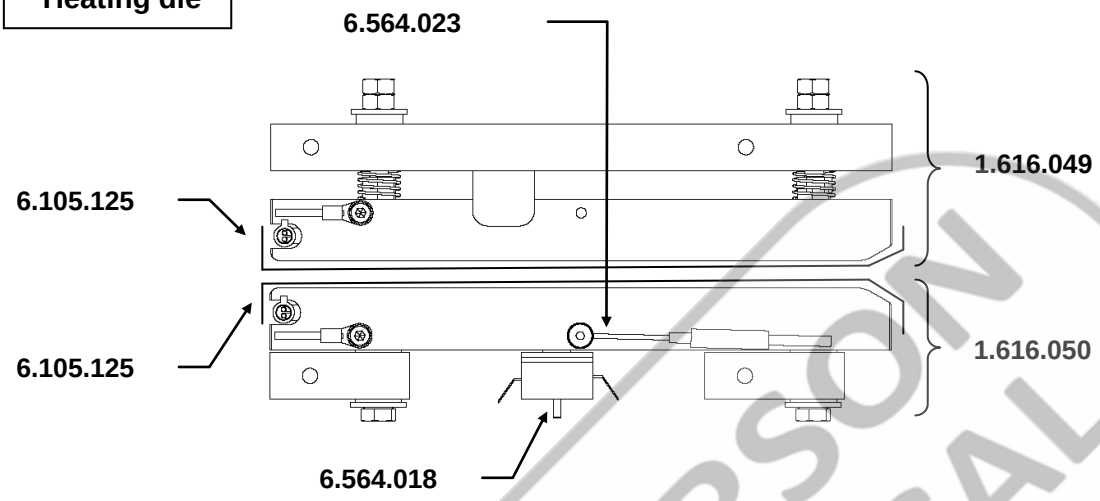
Fax No.

Your order no.:		**Date**	
Machine Model		**Serial number**	
☑	**Designation**	**Part No**	**qty**
☐	Temperature control 100 - 245V	6.564.042	
☐	Printer control	1.461.013	
☐	DMS Module **Only hm 780 DC-V**	1.410.018	
☐	SST Module	1.461.014	
☐	Switched –mode power supply	6.533.001	
☐	Light barrier printer	1.561.003	
☐	Light barrier motor	1.561.010	
	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	
☐	Motor ink ribbon	1.212.012	
☐	Temperature limit switch	6.564.018	
☐	Thermocouple	6.564.023	
☐	Fan 24V	6.212.028	

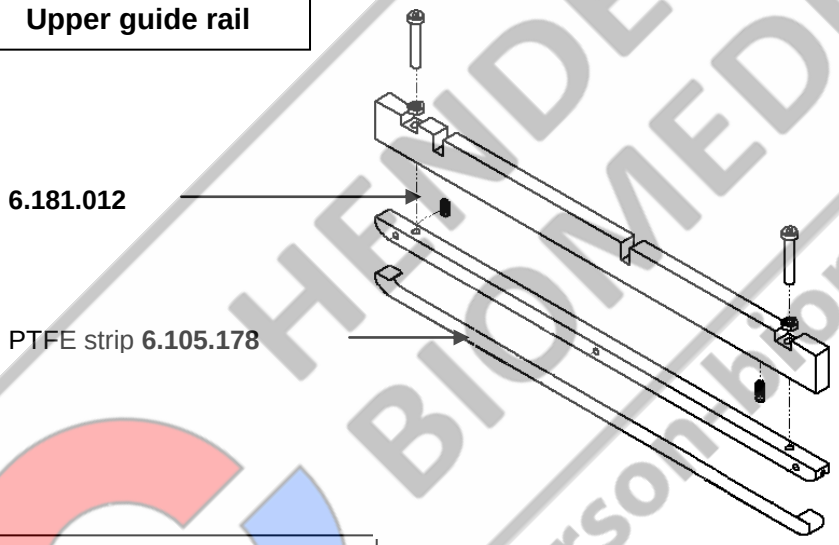
Signature

4.6 Replacement part orders- allocation of article numbers

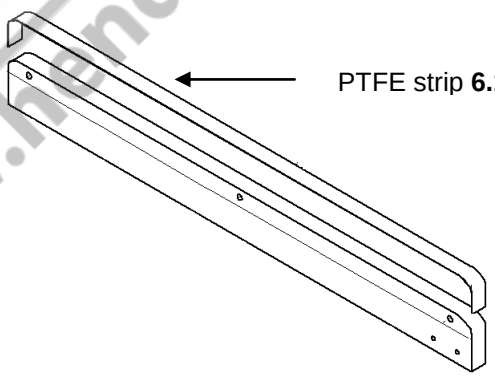
Heating die



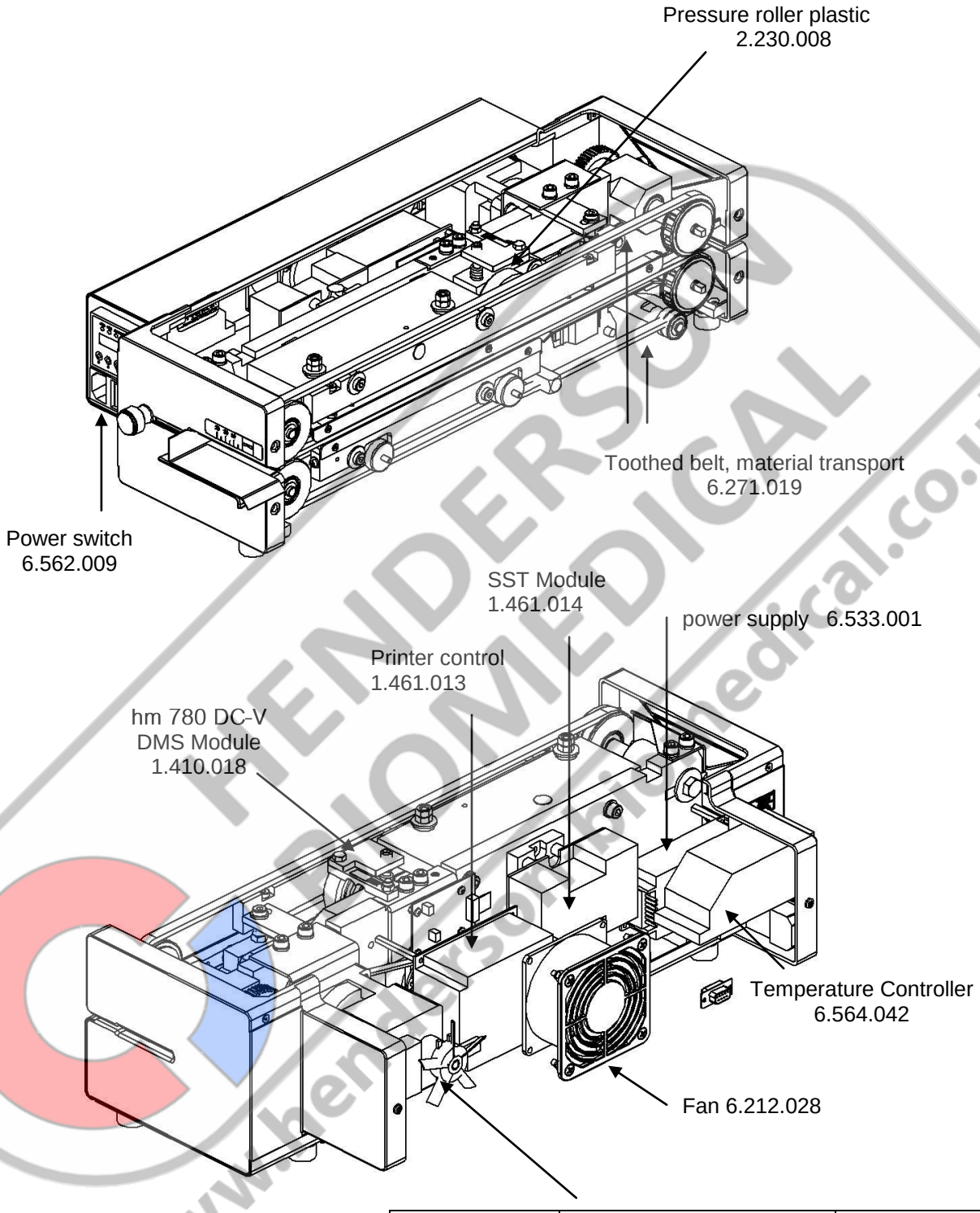
Upper guide rail



lower guide rail



4.7 Spare part ordering – Complete overview



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

4.8 Information about replacing wearing and spare parts

! Please use only genuine replacement parts

Replacing ink ribbon

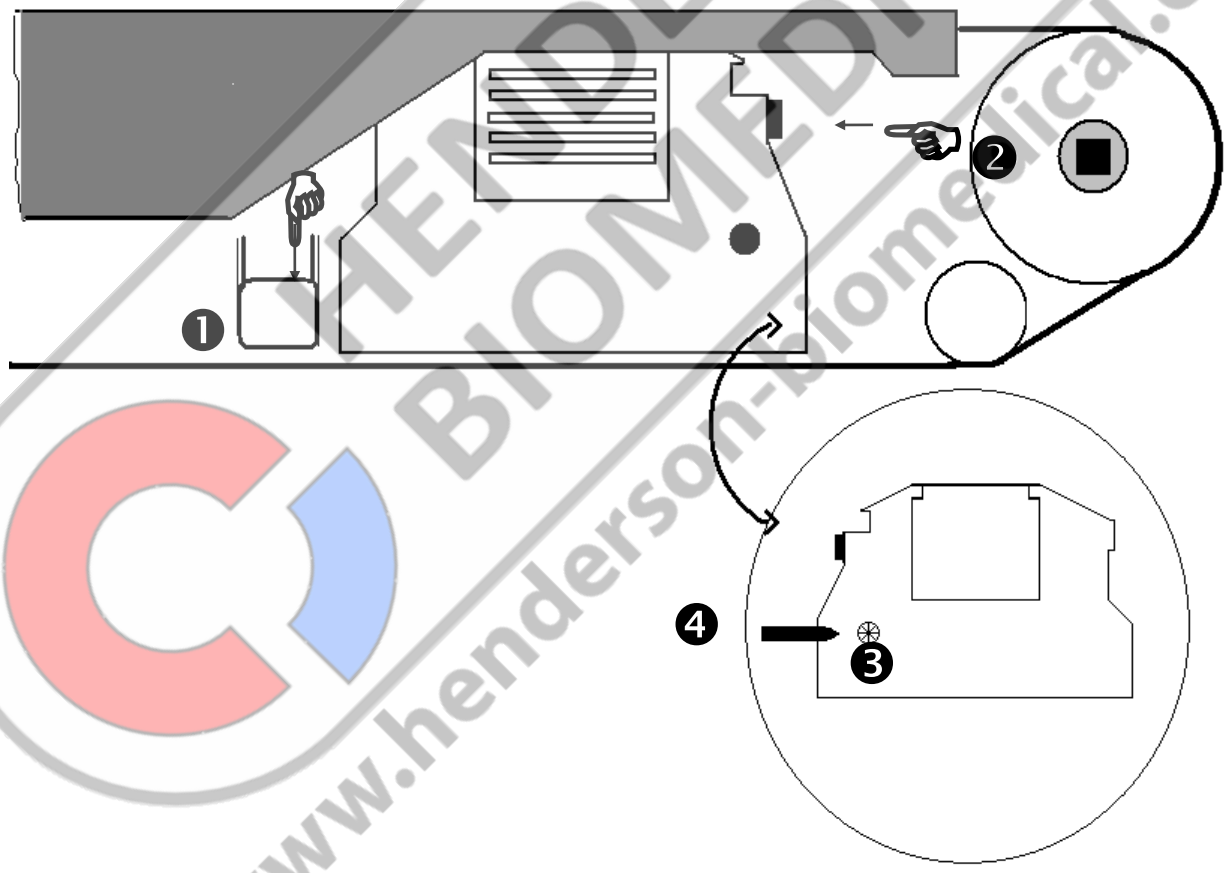
➔ **Switch off machine**

- 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 rink 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

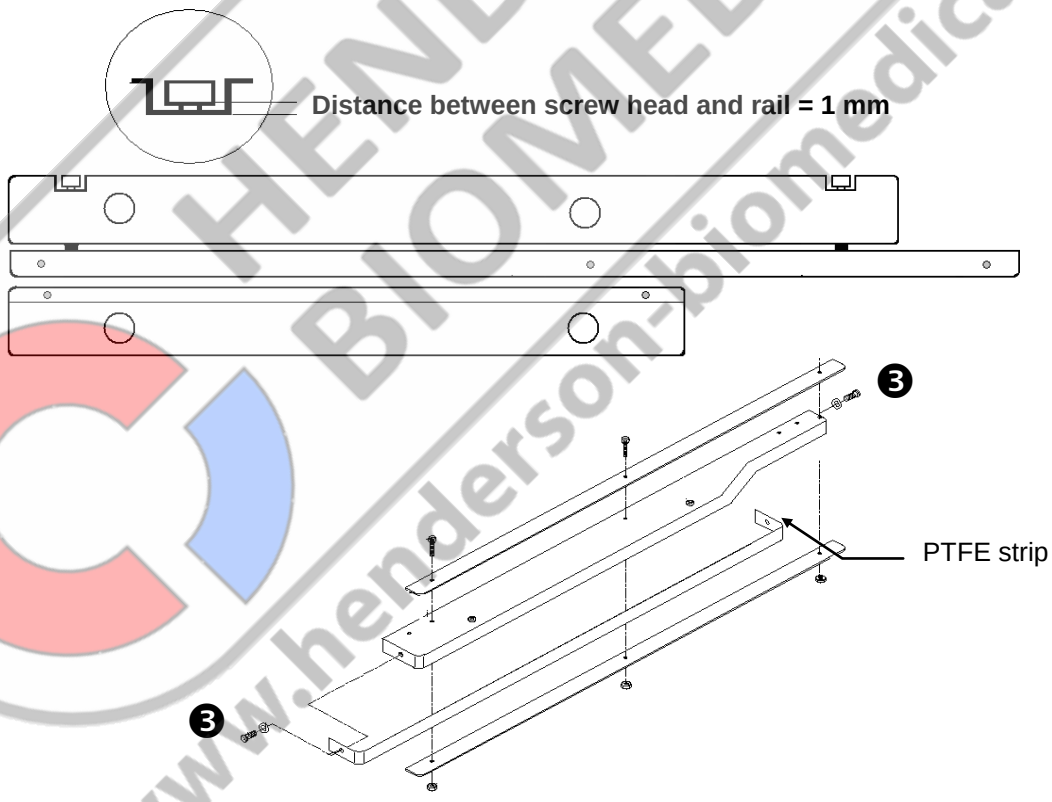
Replacing PTFE strip on guide rail

➔ Switch off machine and DISCONNET POWER PLUG !

- Open housing
- Remove mounting screws ❶ for upper guide rail and remove guide rail **or**
- Remove mounting screws ❷ for lower guide rail and remove guide rail
- Remove mounting screws ❸ 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 ❸
- 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



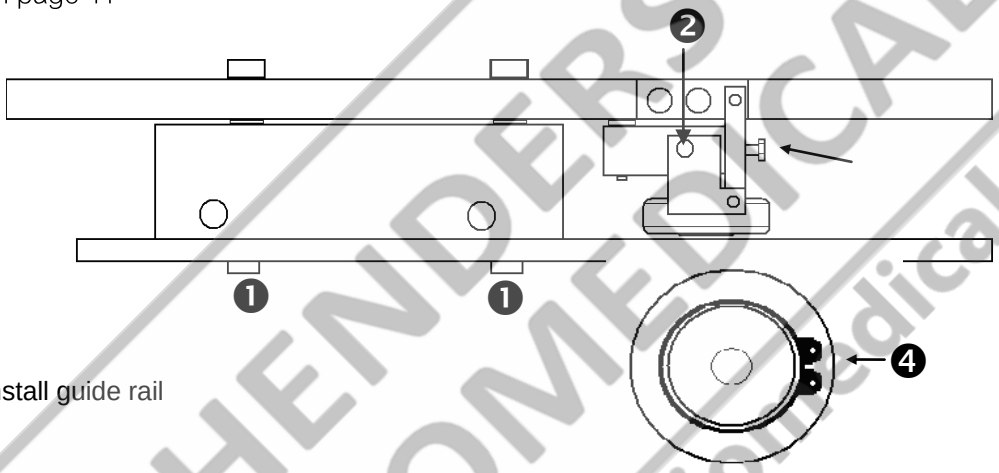
Maintenance Information

! Please use only genuine replacement parts

Replacing pressure roller

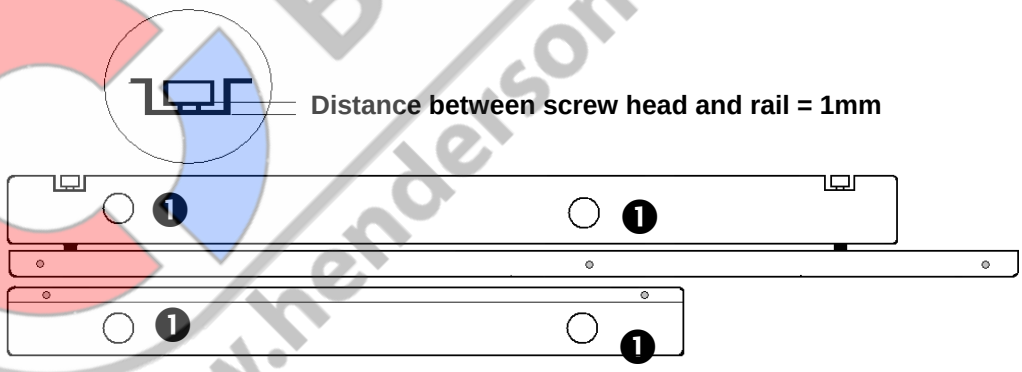
➔ Switch off machine and DISCONNET POWER PLUG !

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



- Install guide rail

When installing the upper guide rail before fastening screws ❶, 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



- Close housing

4.9 Process parameters adjustment

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

4.9.1 Temperature control

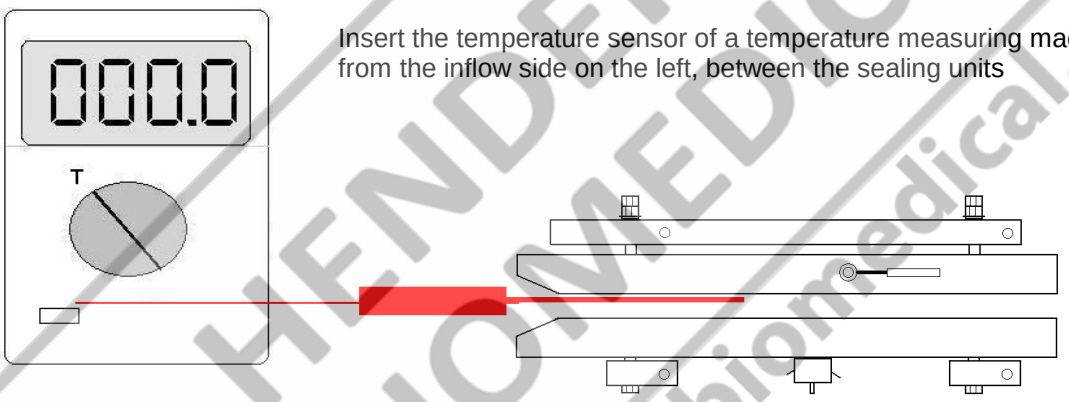
The temperature control adjustment should always be carried out after replacing a heating element,
after replacing the temperature sensor and after replacing the temperature control

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

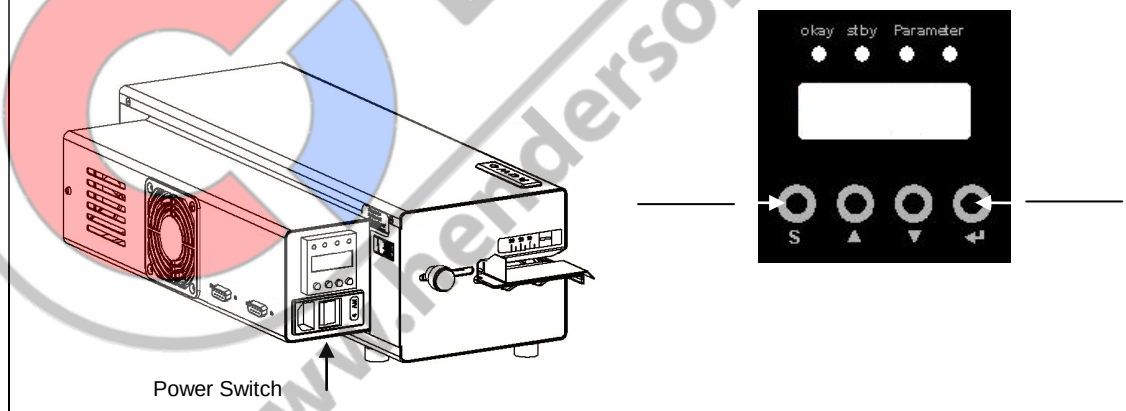
After reaching the set temperature, this is stabilized for 120 s.
At the end of 120 s, the temperature value
measured with the temperature gauge is input

Process

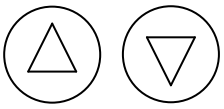
Insert the temperature sensor of a temperature measuring machine from the inflow side on the left, between the sealing units

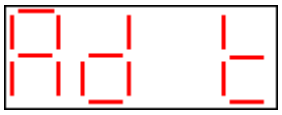


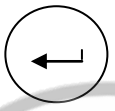
Press both buttons simultaneously and switch on the machine.



Select temperature adjustment





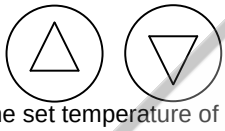


Confirm selection

The set temperature of the machine 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

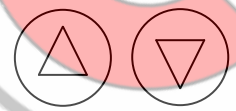


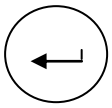
Confirm input

The set temperature of the machine 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





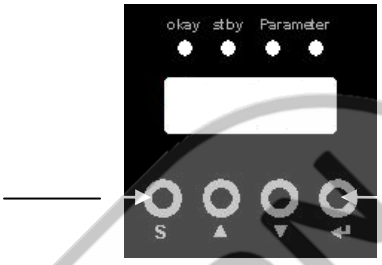
Confirm input

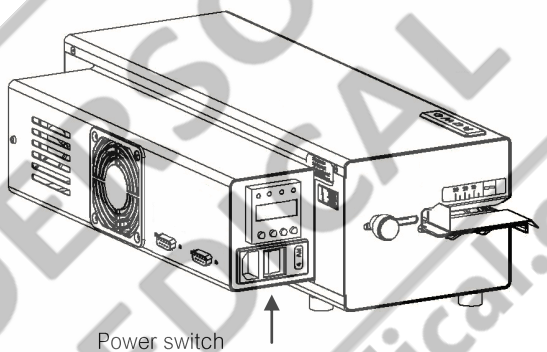
4.9.2 Contact pressure **ONLY hm 780 DC-V machine**

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.

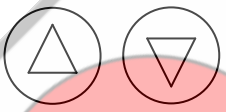
Only then is the contact pressure monitoring active

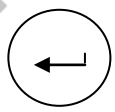
Press both buttons simultaneously and switch on the machine





Select contact pressure setting

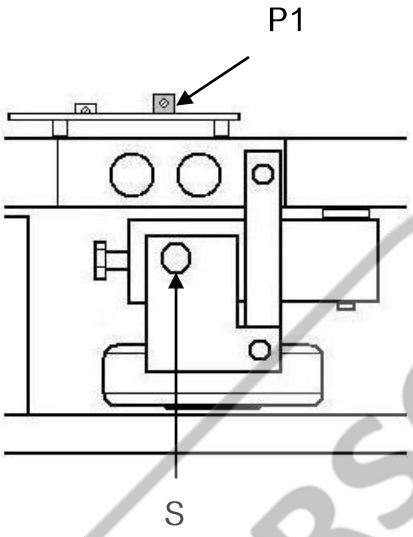




Confirm selection

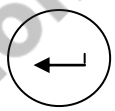
Process

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



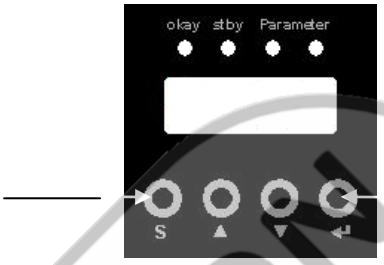
Confirm input

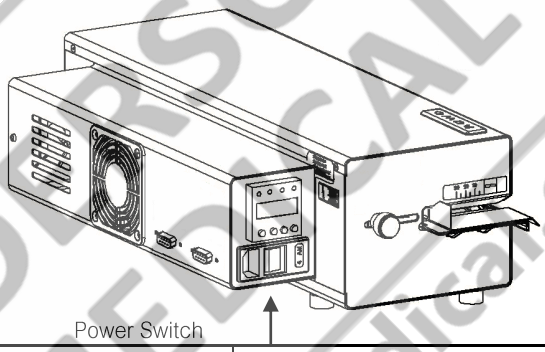
4.9.3 Motor monitoring configuration

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 machine





Select motor monitoring configuration

Select motor power frequency

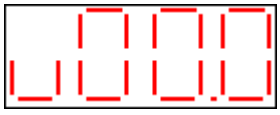
The motor is started and for 5s the measured sealing speed is displayed

50Hz

60Hz

Display motor hm 780 DC-V

Display motor hm 780 DC

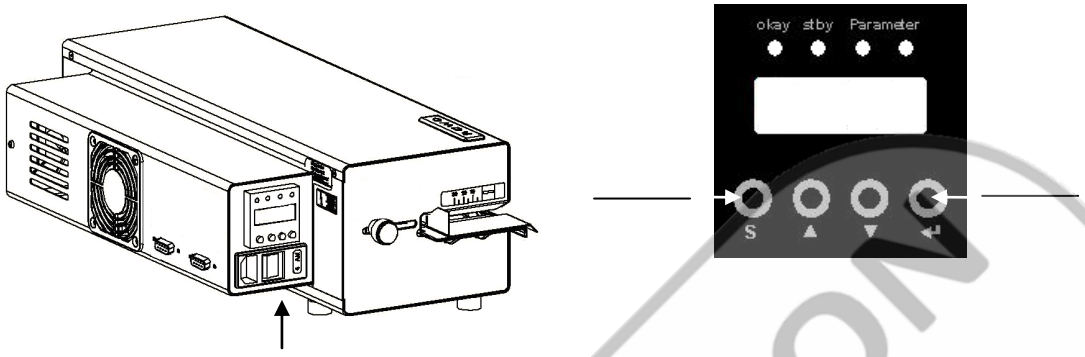


Confirm selection

Confirm selection

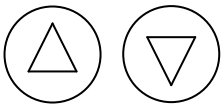
4.9.4 Setting the transmission rate (baud rate) of the serial interface

Press both buttons simultaneously and switch on the machine



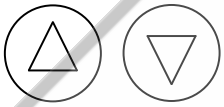
Power Switch

Select baud rate setting



Select baud rate

1200Bd – 57600Bd



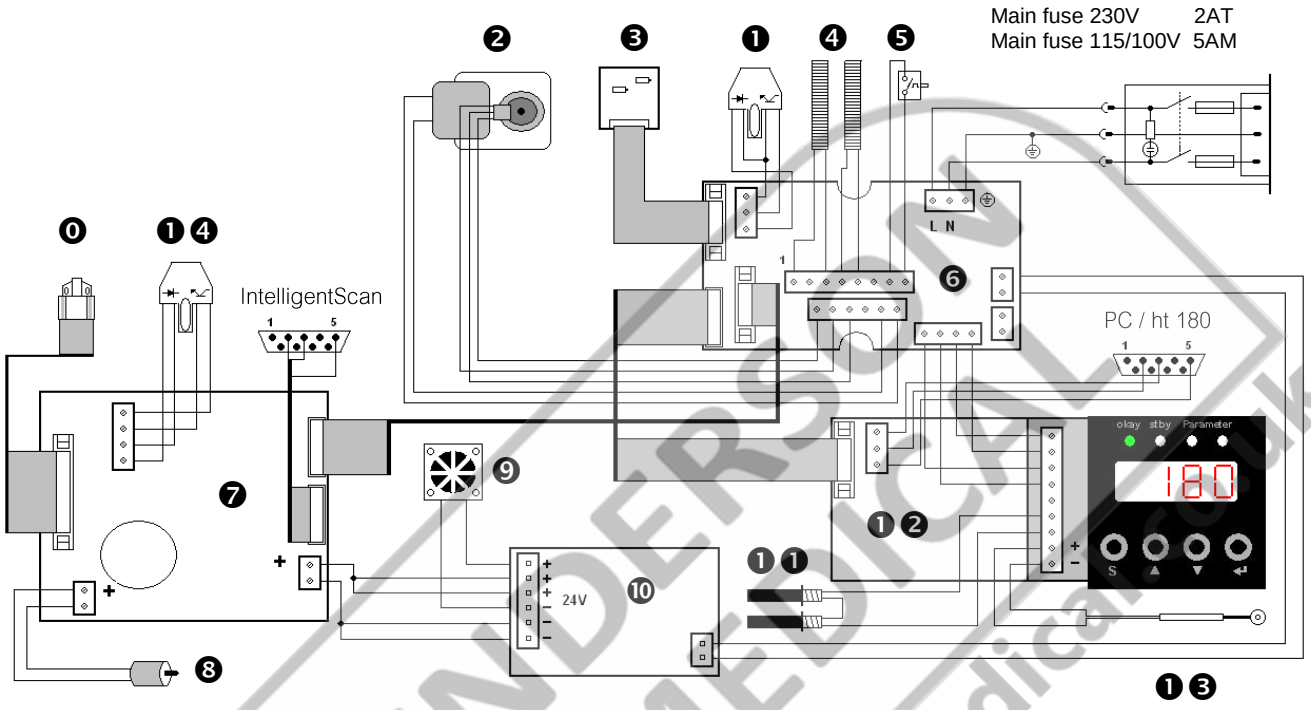
Confirm selection

Example: Baud rate 57600Bd

Confirm selection

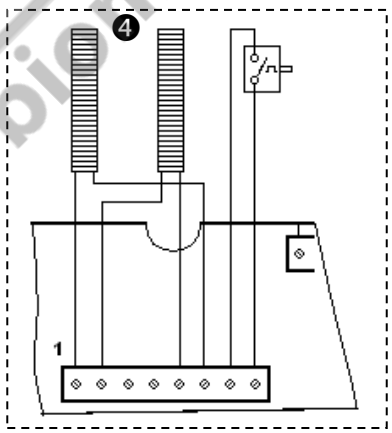
5 Technical Data

5.1 Circuit and Wiring Diagram hm 780 DC-V

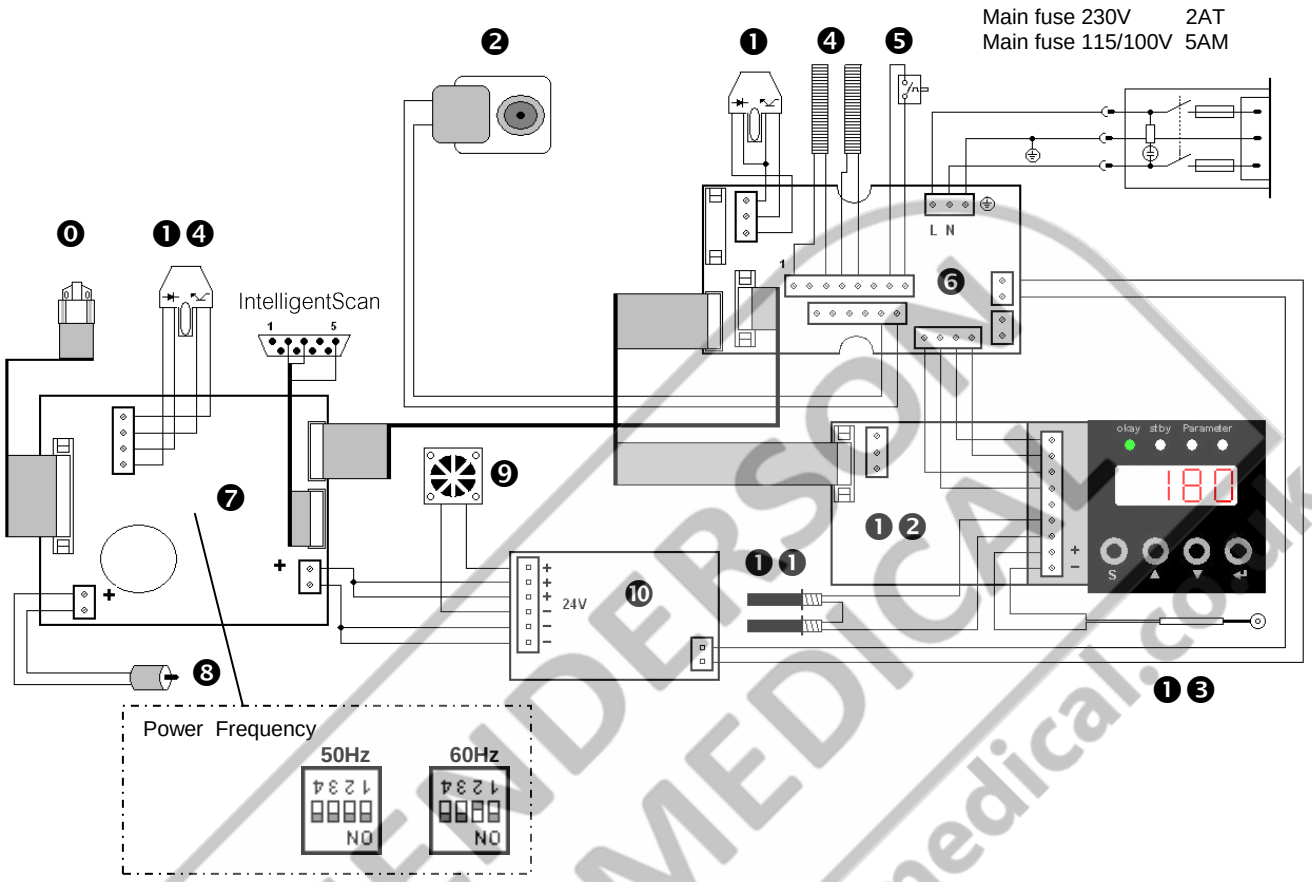


Heating elements connection at 115/100 V

⓪	Print head	1.653.002
❶	Light barrier motor	1.561.010
❷	Gear motor 230V Gear motor 115V Gear motor 100V	1.212.020 1.212.021 1.212.022
❸	DMS-Module	1.410.018
❹	Heating cartridge	6.536.024
❺	Temperature limit swwitch	6.564.018
❻	SST Module	1.461.014
❼	Printer control	1.461.013
❽	Motor ink ribbon	1.212.012
❾	Fan	6.212.028
❿	Switched –mode power supply	6.533.001
❶❶	Reed contact	6.543.011
❶❷	Temperature control	6.564.042
❶❸	Thermocouple	6.564.023
❶❹	Light barrier printer	1.561.003

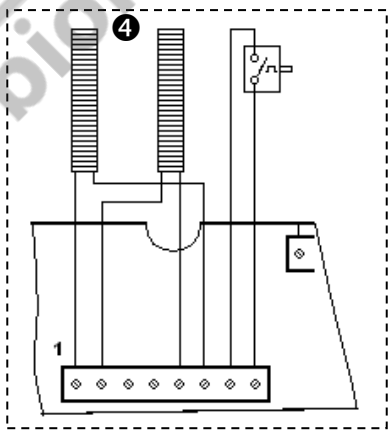


5.2 Circuit and Wiring Diagram hm 780 DC



⓪	Print head	1.653.002
❶	Light barrier motor	1.561.010
❷	Gear motor 230V Gear motor 115V Gear motor 100V	1.212.026 1.212.027 1.212.028
❸		
❹	Heating cartridge	6.536.024
❺	Temperature limit swwitch	6.564.018
❻	SST Module	1.461.014
❼	Printer control	1.461.013
❽	Motor ink ribbon	1.212.012
❾	Fan	6.212.028
❿	Switched-mode power supply	6.533.001
❶❶	Reed contact	6.543.011
❶❷	Temperature control	6.564.042
❶❸	Thermocouple	6.564.023
❶❹	Light barrier printer	1.561.003

Heating elements connection at 115/100 V



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 Width Height	[mm]	560 250 145
Housing cover		Steel AISI 304
Housing buttom		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 und 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

6 Declarations of Conformity

6.1 CE Declaration of Conformity

hawo 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaracción de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade	9.694.026C

Gültig ab: 01.02.2015 — Seite 1/1
Valid from: — Version 2.02

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:
Dichiariamo con la presente che le macchine per saldatura di fogli:
Por este meio se declara que as máquinas de selagem de folhas de plástico:

hm 780 DC, hm 780 DC-V

folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen:
complies with the requirements of the following regulations and harmonised standards:
corresponde aux dispositions suivantes et standards harmonise:
objeto de esta Declaración cumpie con las siguientes disposiciones:
Sono conformi alle seguenti dieposizioni in materia nonché alle seguentie norme armonizzate:
corespondem às sequintes determinações e normas harmonizadas:

EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle maccine nella versione Directiva da UE relativa a maquinaria		2006/42/EG	
EMV-Richtlinie Directive CEM Direttiva CEM	EMC-directive Directiva de CEM Directiva CEM	2014/30/EU	
WEEE-Richtlinie Directive WEEE Direttiva WEEE	WEEE--directive Directiva da WEEE Directiva WEEE	2012/19/EU	
RoHS-Richtlinie Directive RoHS Direttiva RoHS	RoHS-directive Directiva de RoHS Directiva RoHS	2011/65/EG	
Harmonisierte Normen Standard harmonise Norme armonizzate	Harmonized standards Las normas armonizadas Normas harmonzidadas	EN ISO 12100/2010_07 EN ISO 13857/2008_06	EN 60204-1/2007_06 EN 61000-6-1/2007_10 EN 61000-6-3/2011_09

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

Torsten Ehrhardt
Prokurist / authorized officer

hawo GmbH, Obere Au 2, D-74847 Obrigheim, Germany

9.910.007 Version 2.01

hawo GmbH Obere Au 2-4 74847 Obrigheim / Germany	T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 62015 info@hawo.com www.hawo.com	Amtsgericht Mannheim: HRB 441011 Geschäftsführer: Hans Wolf und Christian Wolf Firmensitz: Obrigheim	This document and the contents hereof are considered proprietary and confidential information of hawo and disclosure to unauthorized individuals or dissemination, publication, or copying is prohibited without prior written consent by hawo GmbH, 74847 Obrigheim, Germany.

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

hawo 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration de Conformité Declaración de conformidad Dichiarazione di conformità - Declaração de conformidade	9.694.026D

Gültig ab: 01.10.2012 / Valid from:
Seite 1/1
Version 1.03

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:
Dichiariamo con la presente che le macchine per saldatura di fogli:
Por este meio se declara que as máquinas de selagem de folhas de plástico:

hm 780 DC-V

folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen:
complies with the requirements of the following regulations and harmonised standards:
corresponde aux dispositions suivantes et standards harmonise:
objeto de esta Declaración cumpie con las siguientes disposiciones:
Sono conformi alle seguenti dieposizioni in materia nonché alle seguentie norme armonizzate:
corespondem às sequintes determinações e normas harmonizadas:

Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention(KRINKO) beim Robert Koch-Institut(RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte(BfArM)	KRINKO / BfArM Bundesgesundheitsblatt 2012 55:1244-1310
Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens Packaging for terminally sterilized medical devcies – Part 2: Validation requirements for forming, sealing and assembly processes Emballages des dispositifs médicaux stérilisés au stade terminal – Partie 2: Exigences relatives aux procédes de mise en forme, de fermeture et dàssemblage	DIN EN ISO 11607-2:2006 ANSI/AAMI/ISO 11607-2:2006
Sterilisation – Sterilgutversorgung – Teil 7: Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und –schläuchen Sterilization – Sterile supply – Part 7: Use of sterilizaiton paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels Stérilisation – Approvisionnement en produits stériles – Partie 7: Utilisation de papier pour sterilisation, de matériaux d'enveloppe en non-tissé, matériaux textiles tissés, de sacs en papier, de sachets et gaines scellables	DIN 58953-7:2010

Torsten Ehrhardt
Prokurist / authorized officer
hawo GmbH, Obere Au 2, D-74847 Obrigheim, Germany

hawo GmbH Obere Au 2-4 74847 Obrigheim / Germany	T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 62015 info@hawo.com www.hawo.com	Amtsgericht Mannheim: HRB 441011 Geschäftsführer: Hans Wolf und Christian Wolf Firmensitz: Obrigheim	This document and the contents hereof are considered proprietary and confidential information of hawo and disclosure to unauthorized individuals or dissemination, publication, or copying is prohibited without prior written consent by hawo GmbH, 74847 Obrigheim, Germany.

9.810.007 Version 2.01

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 machines.

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

The manufacturer's calibration of hawo sealing machines 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 machine

Your sealing machine 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 +/- 5°C (+/- 9°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)
Uncoated 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 machine: Rotary sealer

The machine 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.

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 machine.

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 machine can be connected through an interface directly to the batch documentation system. Ask the producer for the exact compatibilities.

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 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 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).

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 machineor if the packaging material has been changed.

As the manufacturer, we recommend annual periodic revalidation. If no changes have been made to the sealing dmachine 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).

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

Servicing and calibration of hawo sealing machine 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)

HENDERSON BIOMEDICAL

LABORATORY EQUIPMENT MAINTENANCE, REPAIR, CALIBRATION AND SALES

Established in 1987, Henderson Biomedical is the UK's leading laboratory equipment sales and service provider. Our knowledgeable team can provide you with excellent sales advice on a range of different types of laboratory equipment including centrifuges, refrigerators, freezers and heat sealers.

Henderson Biomedical is also able to provide you with first class after-sales service and calibration of your laboratory equipment. We are an **ISO 17025 (UKAS) accredited calibration test laboratory** and our team of Field Service Engineers cover the whole of the United Kingdom.

Please contact us for more information on the types of equipment we supply and the different after-sales services we can offer.

Henderson Biomedical
Unit 3, Swan Close
Croydon CR0 2DZ
United Kingdom

Tel: 020 8663 4610

For sales enquiries: sales@henderson-biomedical.co.uk
For all other enquiries: info@henderson-biomedical.co.uk
www.henderson-biomedical.co.uk