Instruction manual

from version 3.0

hd 680 DE-V

9.693.010

Version 2.01

ENGLISH

Table of Contents

1 Introduction

Preface

First of all we would like to sincerely thank you for buying the cycle sealing machine.

In these instructions you will find information about the machine, its function and operation.

Please read these operating instructions thoroughly before putting the machine into operation so that you become familiar with its capabilities and can use its functions optimally.

Always keep these instructions close to the machine.

Important notice:

This machine is a film rotary sealing machine for closing sterile barrier systems.

Please observe chapter "*Correct use*" in these operating instructions in this respect.

In accordance with the purpose, CE certification based on the EU Directives indicated below has been affixed: 2006/42/EG, 2011/65/E6 and 2004/108/EG.

Directive 93/042 EEC is not applicable to welding and sealing machines.

The limit values of IEC 60601-1 cannot be used with electrical re-tests.

The manufacturer shall accept no liability whatsoever for damage caused by tests which are not listed in the Declaration of Conformity.

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 update these operating instructions and the functions described in them accordingly.
Should you nevertheless notice errors or points that are unclear, please let us know about them.

These operating instructions are valid for products as from the date of manufacture of 05/2019

2 Before starting

2.1 Finding your way around these operating instructions

Chapter 2 Before starting	In this chapter you will find information about using the machine correctly, its function and advice about operation and installation. PLEASE READ THIS ESSENTIAL INFORMATION!
Chapter 3 Basic functions	Adjusting and operating the machine are explained here.
Chapter 4 Fault clearance and maintenance	Instruction on finding disturbance sources and rectifying malfunctions. Here you will find out about necessary servicing, wearing parts and spare parts as well as about the allocation of product numbers for spare parts orders.
Chapter 5 Technical data	Here you see the circuit and wiring diagram as well as the machine specification.
Chapter 6 Declaration of Conformity	In this chapter you will find the Declaration of Conformity for the rotary sealing machine.
Chapter 7 Validation	Information for Validation of packaging processes

2.2 Correct use

The machine is only designed for trade and industrial use and must only be used for the prescribed purpose.

SEALING MATERIALS

Sealable paper pouches in accordance with EN ISO 11607-1/EN 868-4	x
Sealable pouches and reels in accordance with EN ISO 11607-1/EN 868-5 of film and paper according EN 868-3	x
Sealable pouches and reels according ISO 11607/EN 868-5 of film and uncoated nonwoven materials of polyolefines according EN 868-9[1]	x (approval and/or tests necessary)
Aluminium-laminate film	x (approval and/or tests necessary)
Sealable PA/PE on request	on request

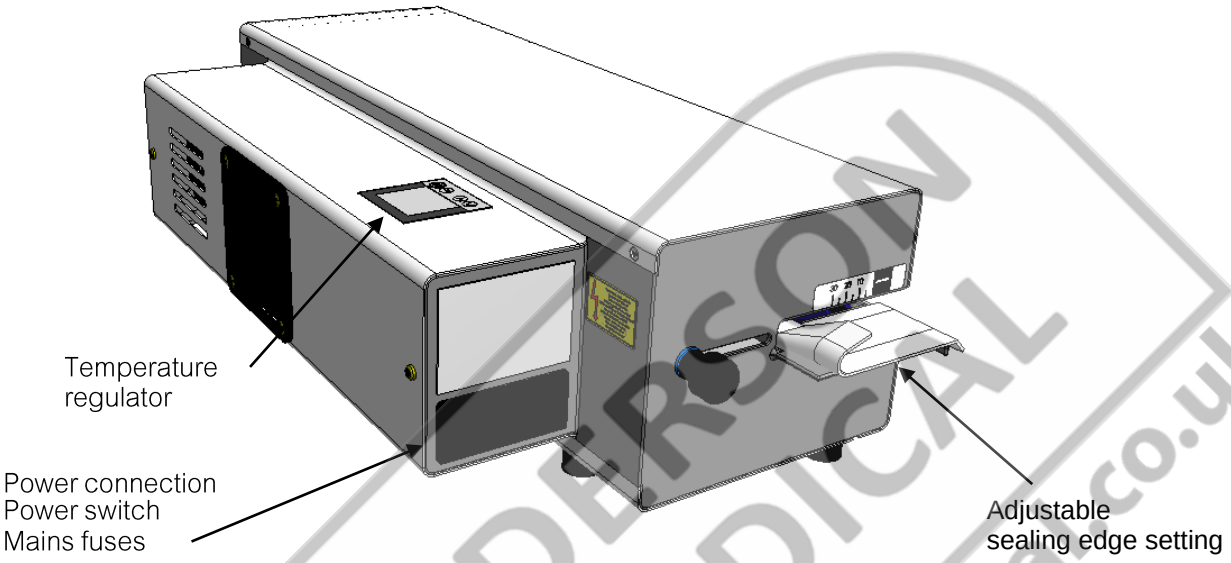
NON - SEALABLE MATERIALS

Polyethylene films	Soft PVC films
Hard PVC films	Polyamide films
Polypropylene films	Coated HDPE

The correct sealing temperature for the packaging materials being used must be identified by means of test sealing's (DIN 58953-7).
The device output depends on the condition of the sealing material used.

[1]Not applicable for sealable pouches and reels according EN ISO 11607-1/EN 868-5 of plastic and uncoated nonwoven materials of polyolefines according EN 868-10.

2.3 Assembly and function



2.4 Sealing process sequence

Step 1: After the sterilisation packaging has been inserted the transport switches on automatically.

Step 2: The sterilisation packaging is now transported and the sealing seam area is heated up by the heating dies positioned above and below to the sealing temperature set.

Step 3: The sealing seam, which is now heated up, is pressed through the sealing rolls and thus sealed.

Step 4: The completed sterilisation packaging is transported to the withdrawal side.

Step 5: If no further material to be sealed is fed in the transport switches off after approximately 30 seconds.

2.5 General safety instructions

The machine must not be installed or operated by persons under the age of 14.

The machine must not be operated without supervision.

If the machine is not being used, switch it off or unplug at the power outlet.

The machine should only be cleaned with a dry or slightly damp cloth.

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

Do not operate the machine if the power cable or the power plug are damaged. Do not use the machine if it does not operate correctly or it is damaged in any way. In case of damage of the power cable or of the machine, you have to bring your machine to an authorized service center

Warning! Never clean the machine wet!

Keep your hair, clothing and gloves away from moving parts! Loose clothes, jewellery or long hair can be caught in moving parts.

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.

2.6 Cleaning

Before cleaning, disconnect the mains plug from the socket and disconnect the device from the power supply with the plug.Clean the device only with a dry or damp soft cloth and a mild cleaning agent. (E.g.: isopropanol, spirit, etc.)
Do not allow any water to find its way into the device.

Caution! Never wet clean the device!

2.7 Installation

The unit must not be installed or operated in potentially explosive atmospheres.

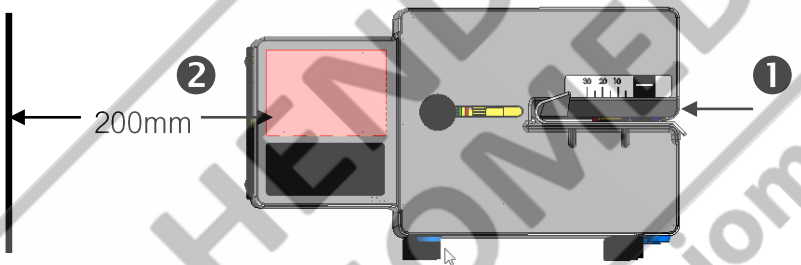
Only use grounded power outlets with a grounding conductor and a stable voltage supply

The machine may only be installed in a dry environment. Heavy dust, steam, dripping water, and splashes of water have a negative impact on the performance of the machine.

Please make sure the operating voltage conforms to the information on the rating plate on the machine.

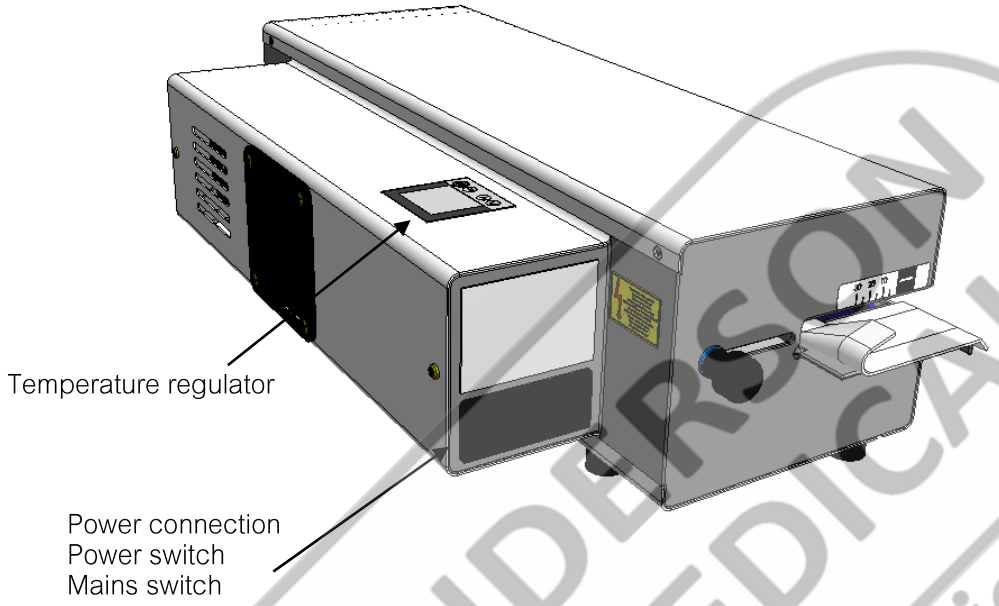
❶ Please do not lift or transport by using the sealing edge adjuster

❷ Leave a gap of 200mm between the machine and the wall



3 Basic functions

3.1 Commissioning



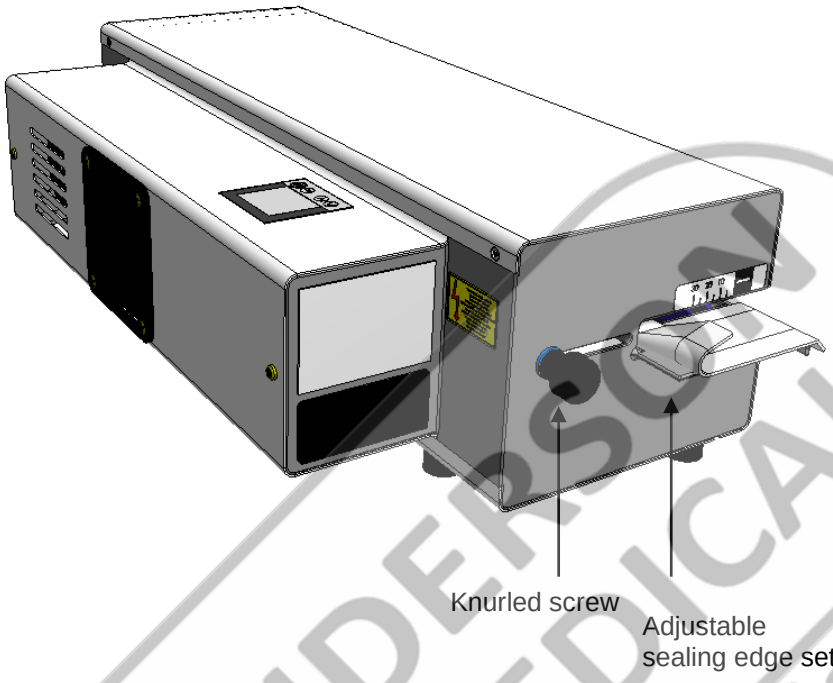
Step 1: Plug power cable into power connection.

Step 2: Switch machine with power switch to setting "1".
Control light in the switch illuminates.

Step 3: Set the desired sealing temperature on the temperature regulator as described in chapter 3.3.

Step 4: As soon as the set sealing temperature is displayed the machine is heated up and ready for operation.

3.2 Operation



Step 1: Set the desired sealing edge width. After the knurled screw has been loosened the lower insertion plate can be set infinitely variably for sealing widths of 0 - 35mm.

Step 2: Insert packaging into the machine over the insertion plate from the left.

Step 3: Take out sealed packaging at the exit side and briefly leave to cool down.

Inspecting the sealing seam
If points that are not tightly sealed are apparent the sealing temperature must be increased. If the foil melts the set temperature is too high.

In accordance with DIN 58953 -7 the appropriate sealing temperature must be identified by performing test sealing.

3.3 Process variable

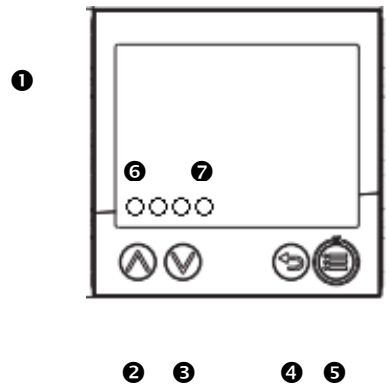
3.2.1 Sealing temperature

The temperature is electronically monitored by means of a temperature sensor.
If the temperature deviates from the setpoint by 5°C (Requirements fromDIN 58953-7), the drive is disabled.

3.2.2 Contact pressure

The contact pressure is electronically monitored by means of a force sensor.
In the event of a deviation from the factory-set nominal value, a warning message is shown on the display.

3.3 Temperature setting



❶ Controller
❷ Temperature adjustment upwards
❸ Temperature adjustment downwards
❹ Back
❺ Menu / Accept
❻ Led – 1 → Prozess status
❼ Led – 4 → heating status

Temperature adjustment

Press button ❺

Controller „MENU“ [User Level] accept by pressing button ❺ twice

Adjustment of temperature with buttons ❷ [+1°C] ❸ [-1°C]

Accept value by pressing button ❺ → OK is visible in the screen for 2 seconds

Back tot he mains screen by pressing button ❹ twice

Werksseitige Einstellung :

Adjusted temperature	190°C
Unit of temperature	°C

3.4 Contact pressure monitoring

The sealing temperature is preset and is monitored continuously.
If the contact pressure is within the specified tolerance limits, the display shows no message. If the limits are exceeded or fallen below, the display shows failure “contact pressure failure”.

During this failure message, the machine stops the sealing process.

4 Fault clearance and maintenance

4.1 Fault clearance checklist

Malfunction	Possible cause	Remedy
Machine does not switch on	Network connection	
	Power cable not plugged in	Check network connection; connect another plug if necessary
	Power cable defective	Replace power cable
	Mains fuse	Replace mains fuse. In the event of fuses blowing repeatedly you must compulsorily have the machine checked!
Machine is not heating	Target temperature too low	Increase target temperature
	Over temperature cut-out has triggered	Press in over temperature cut-out. In the event of repeated triggering you must compulsorily have the machine checked!
	Temperature regulator	Replace temperature regulator
	Heating element	Check heating elements and replace if necessary
	Solid state relay	Replace solid state relay
No material transport	Target temperature not reached	
	Motor defective	Replace motor
	Opto sensor defective	Replace opto sensor
	Contact pressure too low	Adjust contact pressure or replace DMS module
Non-symmetrical material transport	Toothed damaged	Replace toothed belt
	Tooth belt not transporting	Check toothed belt tension
Loud running noise	Motor defective	Replace motor
Sealing seam does not hold up	Sealing temperature too low	Increase sealing temperature
	Clearance between sealing dies is too large	Set the sealing die to 0.5mm
Sealing seam distorted or melted	Sealing temperature too high	Reduce sealing temperature

4.2 hawo Customer Service

You can contact your hawo Customer Service Monday to Friday from 8.00 am to 4.00 pm on +49 (0)6261-9770-0 .

4.3 Maintenance plan

As is the case with all technical machines your machine is also subject to technical wear.
In order to guarantee that your machine is permanently ready to use it should be serviced by a qualified person at least once per year.

Maintenance cycle	cleaning	Teflon strip Guide die	Teflon strip Sealing die	Pressure roller	Toothed belt	Sealing die interval
At least every 3. Month						
According to load, at least once per year						

Key:

 Check

 Replace

 Adjust

4.4 Spare parts service

Easy spare parts ordering by fax!
All you have to do is to copy the order form.
You will find the form on the next page.

- Enter address, fax number and order number
- Enter serial number
- Enter machine type
- Mark required items
- Enter required quantity
- Sign the order
- Fax the order

To: Sender:

_____ _____

Fax no.

Your order no. _____		Date _____	
Machine type _____		Serial number _____	
☑	Description	Item no.	pce
☐	PTFE-strip sealing die	6.105.125	
☐	PTFE-strip guide rail	6.105.138	
☐	Pressing Roll (Synthetic Material)	2.230.008	
☐	Tooth belt big	6.271.001	
☐	Tooth belt small	6.271.002	
☐	Heating Cartridge	6.536.024	
☐	Upper sealing die complete	1.616.020	
☐	Lower sealing die complete	1.616.021	
☐	Temperature controller	6.564.050	
☐	Over temperature cut out	6.564.018	
☐	Thermo couple	6.564.040	
☐	Dual LED	6.571.023	
☐			

Signature _____

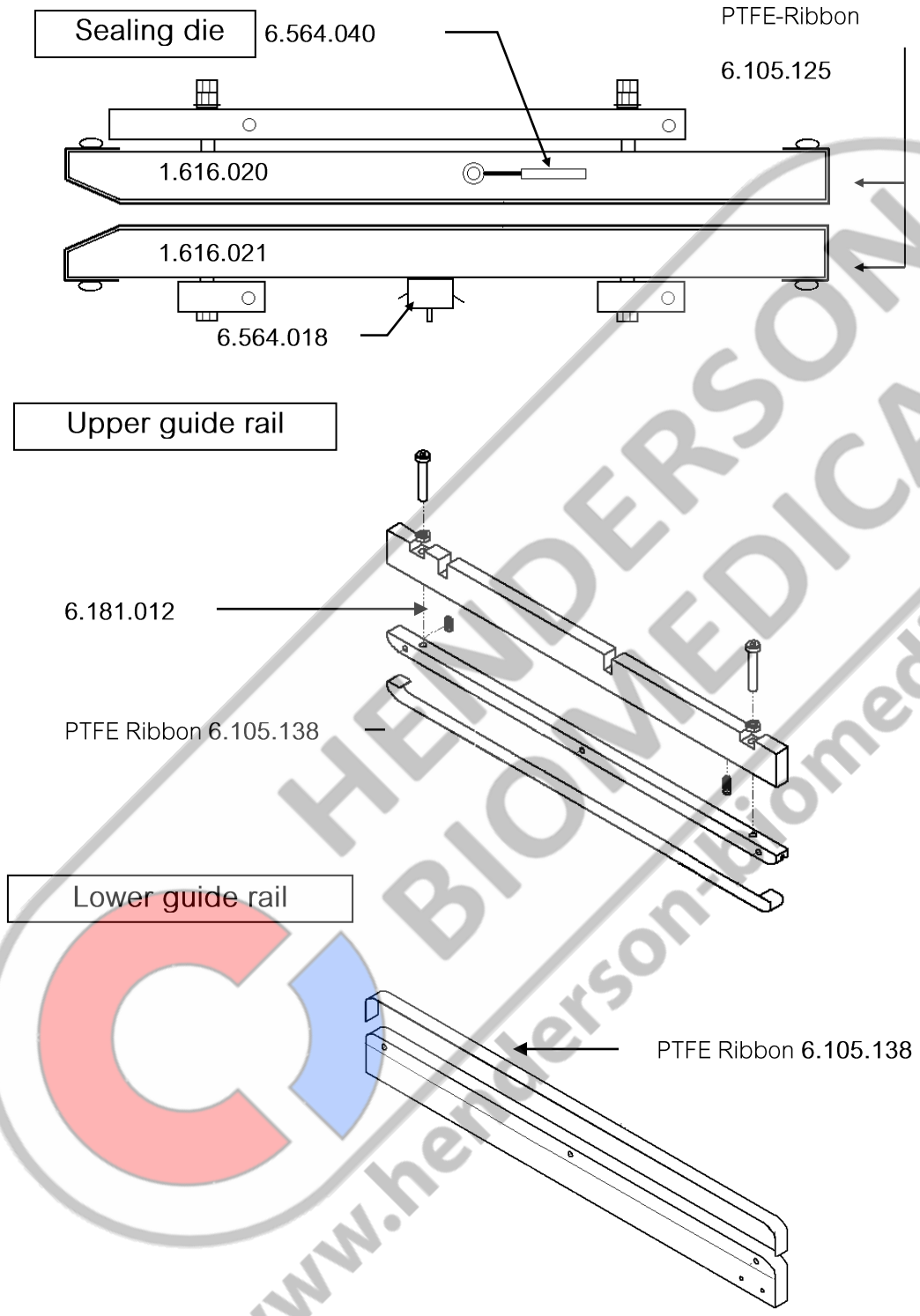
To: Sender:

Fax no.

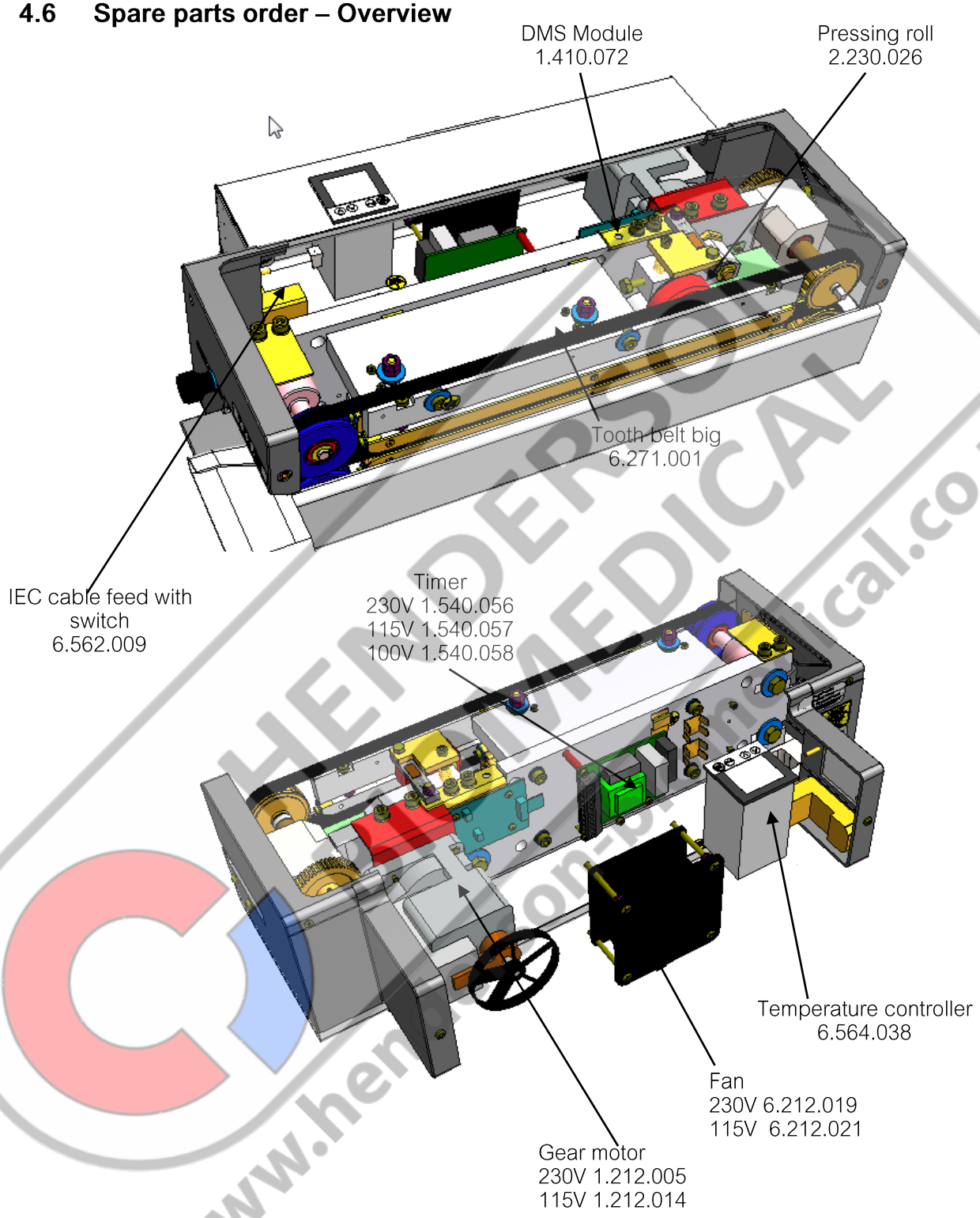
Your order no. _____		Date _____	
Machine type _____		Serial number _____	
☑	Description	Item no.	pce
☐	Timer 230V	1.540.056	
☐	Timer 115V	1.540.057	
☐	Timer 100V	1.540.058	
☐	DMS Module	1.410.072	
☐	Opto- Sensor	1.561.016	
☐	Gear motor 230V	1.212.005	
☐	Gear motor 115V	1.212.014	
☐	IEC cable feed with switch and Fuse element	6.562.009 6.522.049	
☐	Fan 230V	6.219.019	
☐	Fan 115V	6.219.021	
☐	Power cable 230V	6.593.013	
☐	Power cable 115V	6.593.014	

Signature _____

4.5 Spare parts order – product number allocation



4.6 Spare parts order – Overview



4.7 Maintenance – Replacing the PTFE ribbons

Please only use genuine hawo replacement parts !

Please do not open the machine before you haven't disconnected it from the main power !
Please follow the corresponding rules !

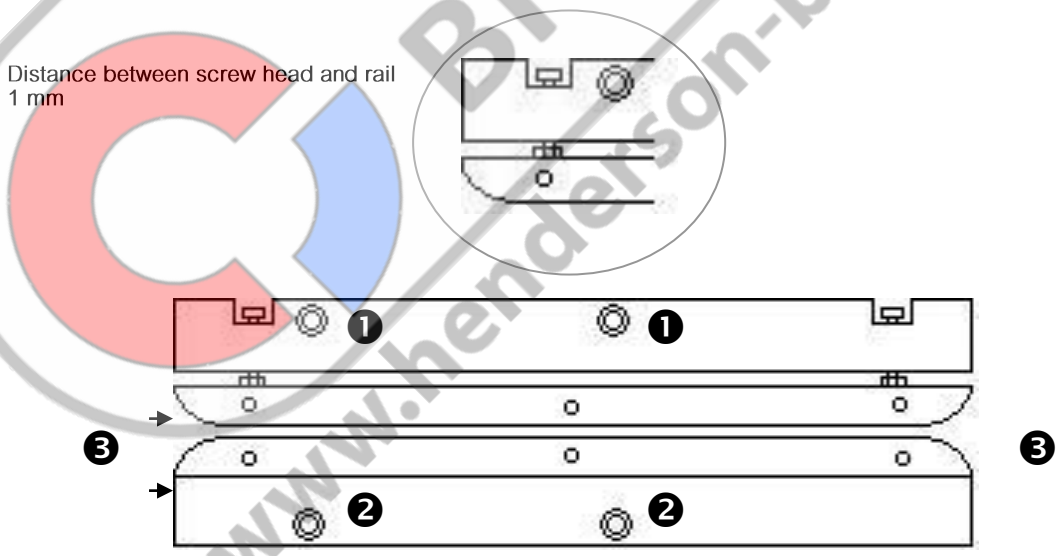
4.7.1 Replacing PTFE strip on guide rail

- 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.

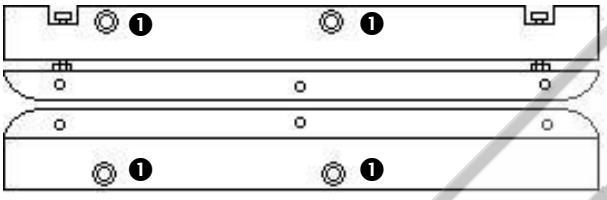
- Close housing



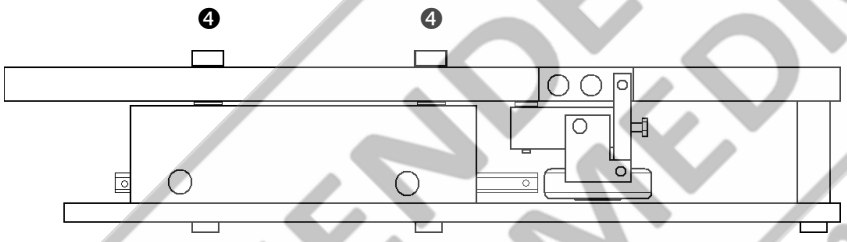
4.7.2 Replacing PTFE strip for upper and lower heating die

- Switch off machine and DISCONNET POWER PLUG !

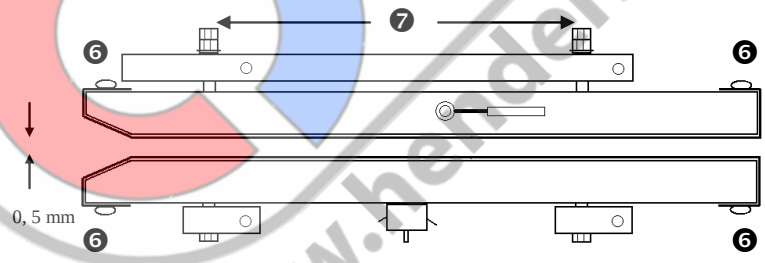
- Open housing
- Remove mounting screws ❶ for upper guide rail and remove guide rail.



- Disconnect electrical connections for heating die
- Remove fastening screw ❹
- Remove top or bottom heating die

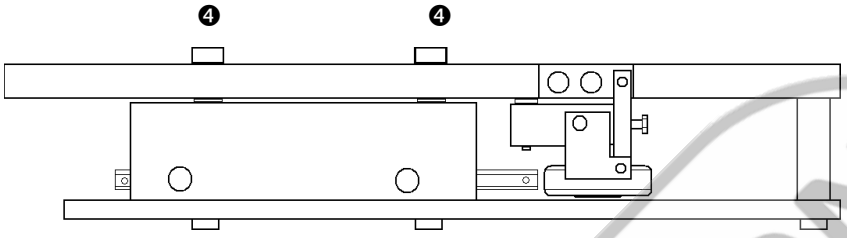


- Unscrew mounting screw ❻ and detach PTFE strip
- Remove backing foil on new PTFE strip and glue new PTFE strip on straight and without wrinkles
- Fasten PTFE strip with screw ❻
- Install heating die



- Detach nuts ❼
- Set distance between the sealing dies to 0.5 mm
- Fasten nuts ❼

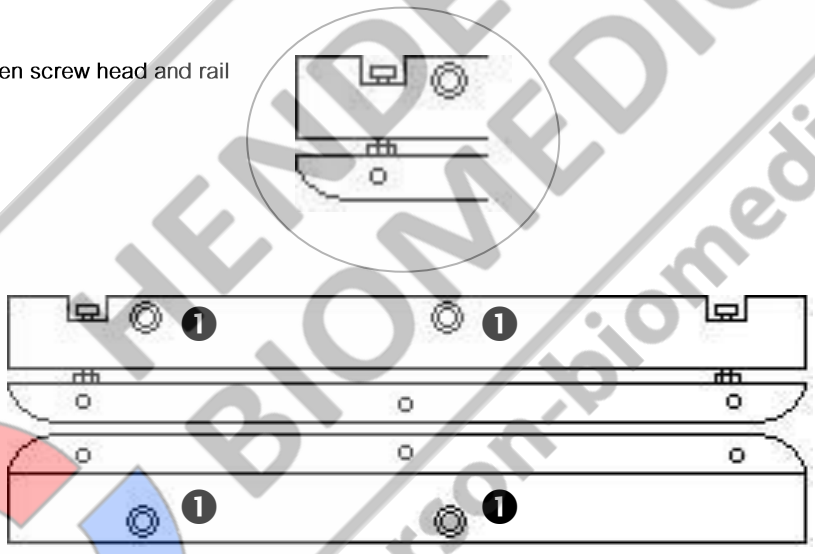
- Fasten fastening screws ❹ of the heating die
- Reconnect electrical connections to heating die



- Install l guide rails and fasten it with fastening screws ❶

- When installing the upper guide rail before fastening , 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
1 mm

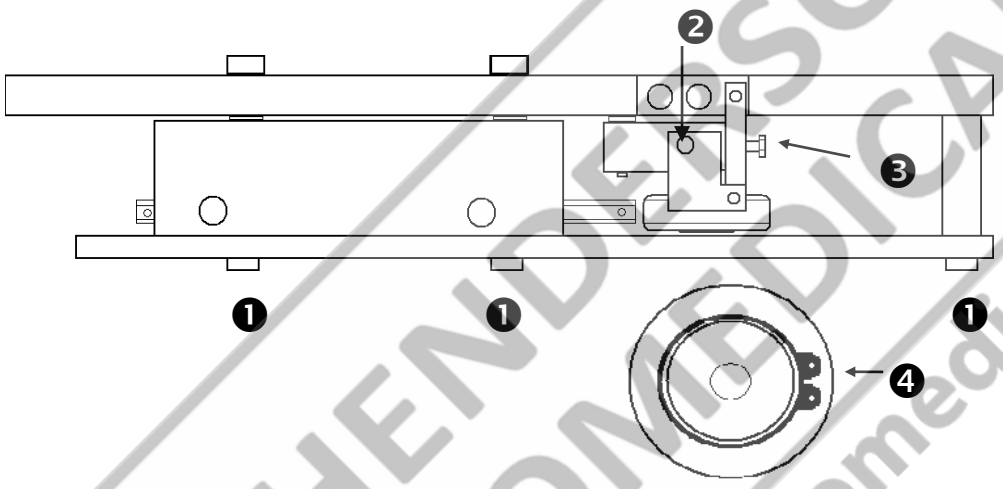


- Close housing

4.7.3 Replacing pressure roller

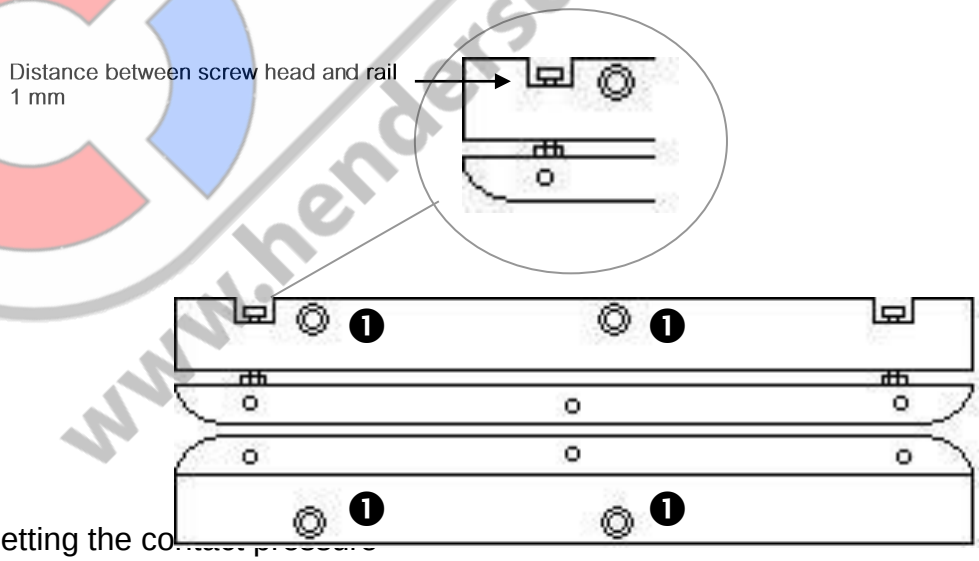
- Switch off machine and DISCONNET POWER PLUG !

- 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



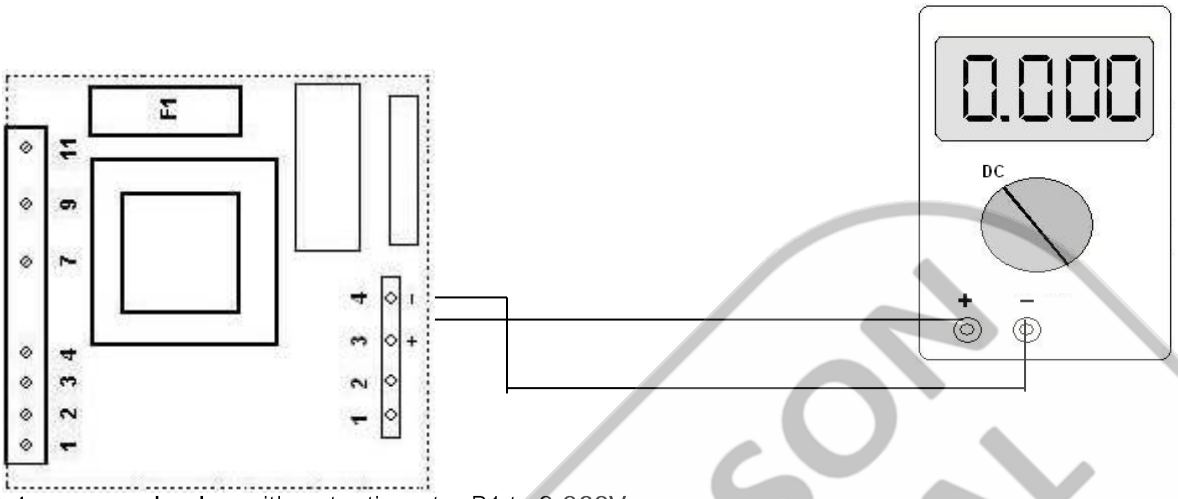
- Install I guide rails and fasten it with fastening screws ❶

- When installing the upper guide rail before fastening , 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



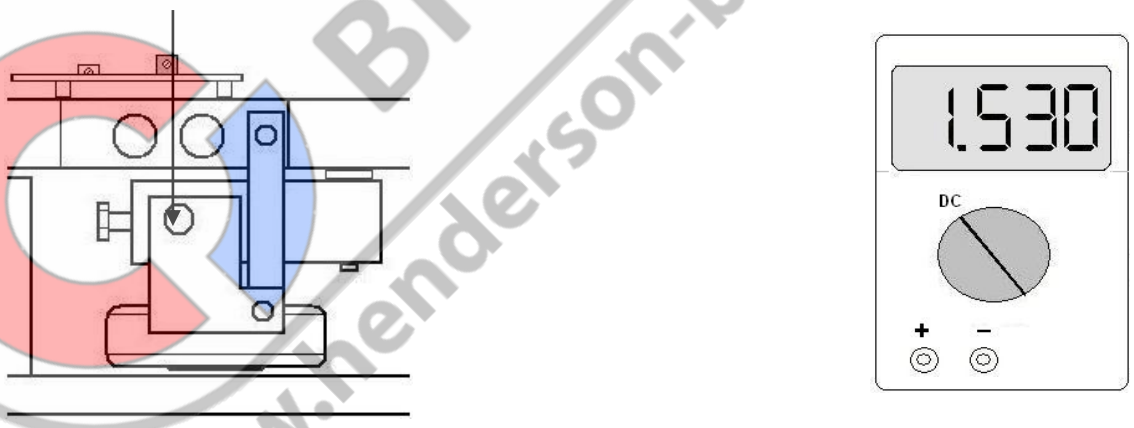
4.7.4 Setting the co

- Connect digital voltmeter to pin 3(+) and pin 4(–) of the time relay

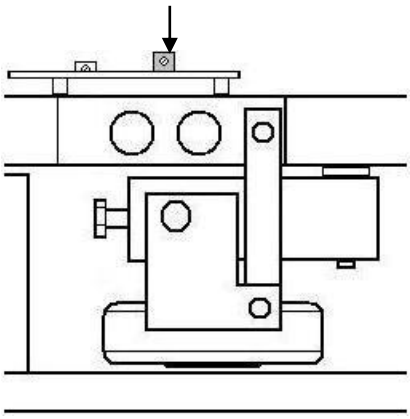


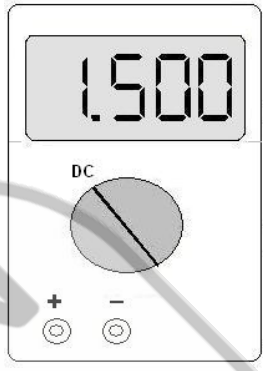
- Set measured value with potentiometer P1 to 0.060V

- Turn screw downwards to measured value 1.530V



- Set measured value with potentiometer P1 to 1.500V



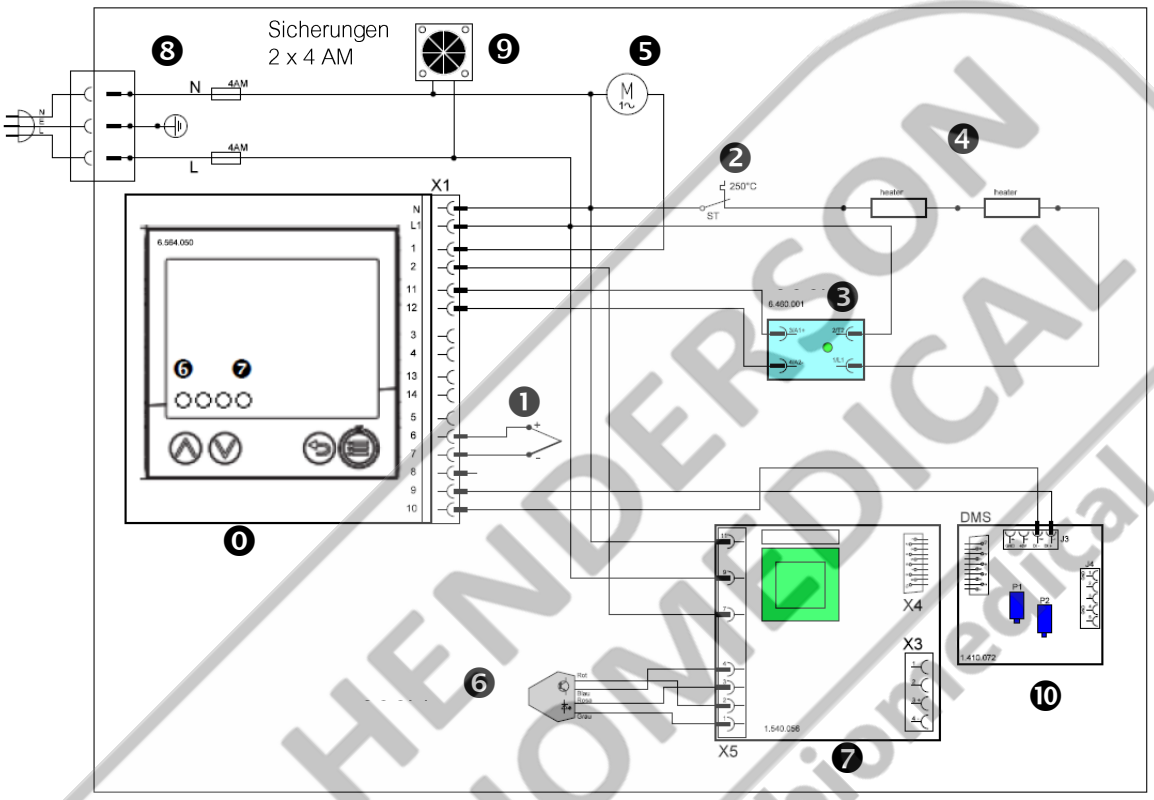


- Close housing

5 Technical data

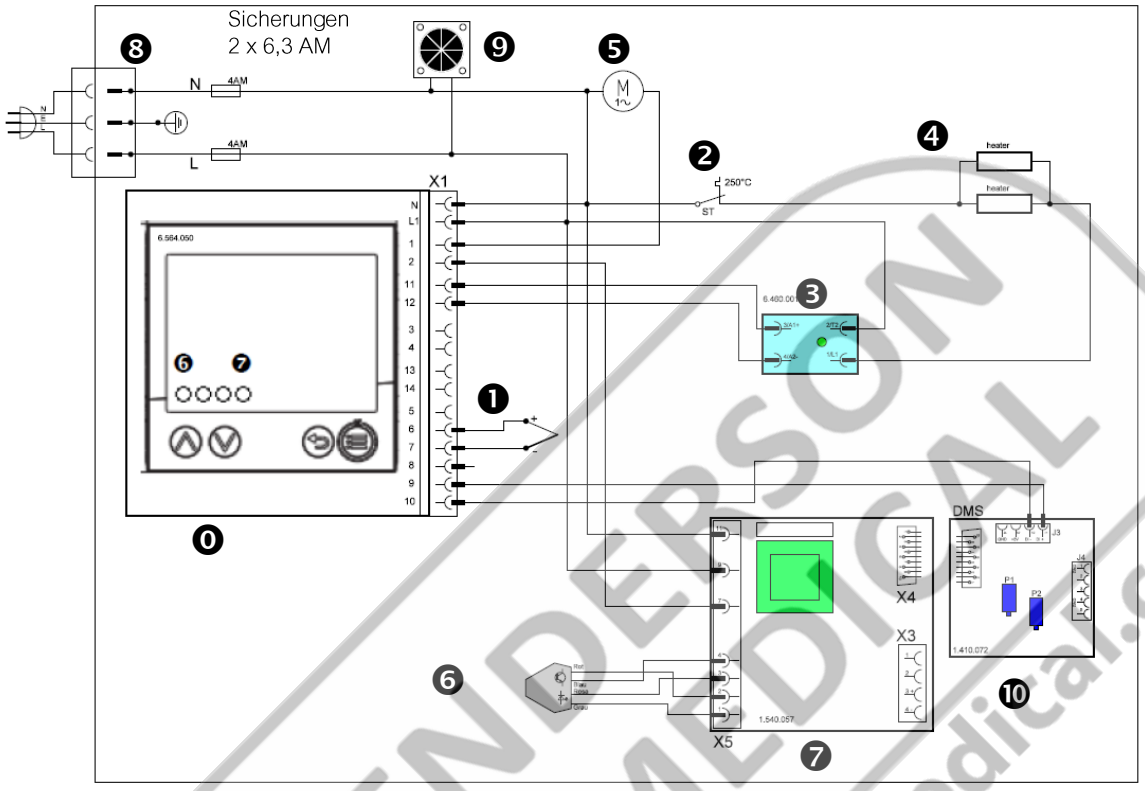
5.1 Circuit and wiring diagram 230V

5.1.1 hd 680 DE-V 230V



⓪	Temperature controller		6.564.050
①	Thermo couple		6.564.040
②	Over temperature cut out		6.564.018
③	SST Relay		6.460.001
④	heating cartridge	115V/200W	6.536.024
⑤	Gear motor 230V		1.212.014
⑥	Optical sensor		1.561.016
⑦	Timer	230V~	1.540.056
		115V~	1.540.057
	Timer	100V~	1.540.058
⑧	IEC cable feed with switch		6.562.009
⑨	Fan	230V~	6.212.019
⑩	DMS Module		1.410.072

5.1.2 hd 680 DE-V 115/100V



⓪	Temperature controller		6.564.050
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③	SST Relay		6.460.001
④	heating cartridge115V/200W		6.536.024
⑤	Gear motor 230V		1.212.014
⑥	Optical sensor		1.561.016
⑦	Timer	230V~	1.540.056
		115V~	1.540.057
	Timer	100V~	1.540.058
⑧	IEC cable feed with switch		6.562.009
⑨	Fan	230V~	6.212.019
⑩	DMS Module		1.410.072

5.2 Specifications

Power connection	[V]	230V/115V /100V50/60HZ
Main fuse 230 V (115V-100V)	[A]	4AT/ 6,3AT
Power consumption max	[VA]	500
Heat dissipation	[kJ/s]	0,1
Noise intensity	[dB/ A]	<70
Ambient temperature	[°C]	5-25
Dimensions length Width Height	[mm]	505 255 145
Weight approx.	[kg]	11,7
Throughput rate	[m / min]	10
Tolerance Throughput rate	[%]	± 10
Sealing temperature	[°C]	220
Tolerance Sealing temperature	[%]	± 2
Motor Stop tolerance limit	[°C]	± 5
Pressure applied	[N]	100
Tolerance Pressure applied	[%]	± 20
Sealed seam hawoflex System	[mm]	12
Sealed edge infinitely adjustable	[mm]	0-30
Length of sealed seam	[mm]	unlimited
Sealing seam distance from pack content	[mm]	30

6 Declaration of conformity

6.1 EC-Declaration

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	9.693.009C

Gültig ab: 01.02.2015
Valid from:

Seite 1/1
Version 3.02

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:

hd 680 DE, hd 680 DE-V, hd 680 DEI-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 de 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_11 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

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6.2 DIN EN ISO 11607-2 / DIN 58953-7 Declaration

hawo 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration de Conformité Declaracción de conformidad Dichiarazione di conformità - Declaração de conformidade	9.693.010D

Gültig ab: 01.02.2019 **Seite** 1/1
Valid from: **Version** 1.06

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:

hd 680 DE-V, hd 680 DEI-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 dispositifis médicaux stérilisés au stade terminal – Partie 2: Exigences relatives aux procédes de mise en forme, de fermeture et dàssemblage	ISO 11607-2:2019
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

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9.910.007 Version 2.01

7 Validation

7.1 General

Main purpose of this 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 in guaranteeing that the packaging system is and remains intact until use.

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 Machines Operator Ordinance.

The international norm EN ISO 11607 - part 2 describes the validation of packaging processes. In order to implement it the German Society for Sterile Supply (issued a Directive for the Validation of Sealing Processes according to EN ISO 11607-2

This directive can be downloaded from the website www.dgsv-leitlinie.de.

The user must always execute the on-site validation in accordance with the norm.

7.2 Preparation

Your sealing machine must be calibrated by the producer. The calibration has to be certified. You can get more information from your supplier or by calling the hawo-service line:
+49 (0) 6261 9770 0.

The certificated calibration must be purchased separately and is not part of the scope of supply!

Furthermore, for the operational qualification you need the hawotest SEAL CHECK indicators. You can get them from your supplier or online at www.seal-check.de.

7.3 Validation schedule information

7.3.1 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 according to DIN 58953-7.

The temperature range “sealing” is still required for further proceeding. 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: 170 – 190 °C
Uncoated HDPE (Tyvek): 130 – 140 °C

7.3.2 Installation qualification information (IQ)

7.3.2.1 QM-system

You can get from hawo free of charge the necessary certificate for the quality management system ISO 9001:2000. Request it at info@hawo.com or by calling: +49 (0)6261 9770 0

7.3.2.2 Type of machine: rotary sealer

The machine is certified EC and is conform to the norm DIN 58953-7. The respective declaration of conformity is to be found in charter 6 and acts as certificate.

7.3.2.3 Service authorization

The service team needs a written authorization by hawo. Request the certificate at your service team.

7.3.2.4 Safety features

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

7.3.2.5 Process variable

Variable are:
- temperature
- contact pressure

7.3.2.1 Control and monitoring of process variable

Temperature

The temperature is controlled and monitored by the temperature regulator.
If the temperature deviates from the predetermined limits, the machine is automatically stopped.
Further working is prevented in this way.

Contact pressure

The sealing temperature is preset and is monitored continuously.
If the contact pressure is within the specified tolerance limits, the signal lamp glows green.
If the limits are exceeded or fallen below, the signal lamp glows red and the drive is locked.
Further working is prevented in this way.

7.3.3 Operational qualification information (OQ)

According to the norm EN ISO 11607-2 section 5.3.2 b the quality characteristics of the sealing are the following:
intact sealing throughout the 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. You can get from hawo an information data sheet, which gives clear statements about their implementation.

For this a sealing has to be provided for the upper limit value and one for the lower limit value. Quality characteristics are to be implemented in both sealings.
After that the sealing temperature is to be determined for daily practice. It is recommended to generate it from the average value of actual temperatures (during the test).

7.3.4 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 or prEN 868-5, Appendix C. 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) 3 pouches of the same material are to be sealed every time at the defined temperature (T) and later are to be sterilized with the predefined sterilization program (reels are to 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.

This seal seam resistance check can be carried out by the supplier or directly by hawo GmbH. Request immediately the necessary documents.

HENDERSON BIOMEDICAL

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