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, DIN 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] Sterile Barrier 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 must 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 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 modify these operating instructions and the functions described in them.
These operating instructions apply to products from software version P242A06 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 "Intended 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 authorised 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 authorised 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 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, condensation may form. Wait until temperature equalisation has taken place.
    Starting up the machine when it contains condensation causes danger to life!
11. Fuse changes and repairs must only be performed by the manufacturer or by one of the manufacturer's authorised 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 might 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 your hair, clothing and gloves away from moving parts!
Loose clothes, jewellery or long hair can be caught in 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.

2 Before starting

2.1 Intended use

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

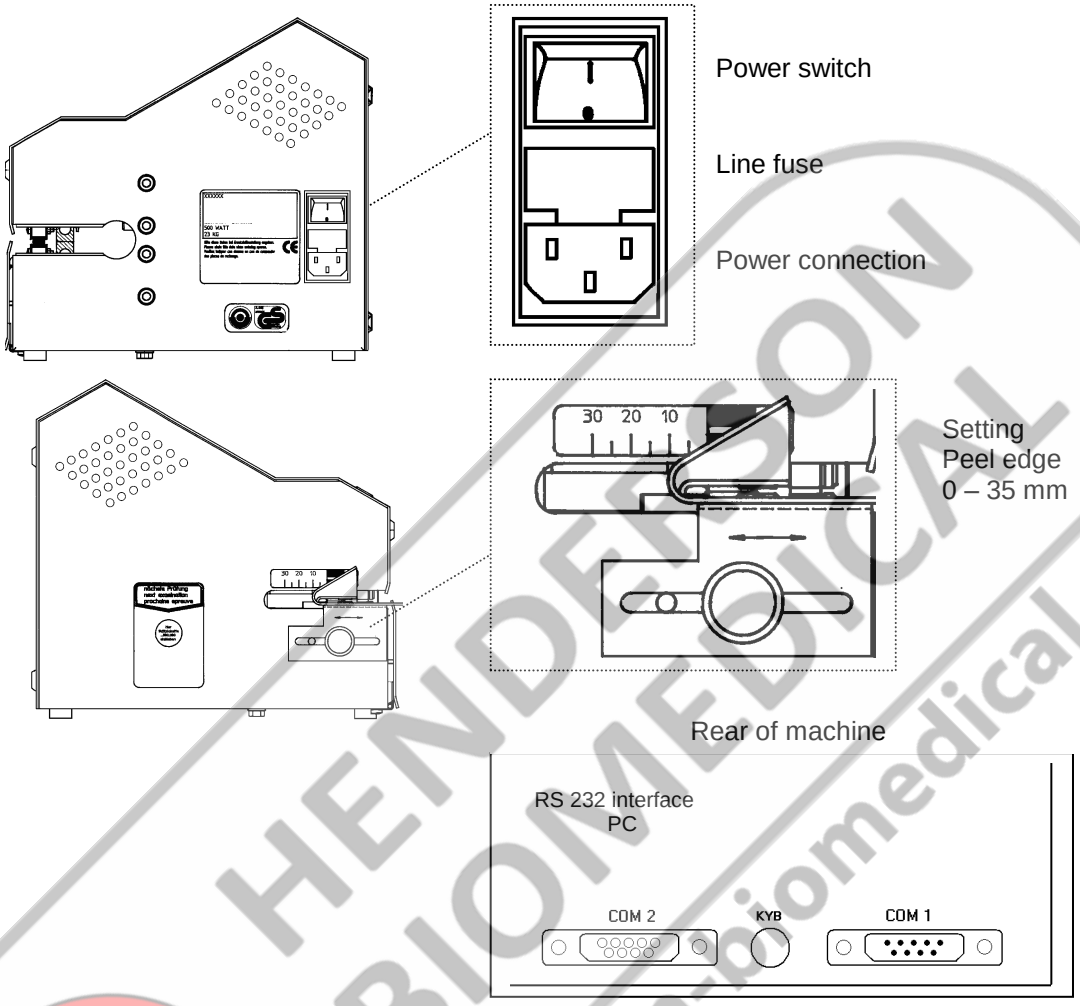
Sealable materials
Pouches and reels in accordance with EN 868-5 and EN ISO 11607-1*
Paper pouches in accordance with EN 868-4*
Uncoated HDPE*
Aluminum laminate film

* 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 films
Soft PVC films
Hard PVC foils
Polyamide films
Polypropylene films

2.2 Design and functions



2.3 Sealing and printing process sequence

1. After the sterilisation packaging has been inserted, the feed process is started automatically by means of photoelectric cell. The sealing speed is monitored.
2. The sterilisation 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. The contact pressure is monitored.
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 sterilisation 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 (Autosafe).

2.4 Installation instructions and commissioning

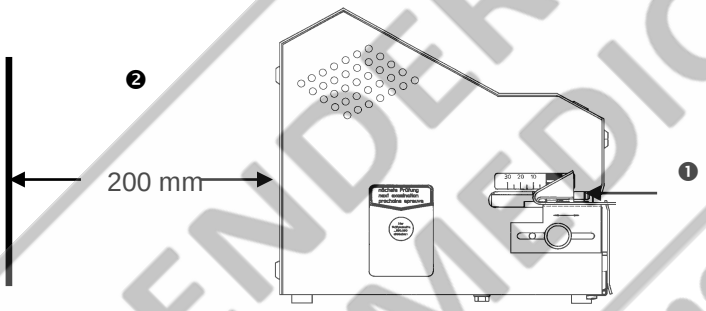
Prior to installation, read the safety instructions in chapter 1.4

2.4.1 Installation

Place the machine on a horizontal surface.

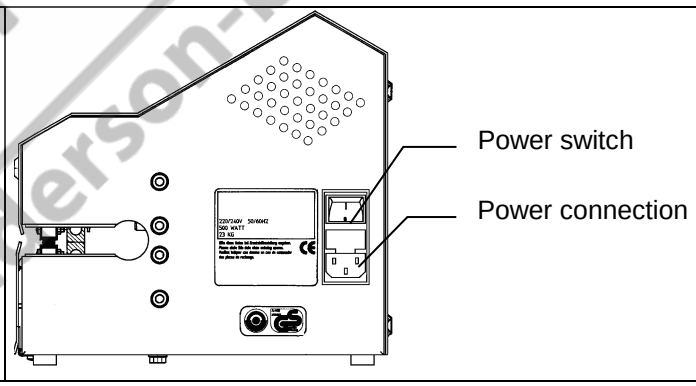
❶ Please do not lift the machine by the infeed section.

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



2.4.2 Commissioning

- Connect the mains cable to the mains
- Plug the mains plug into a socket
- Switch the machine on using the power switch



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

After a short self-test and after the selected sealing temperature has been reached, the machine is operational. This is indicated by the "Nominal temperature" display going out (see chapter 3.1).

3 Configuration of the machine

3.1 After switching on

Switch on machine
Self-test runs for approx. 30s

Default settings
When the machine is switched on for the very first time, the following defaults must be undertaken:

Language

Unit of measurement

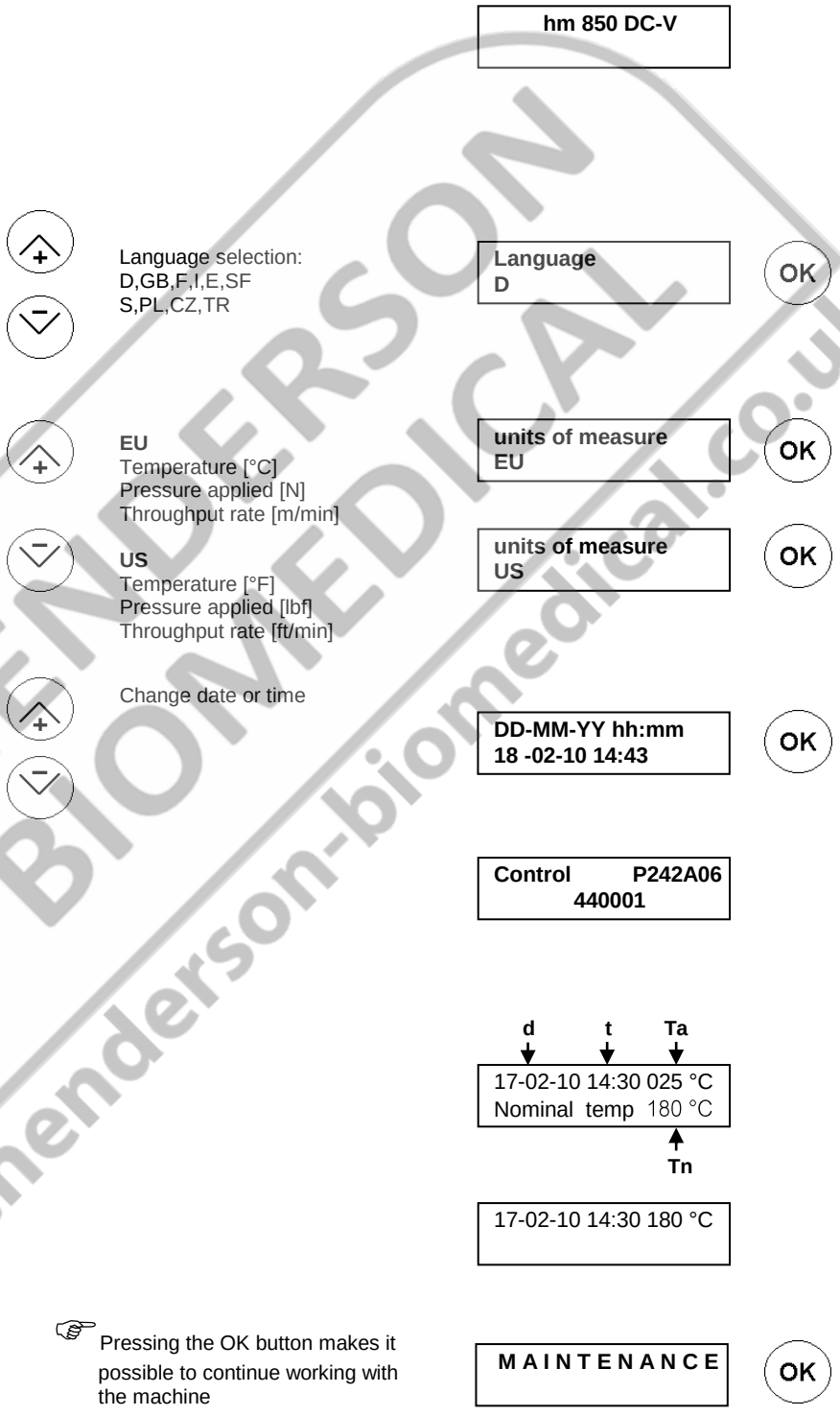
Date and time

Display for approx. 5 s
Program version P242A06
Serial number 440001

Display of
Date and time **d,t**
Nominal temperature **Tn**
Actual temperature **Ta**

The set nominal temperature is reached after about 3 - 4 min, and the machine is ready

Maintenance note
If this display appears, please refer to the maintenance notes on page 27

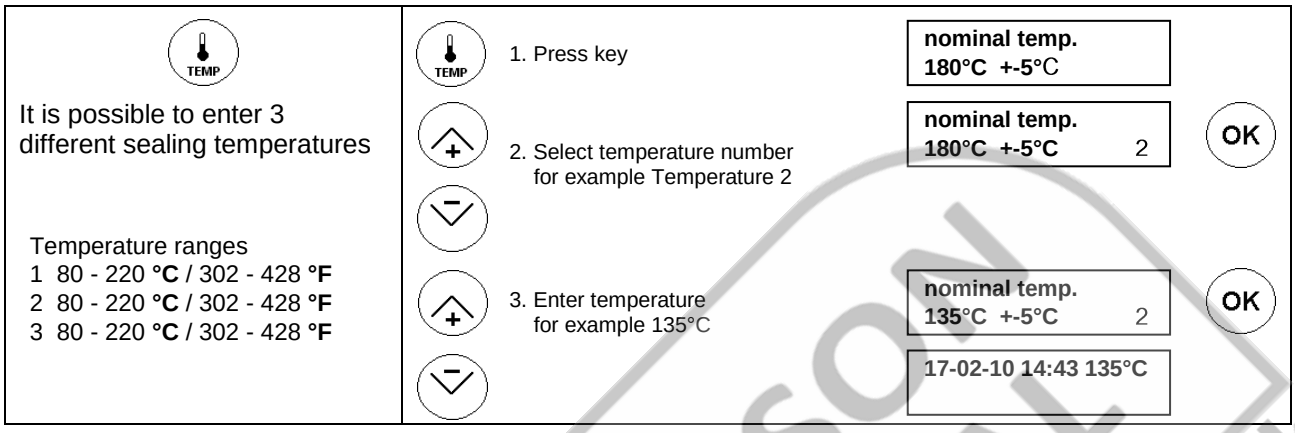


3.2 Programming aids

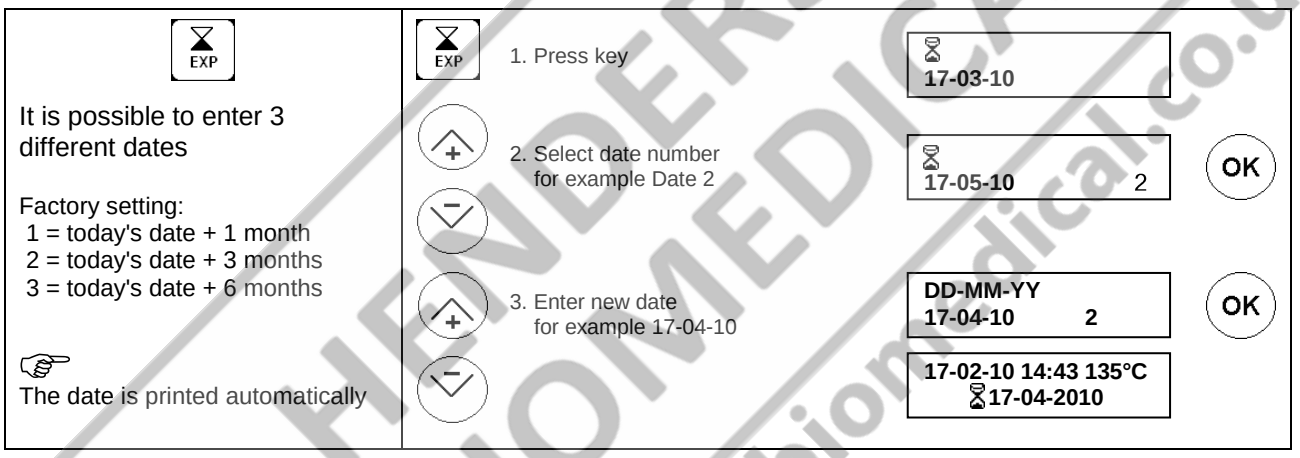
Cursor control e.g. Press right arrow key once	Cursor left  Cursor right  **1x** 	**1**00°C ▲ **Cursor flashes in 1st position** 1**0**0°C ▲ **Cursor flashes in 2nd position**
Change numbers and letters e.g. Press Position +1 key once	 Position +1 Position -1  **1x** 	100°C ▲ 11**0**°C ▲
Input is not activated, return to previous menu	 ESC	
Input is activated	 OK	
Deletes character Batch counter to 0	 C	

3.3 Data input

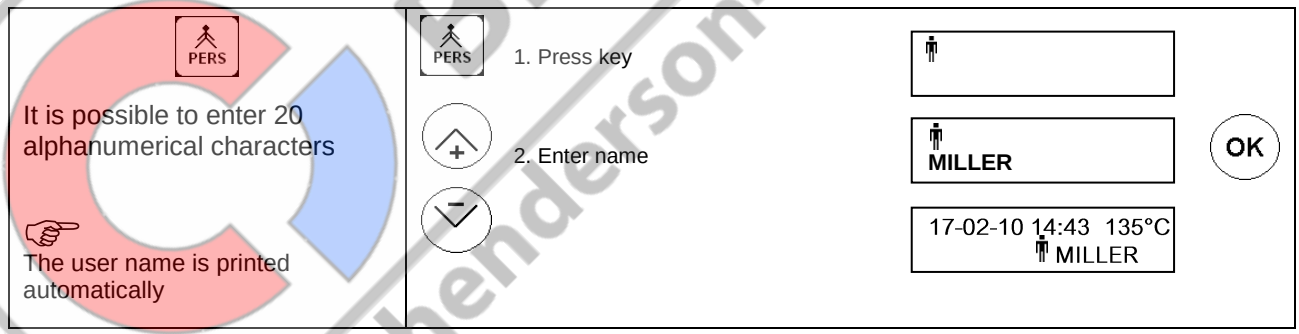
3.3.1 Sealing temperature entry



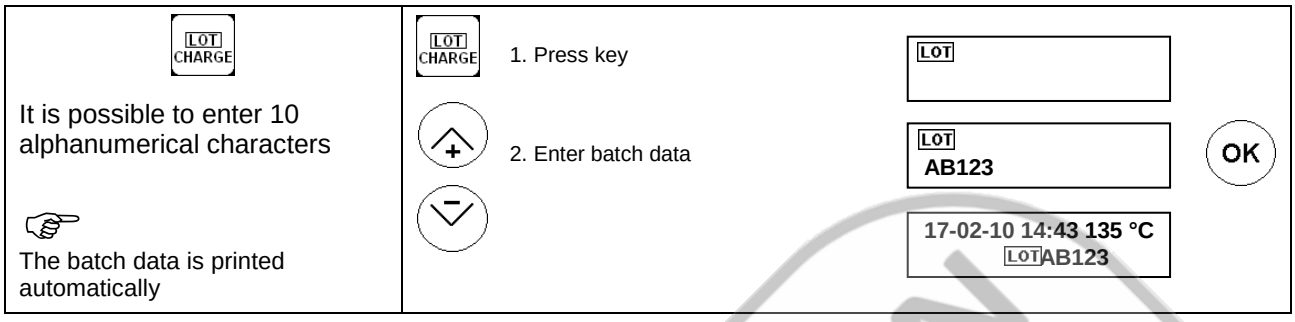
3.3.2 Expiry date entry



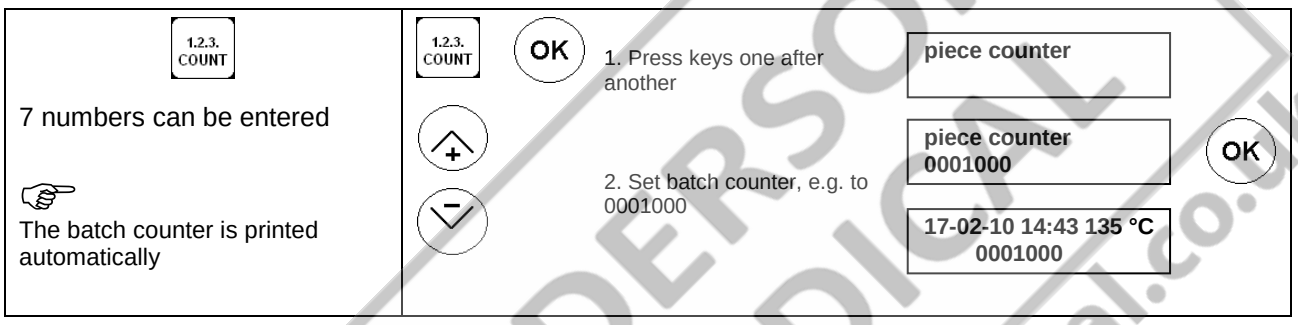
3.3.3 User name entry



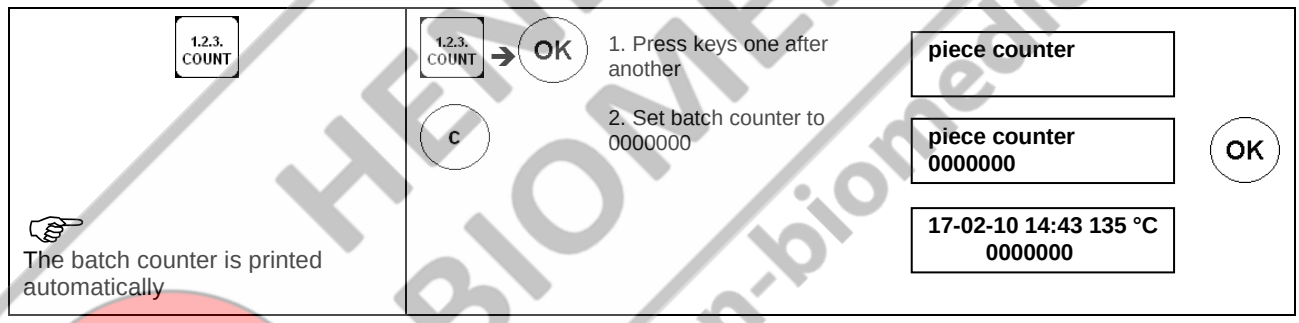
3.3.4 Batch data entry



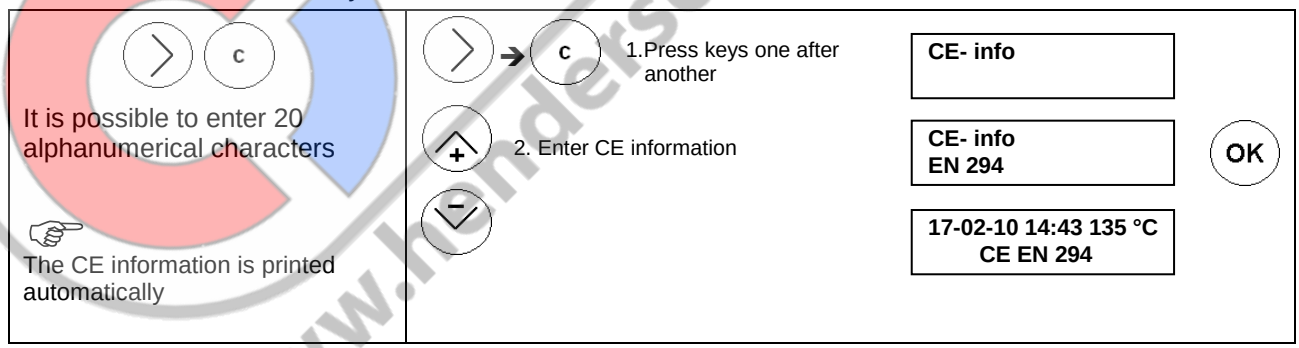
3.3.5 Set batch counter



3.3.6 Set batch counter to zero



3.3.7 CE information entry



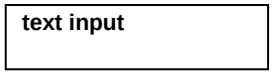
3.3.8 Text entry

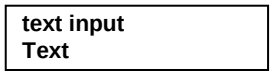
It is possible to enter 20 alphanumerical characters

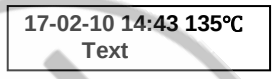
The text is printed automatically

1. Press key

2. Enter text



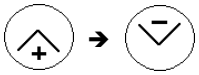


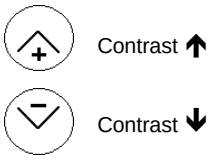


3.4 Operator logon, Machine settings

3.4.1 Display contrast

Press the keys one after another





display - contrast

OK

3.4.2 Language selection

Press the keys one after another

Language selection:
D,GB,F,I,E,SF
S,PL,CZ,TR

set language
GB

OK

3.4.3 Indication of standard print data

Press the keys one after another

Yes
Indication for date, expiry, batch
Operators are printed as a symbol
acc. to EN 980

pictogramm
YES

OK

No
Identification for date,
expiry, batch.
Operators are printed as text

pictogramm
NO

OK

3.4.4 Selection of unit of dimension

Press the keys one after another

EU
Temperature [°C]
Pressure applied [N]
Throughput rate [m/min]

unit of measure
EU

OK

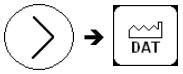
US
Temperature [°F]
Pressure applied [lbf]
Throughput rate [ft/min]

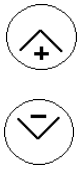
unit of measure
US

OK

3.4.5 Selection of date format

Press the keys one after another





Selection of
date format:

1 dd-mm-yyyy 2 mm-dd-yyyy
3 yyyy-mm 4 mm-yyyy
5 yyyy 6 yyyy-mm-dd

format date & time
DD-MM-YYYY

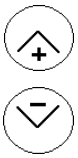
OK

OK

3.4.6 Change of date or time

Press the keys one after another

Change date or time

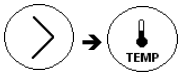


DD-MM-YY hh:mm
18 -02-10 14:43

OK

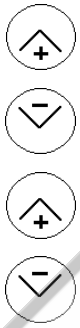
3.4.7 Sealing temperature switch-off tolerance entry

Press the keys one after another



Allocation of a temperature tolerance limit which, if violated, results in the motor being stopped automatically.

Range ±2°C to ±5°C
Factory setting ±5°C



1. Select temperature number for example Temperature 2

tolerance limit
180°C +-5°C

Nominal temperature
135°C +-5°C 2

OK

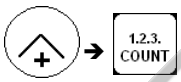
2. Enter tolerance limit for example ±3°

tolerance limit
135°C +-3°C **2**

OK

3.4.8 Display of absolute batch counter

Press the keys one after another

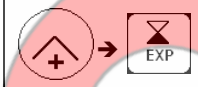


absolute p. counter
0000020

OK

3.4.9 Display of operating hours

Press the keys one after another



operating time
000010 h 38 min

OK

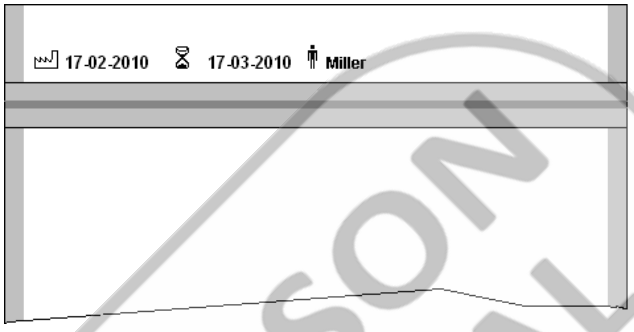
3.5 Printer settings

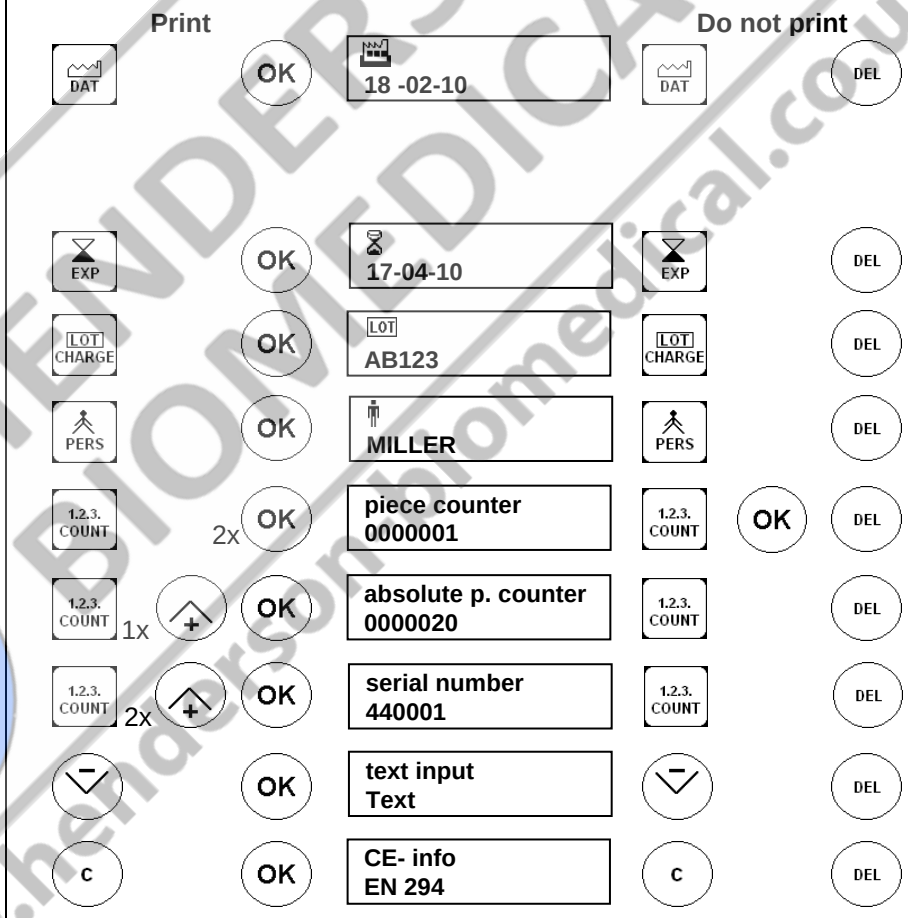
3.5.1 Print data

The sequence of print data is set and cannot be changed
The individual items of information are always printed in this sequence:

- **Date of manufacture, time**
- **Expiry date**
- **Operator name**
- **Batch counter** or
- **Absolute batch counter**
- **Text**
- **CE information**
- **Machine number**
- **Batch data**

For example, printout of sterilisation date, expiry date, personnel number



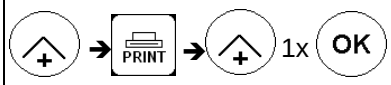


3.5.2 Switch printer off or on

Switch off printer		**17-02-10 14:43 135°C printer off**
Switch on printer		**17-02-10 14:43 135°C**

3.5.3 Print format

Activate settings
Press the keys one after another

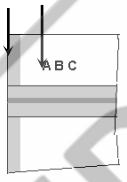


Printer config.
YES

Representation of print format

Print format
0°
OK

Margin adjustment
Positioning of the print data on the package 0 –99 mm from the edge of the package



distance
02 **0-99**
OK

Standard character size
Printout of print data in 6 different widths

character width
0 **0-5**
OK

Character pitch
5 different pitches between the individual characters

character distance
0 **0-5**
OK

3.6 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 infeed 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).

- Sterilisation package 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 sterilisation 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 test sealings (DIN 58953-7).
Sealing must be performed in such a way that the sealing seam meets the quality characteristics required in 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 s considered suitable for checking these quality characteristics.[3] hawotest SEAL CHECK seal indicators are available separately.

[3] see the DGSV guideline for validation of the sealing process

3.7 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 (DIN 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.

3.7.1 Activate and start SEAL CHECK function

OK

OK 1. Press key

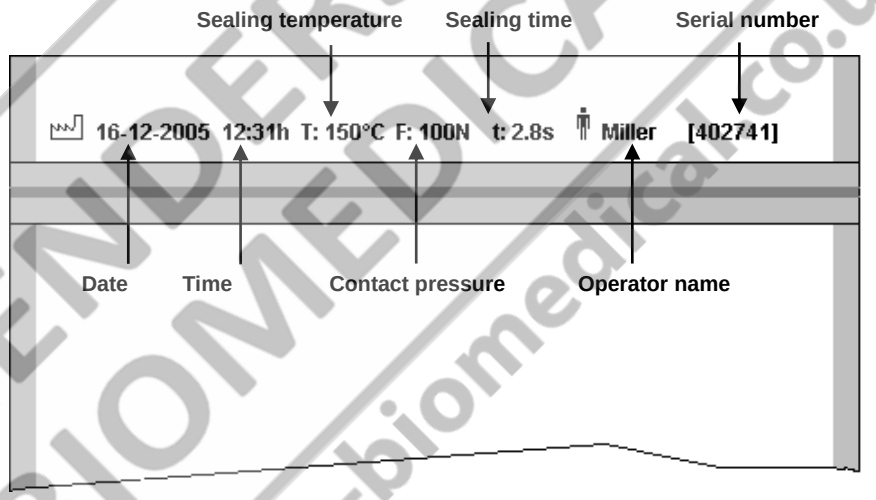
seal check
OK->Start

OK

2. Insert sterilisation package, width min. 200 mm.
If necessary, insert SEAL CHECK indicator strip into the package

seal check
Start

Printing of seal check function



4 Troubleshooting and maintenance

4.1 Troubleshooting checklist

The troubleshooting suggestions marked with an * are only allowed to be carried out by the manufacturer or a service partner authorised by the manufacturer.

Malfunction	Possible cause	Remedy
Machine fails to switch on No data on the display	Power supply Power cable not plugged in	Check power supply If necessary, plug into a different power outlet
	Power cable defective	Replace power cable
	Line fuse	Replace line fuse! ! If the fuse blows again, it is imperative to have the machine tested.
	Control board	Replace control board.*
	Indicator card	Exchange indicator card*
Machine fails to heat up	Set temperature is too low	Increase nominal temperature (see pg. 14)
	Temperature limitation activated	Reset temperature limiter by pressing in the pin! If it still trips it is imperative to have the machine tested
	Temperature sensor	Replace temperature sensor.*
	Heating cartridge	Check heating cartridges and replace if necessary*
	Control board	Replace control board*
No transport	Transport belt - Damaged - No transport	Replace transport belt Check belt tension
	Front flap not closed	Close front flap
	Motor sensor	Replace light barrier
	Front flap not closed	Replace front flap sensor
	Motor	Replace motor*
	Control board	Replace control board*
Uneven material feed or loud running noise	Transport belt guide	Renew PTFE belt on guiding die (see pg. 32)
	Transport belt - Damaged - No transport	Replace transport belt Check belt tension
	Motor	Replace motor*

Malfunction	Possible cause	Remedy
Sealed seam will not hold	Temperature too low Contact pressure too low Sealing die - Distance between the sealing dies too large	Increased temperature Readjust pressure of the sealing roller or replace sealing roller* Set distance of the sealing dies to 0.5 mm*
Sealed seam distorted	Pressure applied too high	Readjust pressure of the sealing roller or replace sealing roller.*
Paper side of the package is discoloured or side fold shrunk	Temperature too high	Reduce temperature (see pg. 14)
No printing or printing incomplete	Programming - Print start not set properly Ink ribbon Print head Control board	Reprogram print start see pg. 21) Ink ribbon not inserted properly Replace ink ribbon.(see pg. 31) Replace print head Replace control board*
Printing too faint	Ink ribbon Print head Paper pressure roller	Replace ink ribbon Readjust print head Adjust paper pressure roller
No keyboard function	Keyboard Indicator card Control board	- Check keyboard plug for contact - Renew keyboard Exchange indicator card* Replace control board*

4.2 Error displays

☞ If these error messages are displayed, the first step is to switch the machine off and back on again!

Sealing temperature out of tolerance	flashing →	**17-02-10 14:30 180 °C** **nominal temp. 186 °C**
	Possible cause	**Remedy**
	Temperature sensor defective	Replace temperature sensor*
	Control board defective	Replace control board*

Contact pressure out of tolerance	flashing →	**17-02-10 14:30 180°C** **contact pressure**
	Possible cause	**Remedy**
	DMS module not calibrated	Recalibrate DMS module*
	DMS module defective	Replace DMS module*
	Control board defective	Replace control board*

4.3 hawo customer service

☎ **Your hawo customer service is available from Mon-Fri 8:00 - 17:00 CET on the following number: +49 6261 977031.**
You are also welcome to send questions to the following e-mail address: service@hawo.com

4.4 Maintenance indicator

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 authorised service partners.

Therefore, the maintenance date of the machine is set to 1 year.
If this date is reached, a reminder about the date is given every time the machine is switched on.

Information before reaching the set maintenance date Maintenance date reached	☞ Pressing the OK button makes it possible to continue working with the machine MAINTENANCE OK

4.5 Servicing / calibration

Maintenance cycle	Ink ribbon	PTFE tape Guiding punch	PTFE tape Sealing die	Pressure roller	Toothed belt	Clearance Sealing die	Calibration of critical process parameters
At least every 3 months							
Depending on usage, at least once a year							

Legend:

 **Check**

 **Replace**

 **Adjust**

 **Measure**

4.6 Parts service

☞ **Simply order parts by fax:**

- Please copy the following pages according to the parts required.
  Page 28: Parts required for maintenance and wear
  Page 29: Replacement parts
- Enter machine number.
- Enter machine model.
- Enter address, fax number and order number.
- Mark items required.
- Enter quantity required.
- Sign order.
- Fax order.

To: **Sender:**

Fax no.

Your order no.		**Date**	
Machine model		**Serial number**	
☑	**Designation**	**Art. no.**	**Qty.**
☐	Ink ribbon	6.813.104	
☐	Ink ribbon, red	6.813.224	
☐	PTFE tape Sealing die	6.105.285	
☐	PTFE tape Guide rail 500 mm	6.105.139	
☐	Plastic pressure roller	2.230.008	
☐	Toothed belt, drive 375 mm	6.271.011	
☐	Toothed belt Transport Sealing material 480 mm	6.271.008	
☐	Heating cartridge	6.536.032	
☐	Upper sealing die assembly	1.616.028	
☐	Lower sealing die assembly	1.616.029	
☐			
☐			
☐			

Signature

To: **Sender:**

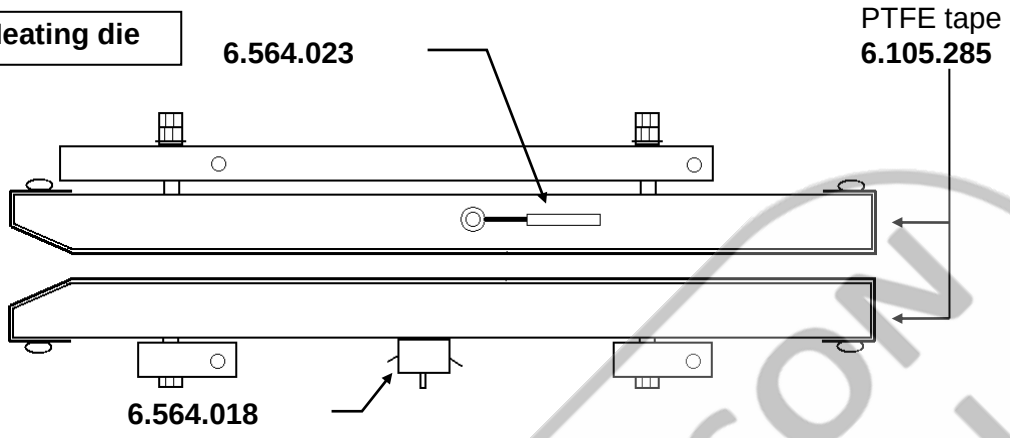
Fax no.

Your order no.		**Date**	
Machine model		**Serial number**	
☑	**Designation**	**Art. no.**	**Qty.**
☐	Print head	1.653.002	
☐	Control board	1.410.088	
☐	Indicator card	1.410.017	
☐	DMS module	1.410.018	
☐	Optosensor	1.561.003	
☐	Gear motor	1.212.011	
☐	Ink ribbon, motor	1.212.012	
☐	Temperature limiter heating cartridge	6.564.018	
☐	Temperature sensor	6.564.023	
☐	Service Dongle	1.561.002	
☐			
☐			
☐			

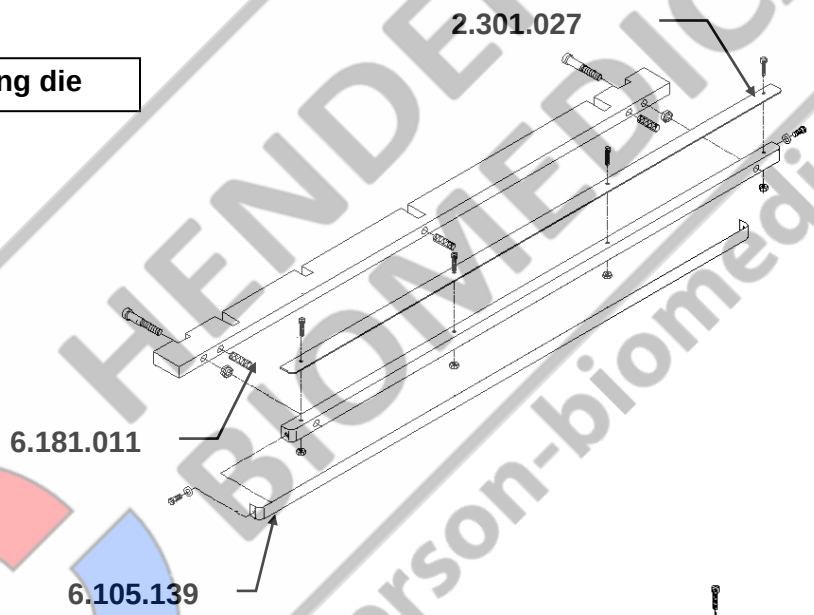
Signature

4.7 Replacement parts order – allocation of article numbers

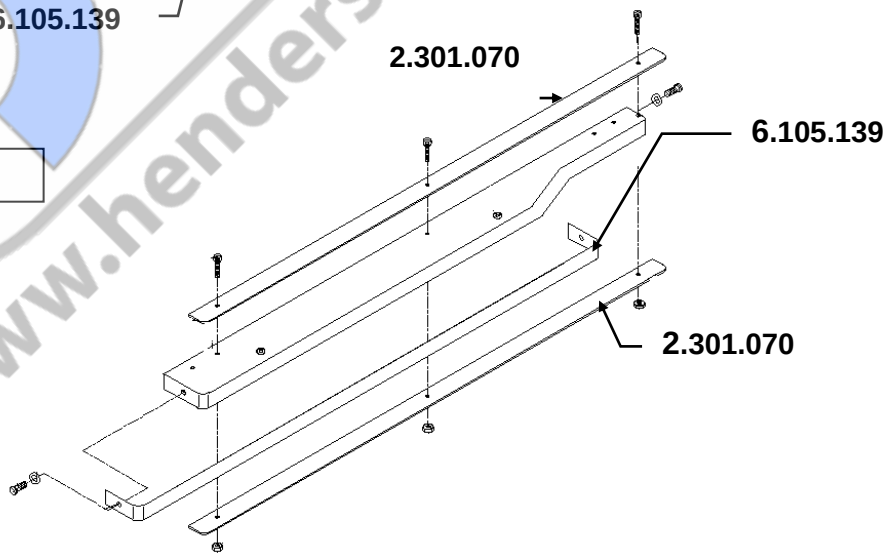
Heating die



Upper guiding die



Lower guiding die



4.8 Information about replacing wearing and spare parts

> ! Please use **only genuine replacement parts**

4.8.1 Replacing ink ribbon

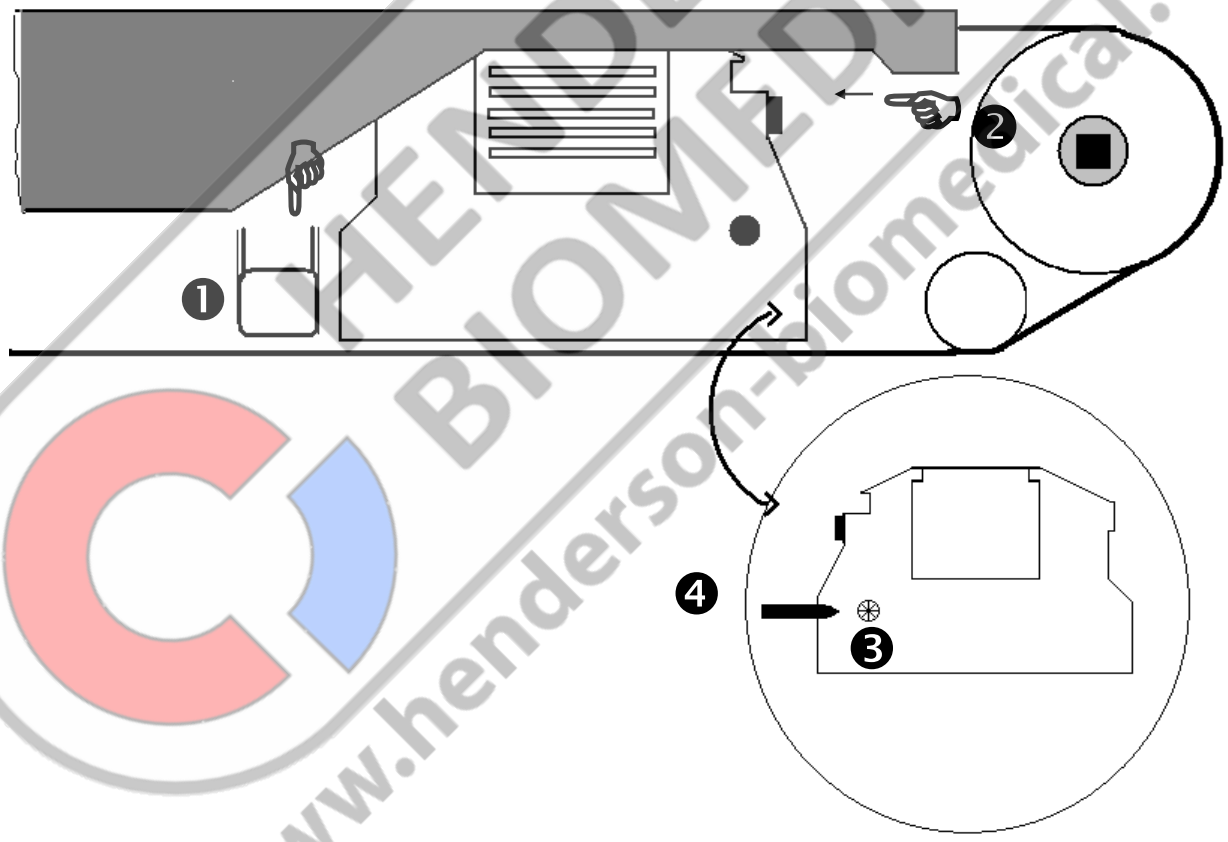
➔ **Switch off the machine**

- Open front flap
- 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**

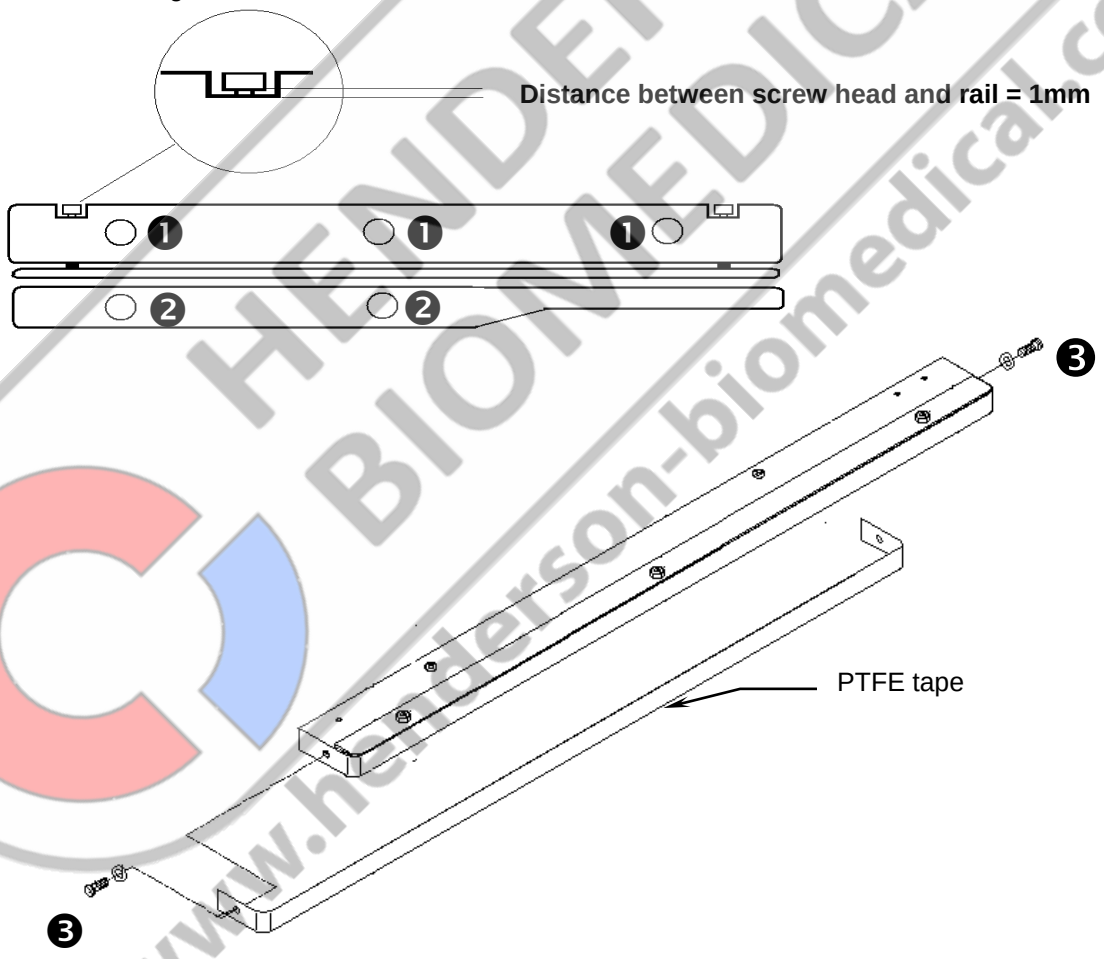
4.8.2 Replacing PTFE strip on guide rail

➔ Switch off machine and DISCONNECT 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 rails.

☞ 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



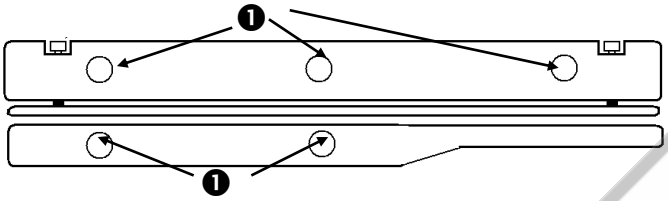
Maintenance information

! Please use **only genuine replacement par**

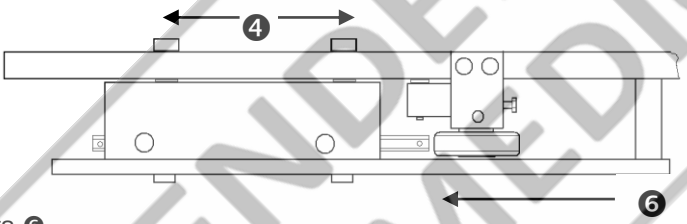
4.8.3 Replacing PTFE strip for upper and lower heating die

➔ **Switch off machine and DISCONNECT POWER PLUG!**

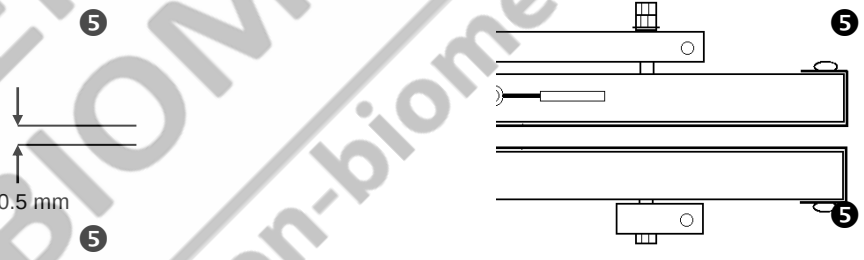
- Open housing
- Remove mounting screws ❶ for upper guide rail and remove guide rail.



- Disconnect electrical connections for heating die
- Remove fastening screws ❹
- Remove top or bottom heating die
- Unscrew mounting screw ❺ 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 screws ❺
- Install heating die
- Fasten fastening screws ❹ of the heating die
- Reconnect electrical connections to heating die

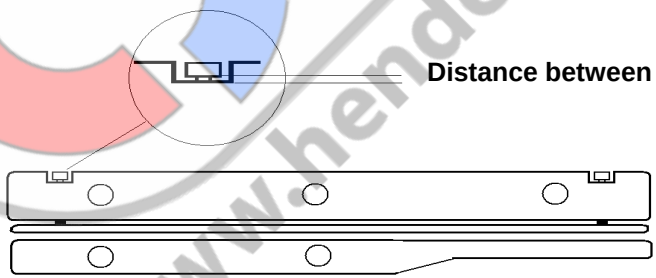


- Detach nuts ❻
- Set distance between the sealing dies to 0.5 mm
- Fasten nuts ❻



- 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 1mm on both sides. This ensures the correct contact pressure for the guide rail.



Distance between screw head and rail = 1mm

- Close housing

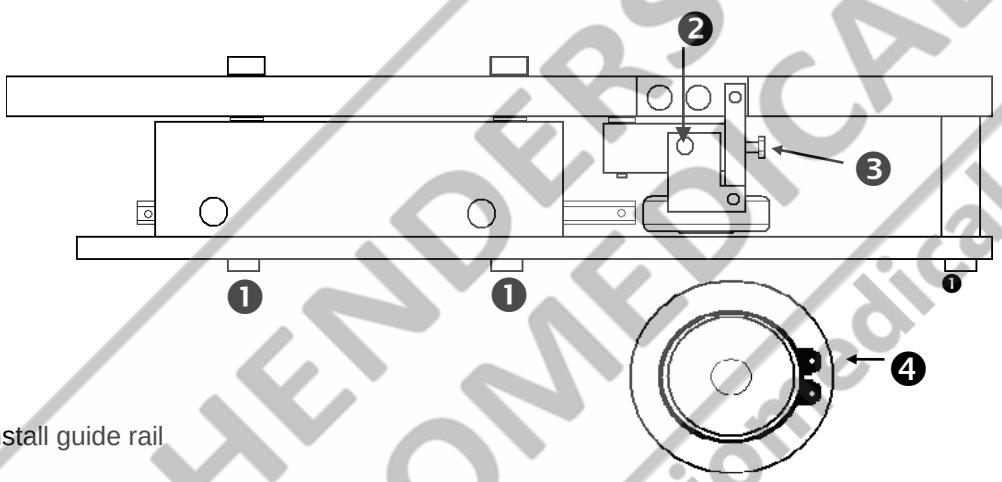
Maintenance information

! Please use **only genuine replacement parts**

4.8.4 Replacing pressure roller

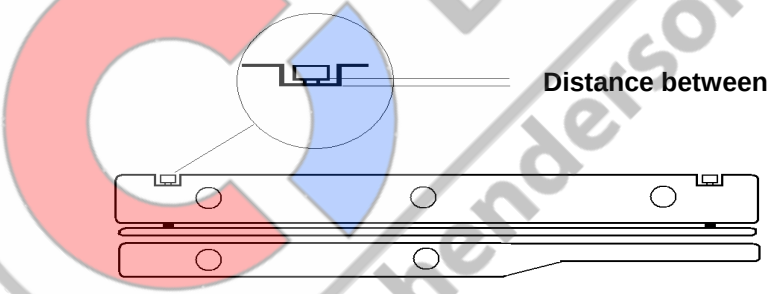
➔ **Switch off machine and DISCONNECT POWER PLUG!**

- 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
- Insert pressure roller fully into holder, align centrally with the lower roller
- Tighten mounting screw ❸
- Adjust contact pressure by screwing in adjustment screw ❷ according to calibration instructions on page 39



- 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 1mm on both sides. This ensures the correct contact pressure for the guide rail.



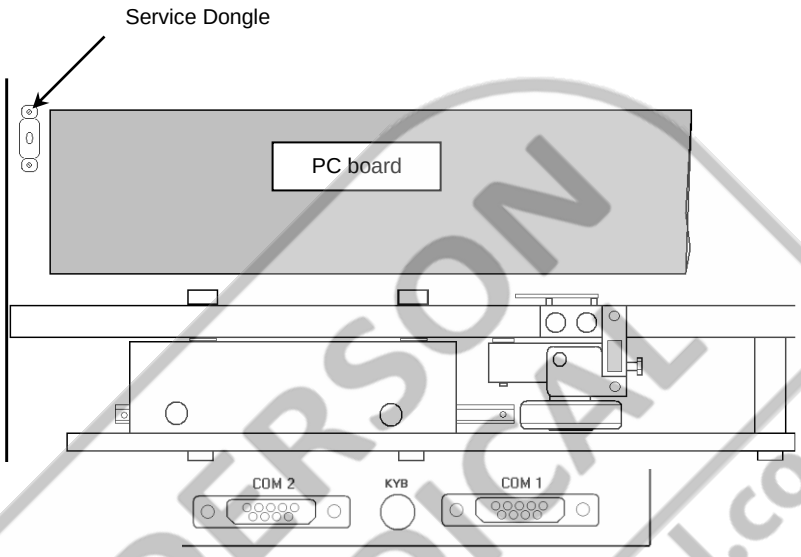
Distance between screw head and rail = 1mm

- Close housing

4.9 Service settings

4.9.1 Activate service menu

1. Switch off machine
2. Open housing cover
3. Remove service dongle
4. Plug service dongle into the COM1 connector (rear of machine)
5. Switch on machine



4.9.2 Adjusting contact pressure

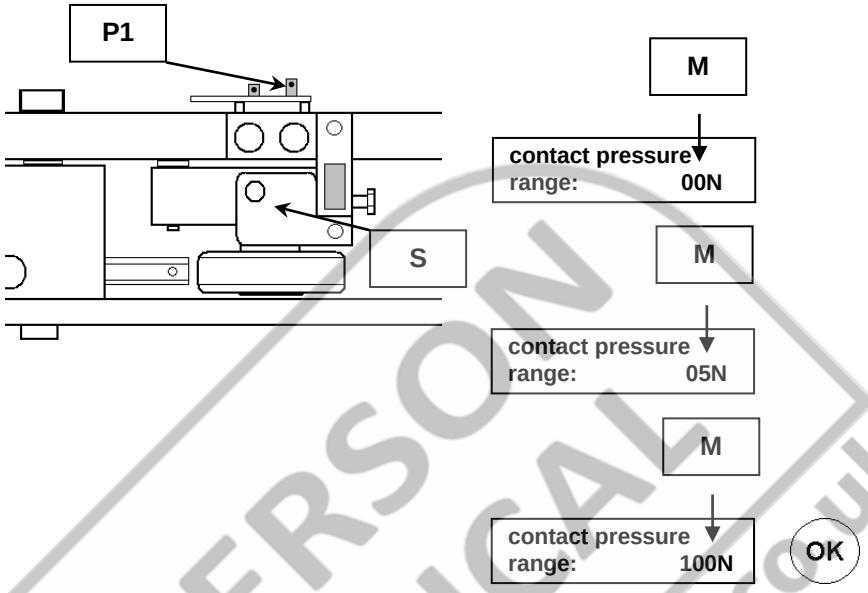
Press key after activating the Service menu

OK

1. Undo screw **S** until measurement **M** no longer changes

2. Use potentiometer **P1** to set measured value **M** to 5 N

3. Set measured value **M** to 100 N by screwing in the screw **S** and confirm setting



4.9.3 Adjusting temperature control

1. Insert temperature sensor from the infeed side between the sealing dies

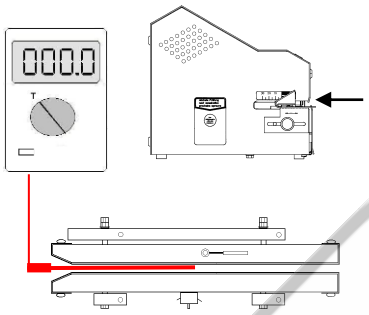
2. Activate the service menu and press the keys one after another

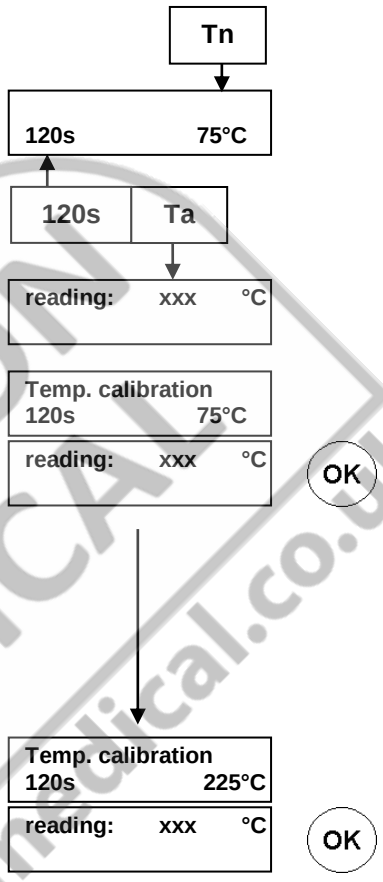
2x OK → TEMP

The temperatures
75°C , 125°C,175°C and
225°C are measured one after another and the difference between nominal value **Tn** and actual value **Ta** is corrected.

After a set temperature has been reached it isstabilized for 120s.

When 120s have elapsed
the corrected value is input **Ta**





4.9.4 Setting the margin

1. Activate the service menu and press the keys one after another

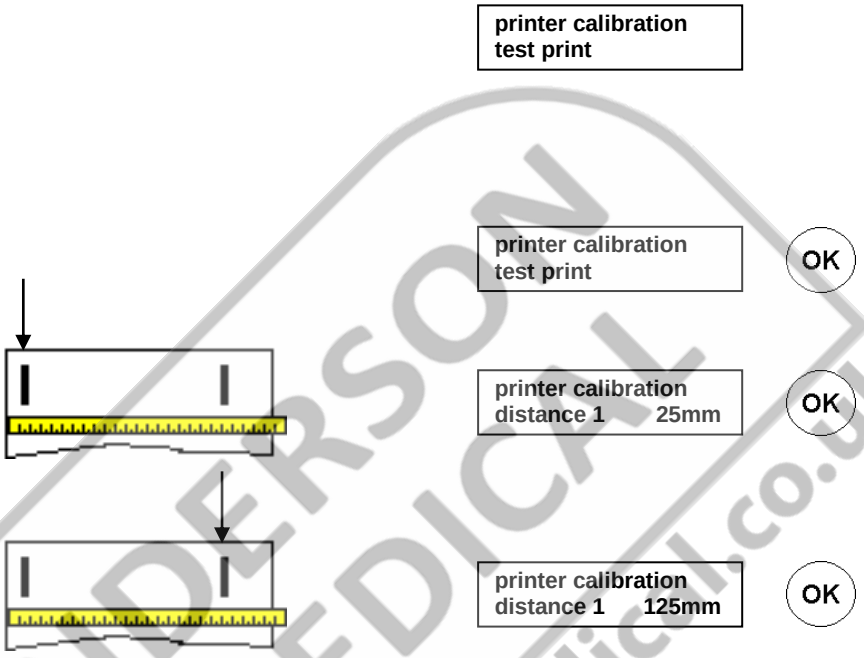
2x OK ➔ PRINT

2. Insert package, dimension > 150 mm.
   Two perpendicular lines are printed.

3. Acknowledge test printout

4. Measure distance 1 between the edge of the package and the first bar and enter the measurement in mm

5. Measure distance 2 between the edge of the package and the second bar and enter the measurement in mm



4.9.5 Maintenance date entry

1. Activate the service menu and press the keys one after another

2x OK → EXP

2. Enter date for the next maintenance reminder

DD-MM-YY
12-11-10 OK

4.9.6 Setting of the standby function

1. Activate the service menu and press the keys one after another

2x OK → 1.2.3. COUNT

2. Enter the time for starting the standby function 0-120 min

3. Activate or deactivate standby function

stand by after
010 min OK

Yes
If no sealings are performed, the set sealing temperature is reduced to 60°C after the entered time expires

stand by activate
YES OK

No
Standby function not active

standby activate
NO OK

4.9.7 Activation of default settings

1. Activate the service menu and press the keys one after another

2x OK → DEL

2. Activate or deactivate default settings

Yes
If the default settings are activated then the following settings must be performed after the very first switch-on:

Language
Date and time
Unit of measurement

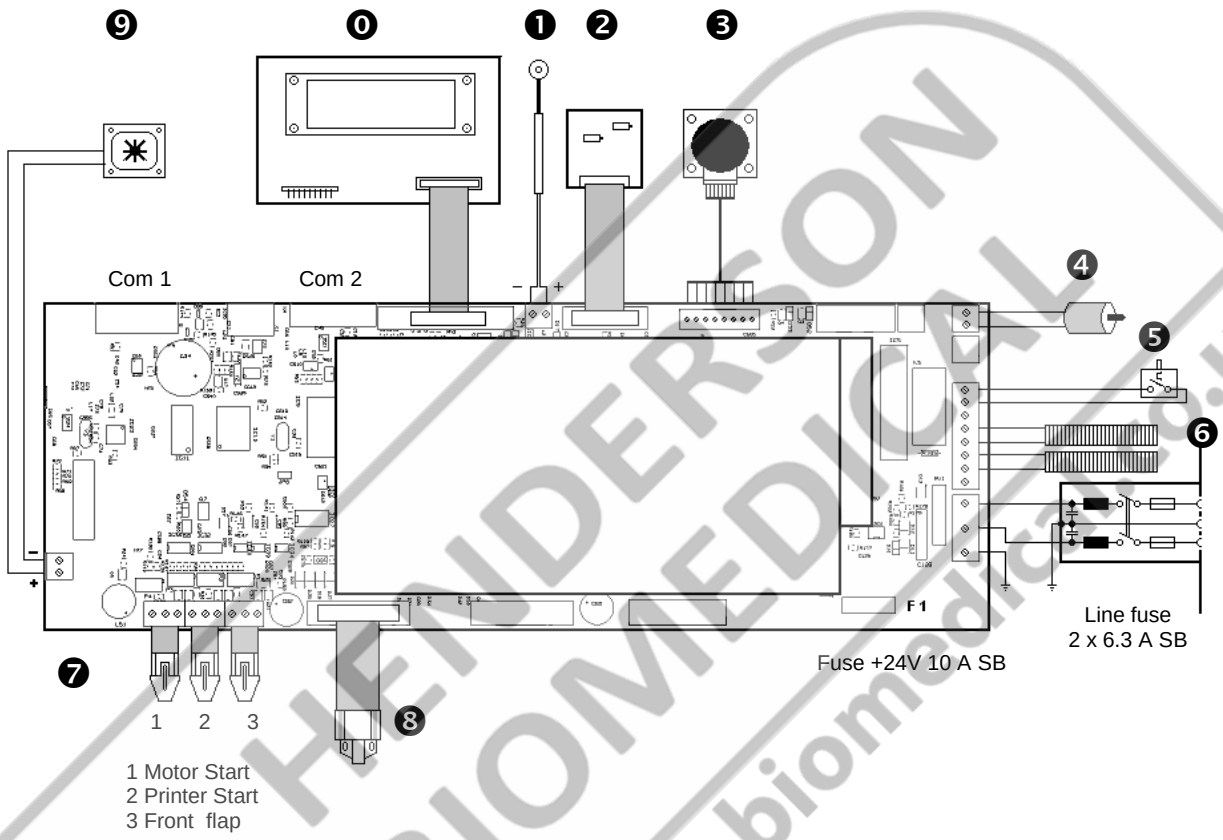
very first time
YES OK

No
No default setting needs to be performed after the very first switch-on.

very first time
NO OK

5 Technical data

5.1 Circuit diagram and wiring diagram



⓪	Indicator card	1.410.017
❶	Temperature sensor	6.564.023
❷	DMS module	1.410.018
❸	Gear motor	1.212.011
❹	Ink ribbon motor	1.212.012
❺	Temperature switch	6.564.018
❻	Heating cartridges 115V/200W	6.536.032
❼	Optosensors	1.561.003
❽	Print head	1.653.002
❾	Fan	6.212.024

5.2 Specifications

Connection data

Power connection		[V]	100 - 240
Power frequency		[Hz]	50 / 60
Power consumption	max.	[W]	400
Main fuse 100V – 240V		[A]	6,3 T

Mechanical system

Dimensions including infeed section	Length Width Height	[mm]	710 260 240
Housing cover			Stainless steel AISI 304
Housing bottom			Metal, powder-coated
Weight		[kg]	23
Sealed edge infinitely adjustable		[mm]	0 – 35
Sealing seam width		[mm]	12
sealing system			hawoflex™
Length of sealing seam		[mm]	unlimited
Distance from medical product		[mm]	>30 (acc. to DIN 58953-7)

Process parameter / Sealing parameter

Sealing temperature	max.	[°C]	220
Tolerance limit motor stop		[°C]	± 2 – ±5 (adjustable)
Contact pressure		[N]	100
Contact pressure deactivation tolerance		[%]	±20
Sealing speed		[m / min]	10
Deactivation tolerance Sealing speed		[%]	±10
Temperature ranges			3
Temperature control tolerance		[%]	±2

Electronics and communication systems

System		Microprocessor
Interfaces:	RS-232 connector USB with adapter	yes available as option (art. no.: 1.596.024)
Data rate (baudrate) Serial interface PC		9.600
Electrical protection class		1

Environmental parameters

Environment temperature	[°C]	5-25
Heat dissipation	[kJ/s]	0,1
Noise intensity acc. to Machinery Directive 2006/42/EC Appendix I 1.7.4.2 u.)	[dB/ A]	<70

6 Declarations of conformity

6.1 EC- Declaration of conformity

hawo 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaración de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade	0.992.060C

Gültig ab: 01.02.2015
Valid from:

Seite 1/1
Version 5.02

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 850 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 da 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

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

9.910.007 Version 2.01

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

hawo 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration de Conformité Declaración de conformidad Dichiarazione di conformità - Declaração de conformidade	0.992.060D

Gültig ab: 01.10.2012 / Valid from:

Seite 1/1 / Version 1.05

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 850 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 cumple 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 procédés de mise en forme, de fermeture et dàssemblage	DIN EN ISO 11607-2:2006 ANSI/AAMI/ISO 11607-2:2006
Sterilisation – Sterigutversorgung – 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

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Amtsgericht Mannheim: HRB 441011
Geschäftsführer:
Hans Wolf und Christian Wolf
Firmensitz: Obrigheim

7 Validation

7.1 General

The main purpose of every packaging system for medical products, which are sterilised 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 Machines 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 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 authorised service partners. For further information, please contact your authorised service partner or the hawo Service Hotline: +49 (0) 6261 9770 0 (keyword: Maintenance 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 disconnection tolerance (A) 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
Uncoated HDPE (Tyvek™): 130 – 140 °C
(when using uncoated HDPE materials (e.g. Tyvek™) the deactivation tolerance must be reduced if necessary)

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 authorisation

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

7.3.1.2.4 Safety features

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

* required in DIN 58953-7

7.3.1.2.5 Critical parameters

Parameters	Disconnection tolerance preset	adjustable
Sealing temperature	+/- 5°C *	+/- 2 - 5°C***
Contact pressure	+/- 20% of the set value	not possible
Sealing speed	+/- 10% of the set value	not possible

* required in DIN 58953-7
*** when using uncoated HDPE materials (e.g. Tyvek™), the required disconnection tolerance of +/- 5°C may not be sufficient

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 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 SEAL CHECK function (also refer to section 3.10 for information).

2. ht 180 PT-USB (order number 0.712.005)
   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 machines can be connected through an interface directly to the batch documentation system. Ask the producer for the exact compatibilities.

4.

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 sterilisation. The test is performed by determining the seal strength acc. to DIN EN 868-5, Annex D. The packages must be sterilised before the test. Records (batch documentation) of sterilisation 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 sterilised using the predefined sterilisation program (reels must be sealed on both sides). Each pouch is to be attributed to a different sterilisation batch (if available) in order to consider all influencing variables in the sterilisation batches.

Seal seam resistance must be determined by a qualified validator (e.g. directly by hawo GmbH or by an authorised 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 machine or if the packaging material has been changed.

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

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

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