



INNOQ SEAL 100

ROTARY SEALER

OPERATING INSTRUCTIONS

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1 Introduction

1.1 Preface

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

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



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

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 relate to daily practice.

1.3 Important notice



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

The Medical Device Directive 93/42/EEC and Medical Device Regulation 2017/745 (MDR) is not applicable to sealing devices.

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 device 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

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

These operating instructions apply to products from the INNOQ SEAL 100 series.

1.4 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!

1.5 Safety instructions



1. Our products are in a flawless condition in terms of safety technology when they leave the plant.
2. To maintain this condition, the contents of these safety instructions as well as type plates, labelling and safety instructions attached to the device must be observed while handling the device (transport, storage, installation, commissioning, operation and maintenance).
3. This device is suitable for processing laminated films in the heat-sealing process. See also chapter 2.1 "Intended use".
4. Please check the packaging, and lodge a complaint for any damage with the carrier or parcel service immediately, before installing the device.
5. Before commissioning, ensure that the device does not show any evidence of damage. In case of doubt, contact the manufacturer or a service partner authorised by the manufacturer.
6. Do not operate the device if the power cable or the power plug is damaged. Do not use the device if it does not operate correctly or it is damaged in any way. If the mains cable or the device have been damaged, the device must be repaired by the manufacturer or by one of the manufacturer's authorised service partners.
7. The device must be connected using the mains cable included in the scope of delivery to a protective contact socket with a stable voltage. Operation on IT networks is not permitted.
8. Place the device on a stable base.
9. The device must not be installed or operated in potentially explosive areas.
10. If the sealing device is brought directly from a cold environment into a warm environment, condensation may form. Wait until temperature equalisation has taken place.
Starting up the device when it contains condensation causes danger to life!
11. Repairs and the replacement of wear parts / spare parts must be performed only by the manufacturer or by one of the manufacturer's authorised service partners.
12. Switch off the device when it is not in use, or remove the power plug from the socket.
13. Before cleaning: Disconnect from the mains! Clean the device only with a dry or damp soft cloth and a mild cleaning agent. Do not allow any water to find its way into the device. Caution! Never wet clean the device!
14. Do not insert pointed or flat items into the import slot of the device. This can result in damage to the device and instruments.
15. Do not insert items into the louvres of the device. You may receive an electric shock or the device could be damaged.
16. Do not use the device if you have any doubts about its safety.
17. The device must not be installed or operated by persons under 16 years of age.

- 18. The device must not be operated unsupervised.
- 19. It is forbidden to operate the device under the influence of drugs or alcohol.



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



- 21. The device contains valuable materials that can be recycled and reused. The device should therefore be disposed of at a public disposal facility near you. The device has been labelled in accordance with Directive 2012/19 EU (WEEE) on waste electrical and electronic equipment. This directive governs the return and recycling of scrap equipment within the EU.

2 Before starting

2.1 Intended use

SEALING MATERIALS

Sealable paper pouches in accordance with EN ISO 11607-1/EN 868-4	x
Sealable pouches and tubes in accordance with EN ISO 11607-1/EN 868-5 made of film and paper as per EN 868-3	x
Sealable pouches and tubes in accordance with ISO EN 11607-1/EN 868-5 made of film and uncoated materials made of polyolefins as per EN 868-9 (e.g. Tyvek® ¹)	x ²
Sealable pouches and tubes in accordance with ISO 11606-1/EN 868-5 made of PP fleece or PP non-woven	x ²

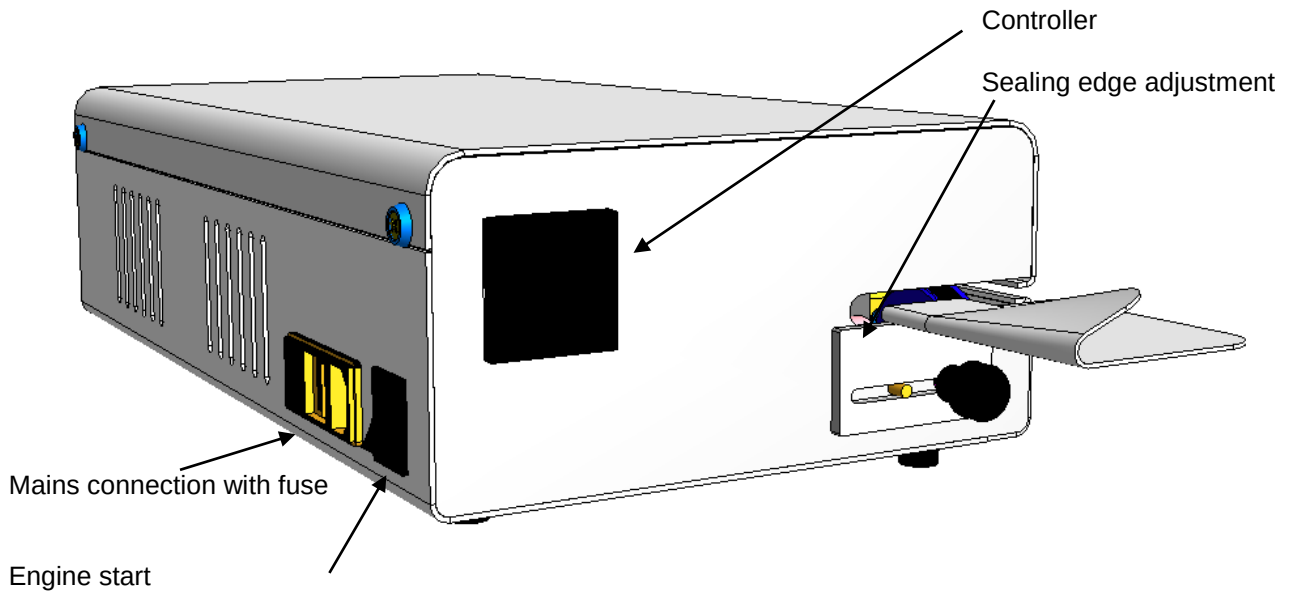
NON-SEALABLE MATERIALS

Soft PVC films
Polyamide films
Coated HDPE
Aluminium-laminate film
Polyethylene films
Hard PVC films
Polypropylene films

¹ Tyvek® is a registered trademark of E.I. du Pont Nemours.

² Release and / or test required

2.2 Design and functions



2.2.1 Sealing process sequence

- Step 1:** After the sterilisation packaging has been inserted, the feed is automatically switched on.
- Step 2:** The sterilisation packaging is now transported and the area is heated to the set sealing temperature.
- Step 3:** The sealing seam, which is now heated, is pressed together by the sealing rollers and sealed.
- Step 4:** The finished sterilization packaging is transported to the extraction side.
- Step 5:** If no item to be sealed is fed in, the feed switches off after approximately 30 seconds.

2.3 Installation



The device must not be installed or operated in potentially explosive areas.

Only use sockets that are equipped with a protective conductor and where the mains voltage is stable.



The device may only be installed in a dry environment. Heavy dust, steam, dripping water or splashing water impair the function of the device.

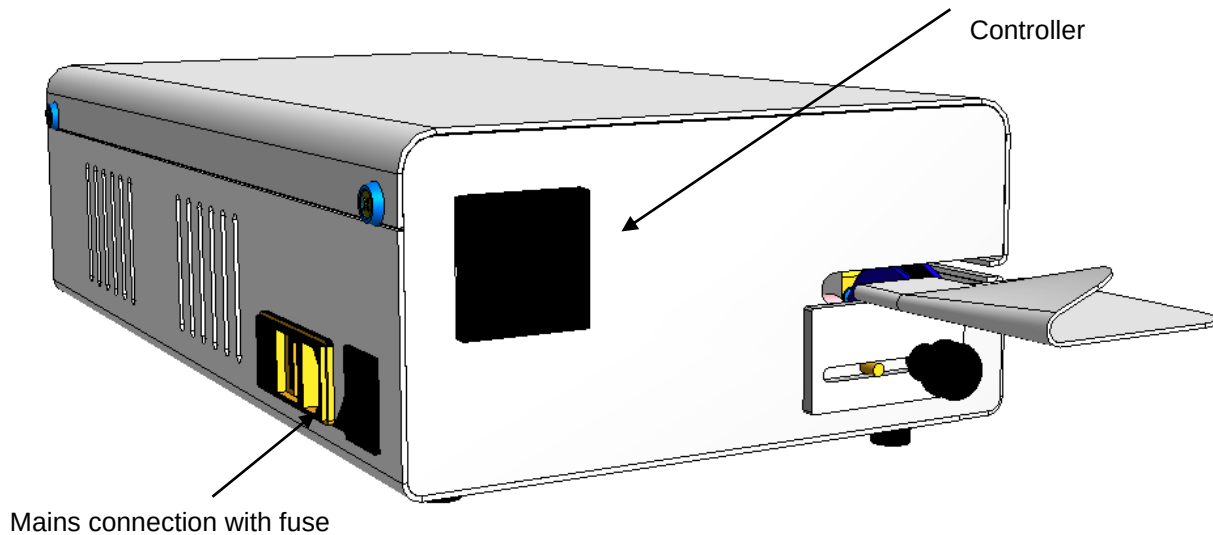
Please make sure that the operating voltage corresponds to the specifications on the device's type plate.

- ❶ Please do not transport the device on the peel edge setting.
- ❷ The distance from the device to a wall must be at least 200 mm!



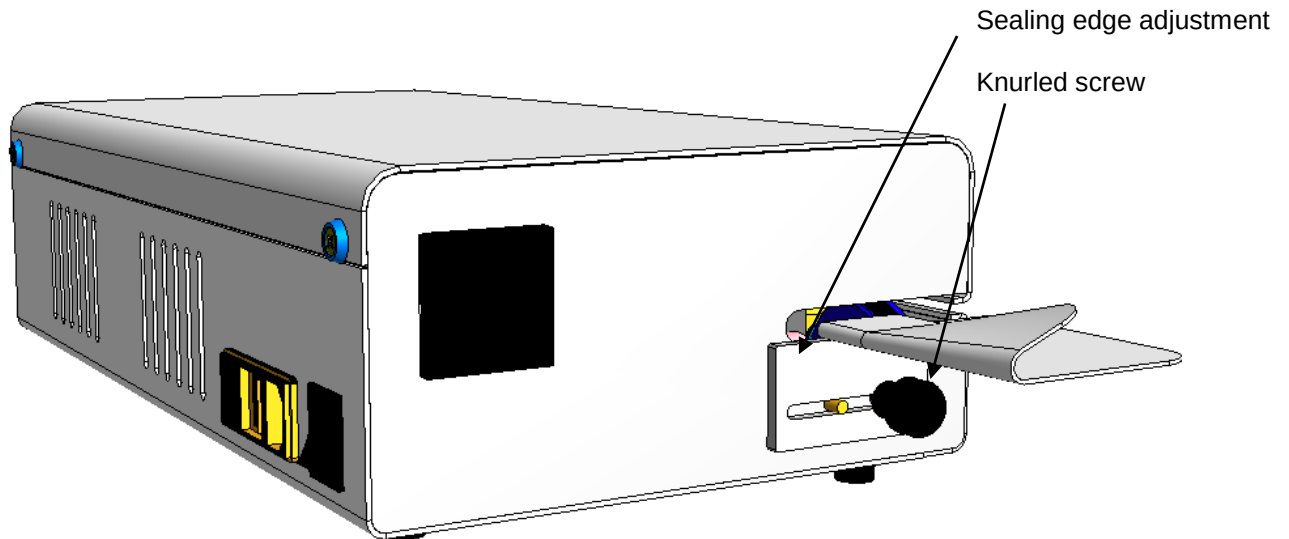
3 Basic functions

3.1 Operation



- Schritt 1: Plug the mains cable into the mains connection.
- Schritt 2: Switch on the device with the mains switch in position "1".
The indicator light in the switch is lit.
- Schritt 3: Set the required sealing temperature on the temperature controller as described in Chapter 3.3.
- Schritt 4: The device is heated up and ready for operation as soon as the set sealing temperature is displayed.

3.2 Operation



Schritt 1: Set the required sealing edge width. After loosening the knurled screw, the lower insertion plate can be continuously adjusted for sealing edge widths of 0 - 30mm.

Schritt 2: Insert packaging into the device from the left via the insertion plate.

Schritt 3: Remove the sealed package on the outlet side and allow to cool down briefly.



Check of the sealing seam

If leaks appear, the sealing temperature must be increased. If the film melts, the set temperature is too high.

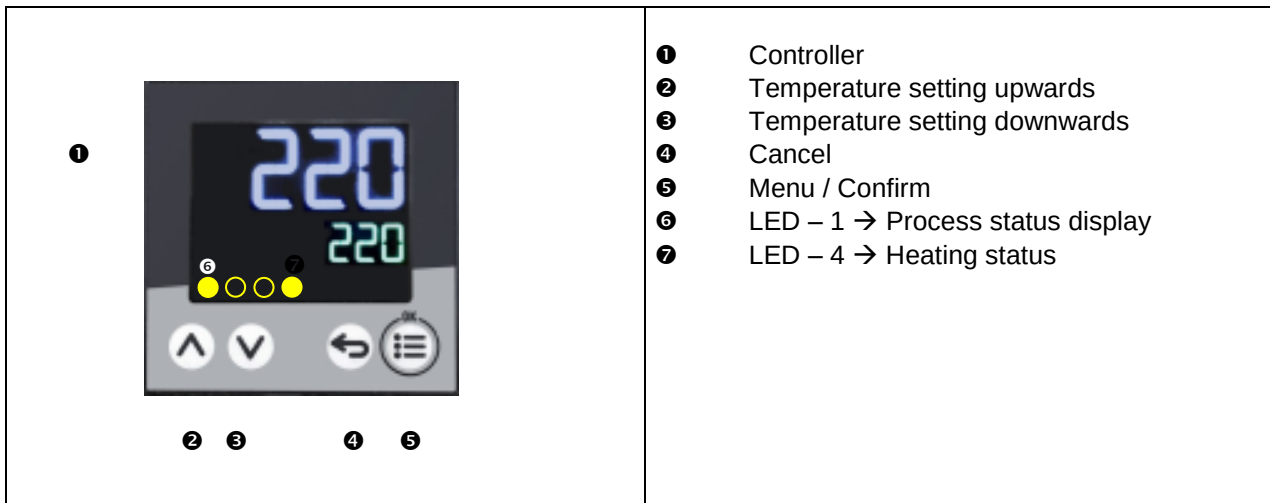
As per DIN 58953 -7, the suitable sealing temperature is to be determined by test sealing.

3.3 Process variables

Sealing temperature

The temperature is monitored electronically by means of a temperature sensor. If this varies from the set value by 5°C (requirements set out in DIN 58953-7), the drive is locked.

3.4 Setting the temperature controller



Input of the set temperature

The **❺** key is pressed once

Confirm "MENU" [User Level] selection level by pressing the **❺** key twice

Setting the temperature with the **❷** [+1°C] **❸** [-1°C] keys

The input is activated with the **❺** key → OK appears for 2 seconds

Exit the input by twice pressing the key **❹**

Default setting:

Set temperature 180 °C

4 Troubleshooting and maintenance

4.1 Troubleshooting checklist

Malfunction	Possible cause	Remedy
Device does not switch on	Power supply	
	Power cable not plugged in	Check the mains connection and, 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 device tested!
Device fails to heat up	Set temperature is too low	Increase set temperature
	Overtemperature fuse has tripped	Push in the overtemperature fuse. If it still trips it is imperative to have the device tested!
	Temperature controller	Replace temperature controller
	Heating cartridge	Check heating cartridges and replace if necessary
	Solid state relay	Replace solid state relay
	Set temperature not reached	
No material transport	Motor faulty	Replace motor
	Microswitch faulty	Replace microswitch
Uneven material transport	Toothed belt damaged	Replace toothed belt
	Toothed belt does not transport	Check the tension of the toothed belt
Loud running noise	Motor faulty	Replace motor
Sealing seam will not hold	Sealing temperature too low	Increase sealing temperature
	Distance between the sealing dies is too large	Set the distance between the sealing dies to 0.5mm
Sealing seam distorted or melted	Sealing temperature too high	Reduce sealing temperature

4.2 Offset – setting the temperature

4.2.1 Revoke key lock



1. Switch on the device
2. Check if the device is heating
3. Press and hold the two keys "Arrow down" & "Menu" simultaneously.
4. Change level from CONFIG. and PARAM. to NONE.
5. Press the Menu/OK key
6. Controller unlocked

4.2.2 Offset – Make setting



1. Press the Menu / OK **1** key
2. MENU level
Switch to **CONFIGURATION** with the arrow keys
3. Press the Menu / OK **1** key
4. CONFIGURATION level
Switch to **ANALOG INPUT** with the arrow keys
5. Press the Menu / OK **1** key
6. ANALOG INPUT level
Switch to **MEASURING VALUE OFFSET** with the arrow keys
7. Press the Menu / OK **1** key
8. Enter offset value
E.g.: TSET: 180°C
TACTUAL: (measured) 184°C
MEASURING VALUE OFFSET input: **+4°C**
9. Press the Menu/OK **1** key
10. Press the Return key twice to return to the display mode.
11. Check values and repeat point 4.2.2 if necessary.

4.2.3 Activate key lock



1. Switch on the device
2. Check if the device heats up
3. Press and hold the two keys "Arrow down" & "Menu" simultaneously.
4. Change level from NONE to CONFIG. and PARAM.
5. Press the Menu/OK key
6. Controller locked

4.3 Servicing plan



Like all technical devices, your device is subject to technical wear. In order to ensure maximum availability, your device should be maintained by a trained professional at least once a year.

Maintenance cycle	Cleaning	PTFE tape Guiding die	PTFE tape Sealing die	Pressure roller	Toothed belt	Distance of Sealing die
At least every 3 months						
Depending on usage, at least once a year						

Legend:



Check



Replace



Adjust

4.4 Spare parts service

Please contact your local sales representative for further information

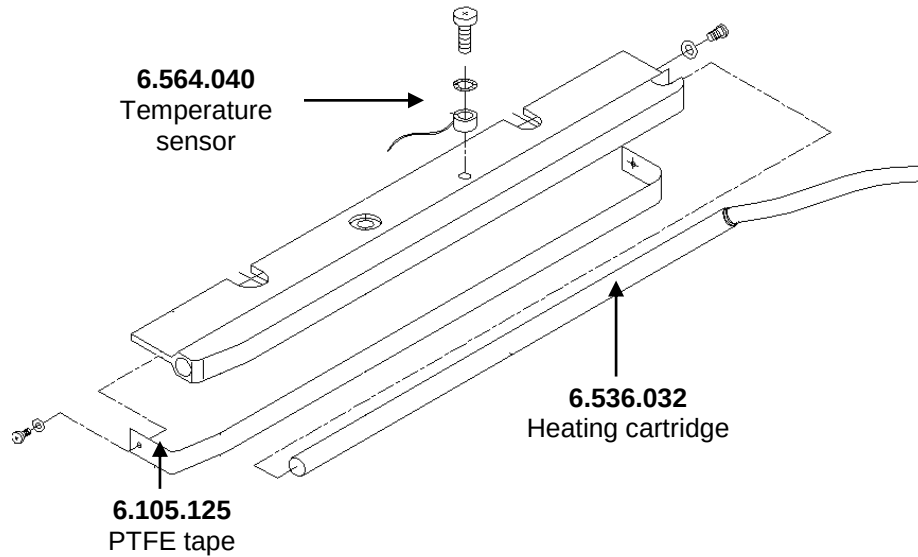
To:
E-Mail:
Fax no. +

Sender:

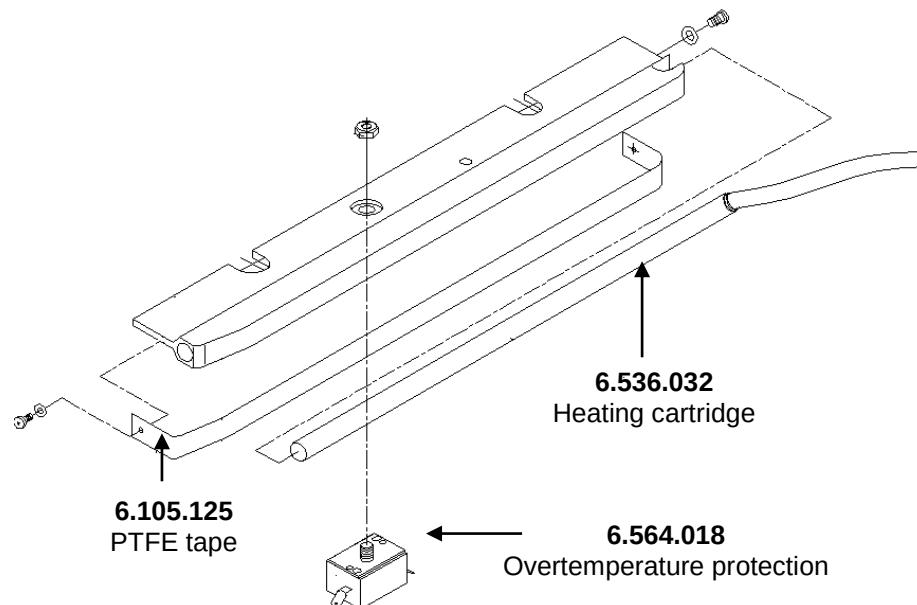
Your order no. _____		Date _____	
Device type _____		Serial number _____	
☒	Designation	Art. no.	Qty.
☐	Pressure roller	2.230.026	
☐	Gear motor 230 V 115 V	1.212.005 1.212.014	
☐	Heating cartridge 115 V/200W	6.536.032	
☐	Fan 230 V 115 V	6.212.019 6.212.021	
☐	PTFE tape heating die	6.105.125	
☐	PTFE tape guiding die	6.105.138	
☐	IEC cable supply with switch	6.562.009	
☐	Safety element for 6.562.009	6.562.049	
☐	Mains cable 230V	6.593.013	
☐	Mains cable 115V	6.593.014	
☐	SST relay	6.460.001	
☐	Temperature sensor	6.564.040	
☐	Digital temperature controller 110 -240 V	6.564.050	
☐	Overtemperature protection	6.564.018	
☐	Toothed belt transport	6.271.001	
☐	Motor – Start switch	6.562.009	
☐			

4.5 Spare parts ordering – allocation of article numbers

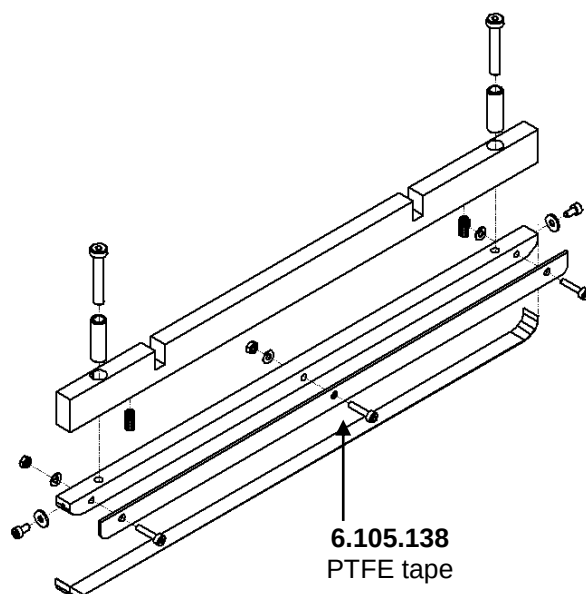
4.5.1 Upper sealing die 1.616.024



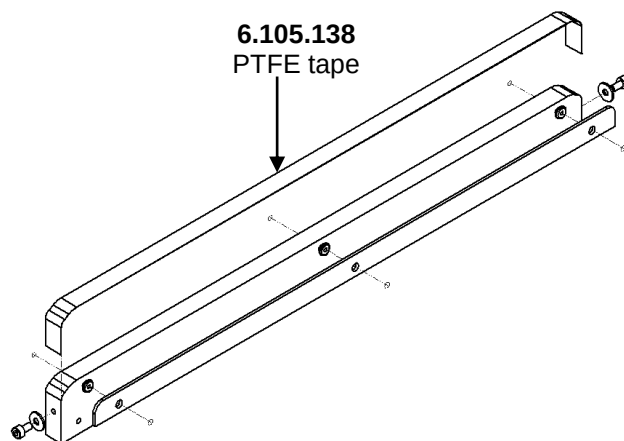
4.5.2 Lower sealing die 1.616.025



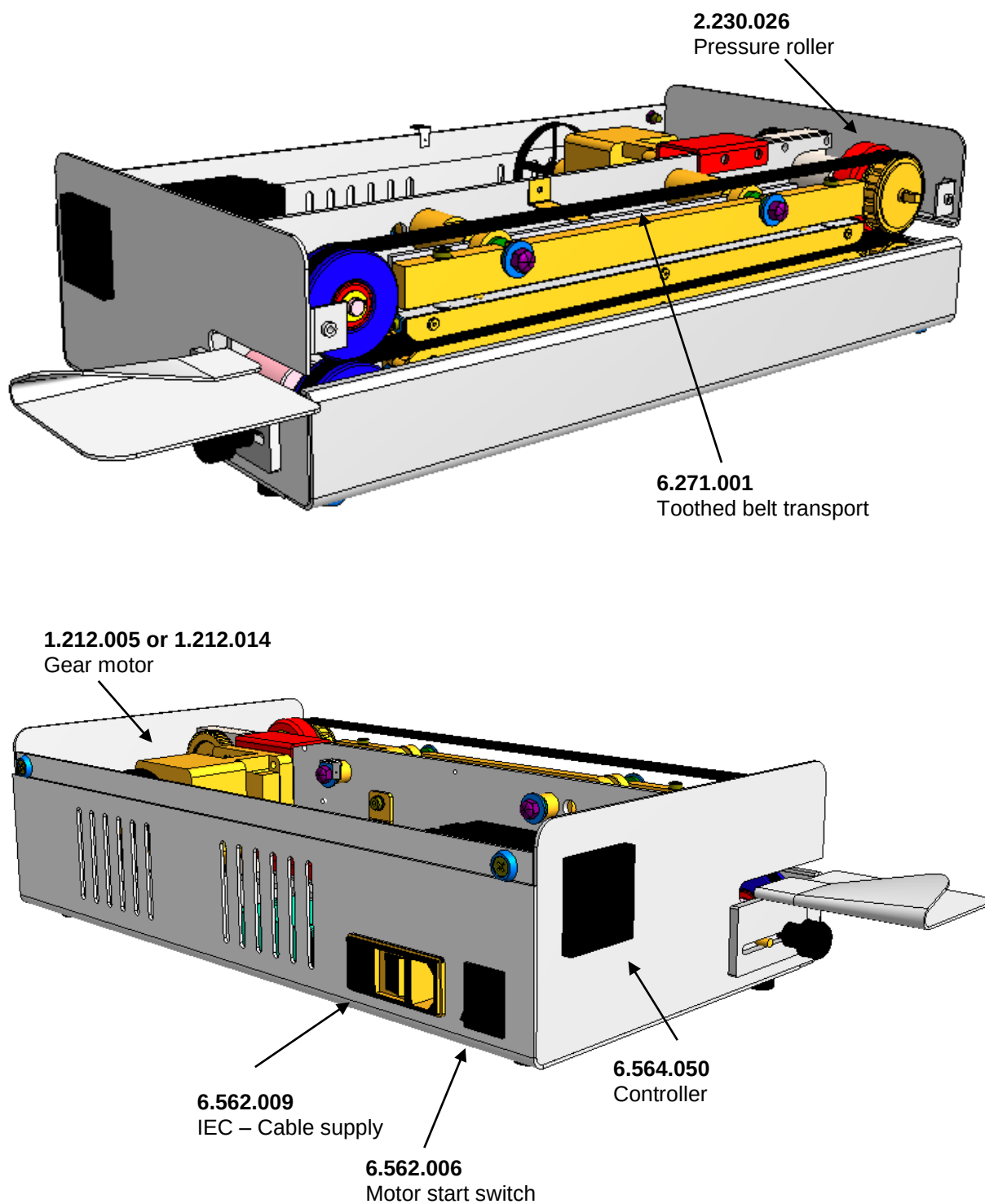
4.5.3 Upper guiding die **1.619.014**



4.5.4 Lower guiding die **1.619.015**



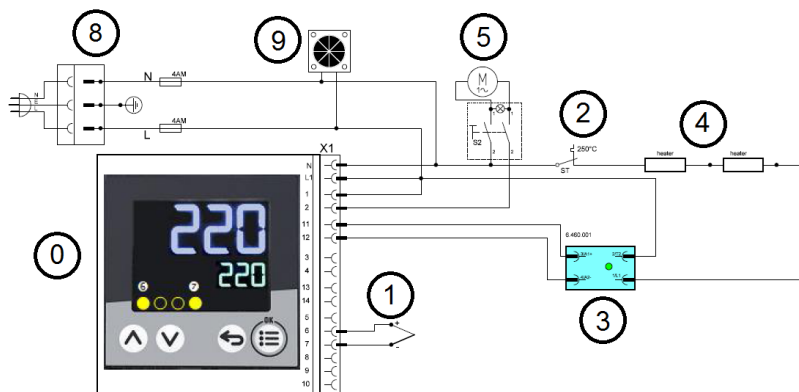
4.5.5 Comprehensive overview



5 Technical data

5.1 Switching and wiring diagram 230V~

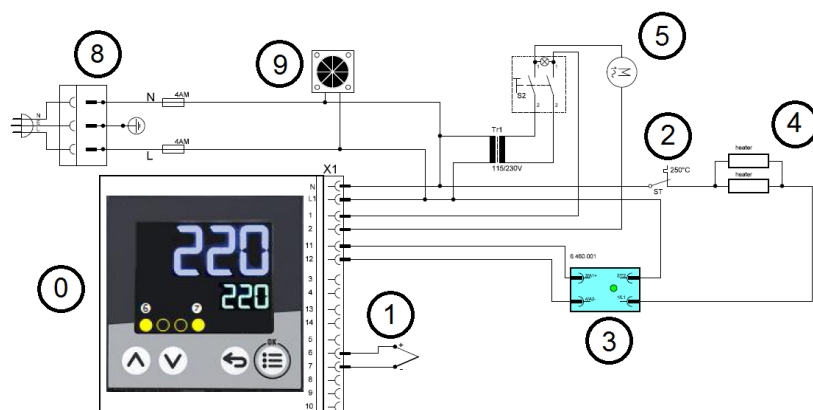
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0	Temperature controller	6.564.050
1	Temperature sensor	6.564.040
2	Overtemperature protection	6.564.018
3	SST relay	6.460.001
4	115V/200W heating cartridges	6.536.024
5	Gear motor 230V 115V	1.212.005 1.212.014
6		
7	Time relay 230V 115V	1.540.056 1.540.057
8	IEC cable supply with switch	6.562.009
9	Fan 230V~ 115V	6.212.019 6.212.021

5.2 Switching and wiring diagram 115V~

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5.3 Specifications

Connection data

Mains connection	[V]	115 / 230
Mains frequency	[Hz]	50 / 60
Power consumption max.	[W]	390
Mains fuse 115V / 230V	[A]	6.3A / 4A

Mechanical system

Dimensions	Length	[mm]	505
Including infeed section	Width		250
	Height		145
Housing			Metal, powder-coated
Weight		[kg]	15
Seal distance from the edge		[mm]	0 – 35
Seal seam width		[mm]	12
Sealing system			Multi – Line
Length of sealing seam		[mm]	Unlimited
Distance from medical product		[mm]	>30 (as per DIN 58953-7)

Process variables/sealing parameters

Sealing temperature max.	[°C]	220
Sealing temperature switch-off tolerance	[°C]	±5
Throughput speed [fixed]	[m / min]	10
Temperature control tolerance	[%]	±2

Electronics and communication systems

System	electronic
Electrical protection class	1

Environmental parameters

Ambient temperature	[°C]	5-25
Heat emission	[kJ/s]	0.1
Noise intensity as per Machinery Directive 2006/42/EC Appendix I 1.7.4.2 u.)	[dB/ A]	<70
Relative humidity	[%]	30-80 non-condensing

6 Declaration of conformity

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaración de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade	9.696.161C																																																																								
Gültig ab: 23.11.2021 Valid from:		Seite 1/1 Version 1.01																																																																								
<p>Hiermit erklären wir, dass die Folienschweißmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: 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:</p> <p style="text-align: center;">INNOQ SEAL 100</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: corresponde aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <table border="0"> <tr> <td>EG - Maschinenrichtlinie</td> <td>2006/42/EG</td> <td></td> <td></td> </tr> <tr> <td>Machinery directive</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Directive "CE" rel. aux machines</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Directiva de Maquinaria de la CE</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Direttiva CE sulle macchine nella versione</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Directiva da UE relativa a maquinaria</td> <td></td> <td></td> <td></td> </tr> <tr> <td>EMV-Richtlinie</td> <td>EMC-directive</td> <td>2014/30/EU</td> <td></td> </tr> <tr> <td>Directive CEM</td> <td>Directiva de CEM</td> <td></td> <td></td> </tr> <tr> <td>Direttiva CEM</td> <td>Directiva CEM</td> <td></td> <td></td> </tr> <tr> <td>WEEE-Richtlinie</td> <td>WEEE-directive</td> <td>2012/19/EU</td> <td></td> </tr> <tr> <td>Directive WEEE</td> <td>Directiva de WEEE</td> <td></td> <td></td> </tr> <tr> <td>Direttiva WEEE</td> <td>Directiva WEEE</td> <td></td> <td></td> </tr> <tr> <td>RoHS-Richtlinie</td> <td>RoHS-directive</td> <td>2015/863/EU</td> <td></td> </tr> <tr> <td>Directive RoHS</td> <td>Directiva de RoHS</td> <td></td> <td></td> </tr> <tr> <td>Direttiva RoHS</td> <td>Directiva RoHS</td> <td></td> <td></td> </tr> <tr> <td>Harmonisierte Normen</td> <td>Harmonized standards</td> <td>EN ISO 12100:2010</td> <td>EN 60204-1:2018</td> </tr> <tr> <td>Standard harmonisé</td> <td>Las normas armonizadas</td> <td>EN ISO 13857:2019</td> <td>EN IEC 61000-6-1:2019</td> </tr> <tr> <td>Norme armonizzate</td> <td>Normas harmonizadas</td> <td>EN IEC 63000:2018</td> <td>EN 61000-6-3:2007+A1:2011</td> </tr> </table> <p>Verantwortliche Person für die Technischen Unterlagen siehe unten Responsible person for technical documentation see below La personne responsable pour la documentation technique est mentionnée au-dessous</p> <p style="text-align: center;">  hawa GmbH 74847 Obrigheim / Germany T +49 (0) 6261 / 9770-0 info@hawa.com </p> <p>Torsten Ehmann Prokurist / authorized officer</p> <p>hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany</p>			EG - Maschinenrichtlinie	2006/42/EG			Machinery directive				Directive "CE" rel. aux machines				Directiva de Maquinaria de la CE				Direttiva CE sulle macchine nella versione				Directiva da UE relativa a maquinaria				EMV-Richtlinie	EMC-directive	2014/30/EU		Directive CEM	Directiva de CEM			Direttiva CEM	Directiva CEM			WEEE-Richtlinie	WEEE-directive	2012/19/EU		Directive WEEE	Directiva de WEEE			Direttiva WEEE	Directiva WEEE			RoHS-Richtlinie	RoHS-directive	2015/863/EU		Directive RoHS	Directiva de RoHS			Direttiva RoHS	Directiva RoHS			Harmonisierte Normen	Harmonized standards	EN ISO 12100:2010	EN 60204-1:2018	Standard harmonisé	Las normas armonizadas	EN ISO 13857:2019	EN IEC 61000-6-1:2019	Norme armonizzate	Normas harmonizadas	EN IEC 63000:2018	EN 61000-6-3:2007+A1:2011
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9.696.161 Version 2.01



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ROTARY SEALER

OPERATING INSTRUCTIONS



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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 (SBS¹).



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

1.3 Important notice



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

The Medical Device Directive 93/42/EEC and Medical Device Regulation 2017/745 (MDR) is not applicable to sealing devices.

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

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

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 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!

1.5 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 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 2012/19 EU 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.

1.6 Notes on the operation of the device



Checking the sealing seam²

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.

1.6.1 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)

² 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 device is intended only for commercial and industrial use, and must be used only for the intended purpose and with the following sealable materials.

SEALING MATERIALS

Sealable paper pouches in accordance with EN ISO 11607-1/EN 868-4	x
Sealable pouches and tubes in accordance with EN ISO 11607-1/EN 868-5 made of film and paper as per EN 868-3	x
Sealable pouches and tubes in accordance with ISO EN 11607-1/EN 868-5 made of film and uncoated materials made of polyolefins as per EN 868-9 (e.g. Tyvek ^{®1})	x ¹
Aluminium-laminate film	x ²
Sealable pouches and tubes in accordance with ISO 11606-1/EN 868-5 made of PP fleece or PP non-woven	x ²

NON-SEALABLE MATERIALS

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

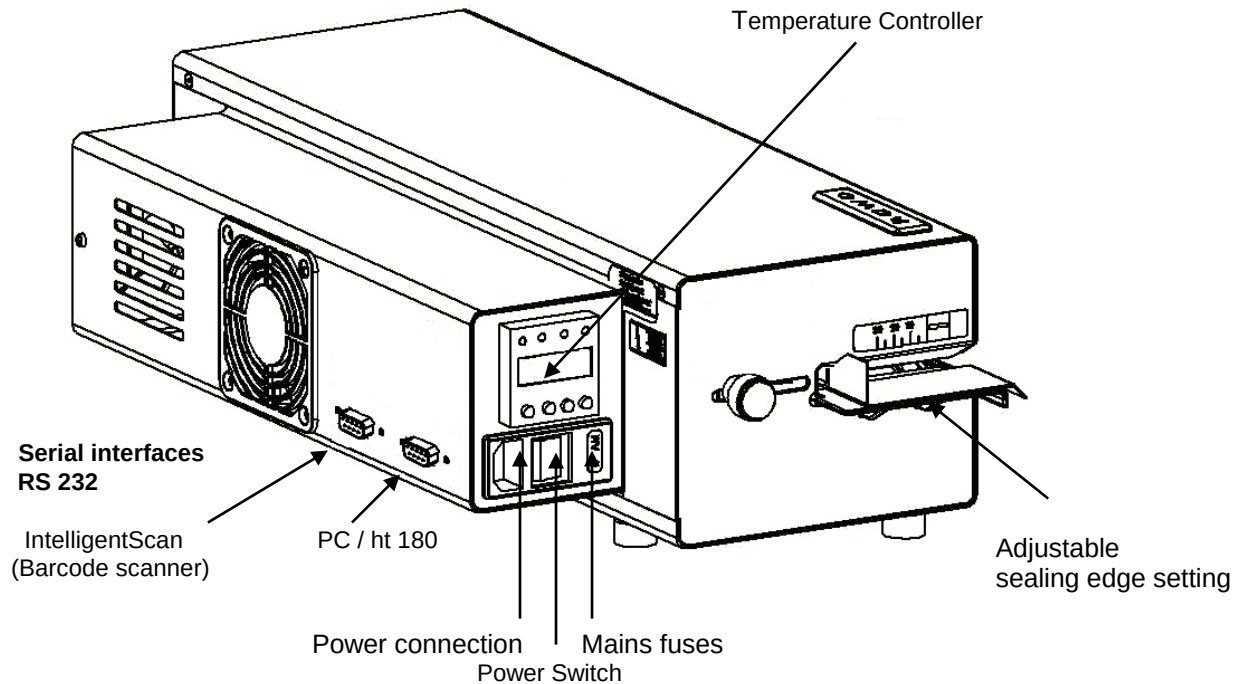
The correct sealing temperature for the packaging materials being used must be identified by means of test sealings (DIN 58953-7).

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

¹ Tyvek[®] is a registered trademark of E.I. du Pont Nemours.

² Release and / or test required

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 sealing machine, besides temperature 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

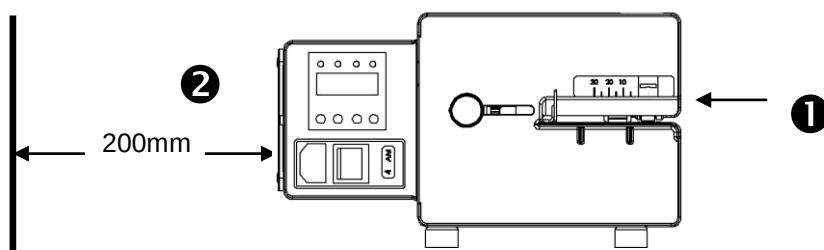


Prior to installation, read the safety notices in chapter 1.4

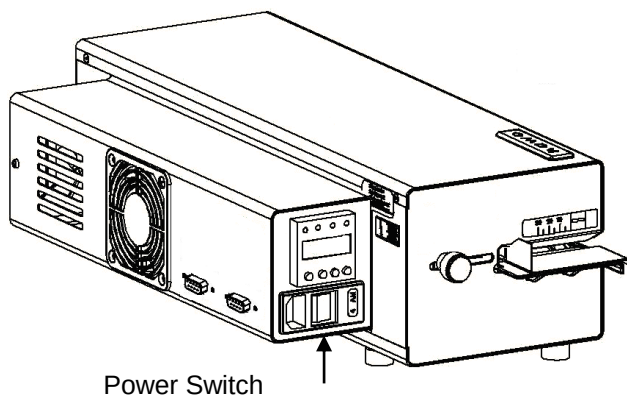
2.3.1 Installation

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

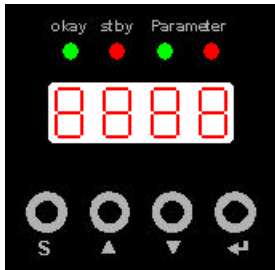
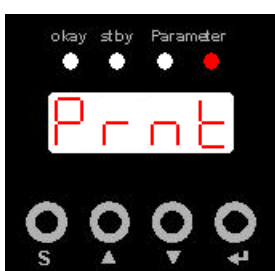


To switch on the machine, press the power switch on the left-hand side.

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 Basic functions

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

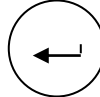
3.2 Inspection light functions



Function				
Machine switched on Warm-up phase	flashes	off	off	off
Sealing temperature = $\pm 5^\circ$ Sealing speed = $\pm 10\%$	on	off	on	off
Sealing temperature <> $\pm 5^\circ$ Sealing speed <> $\pm 10\%$	off	on	off	on
Standby	off	on	off	on
warming up after standby or change in set temperature	flashes	off	off	on

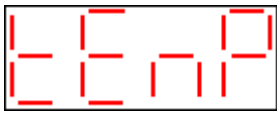
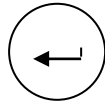
3.3 Button functions



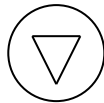
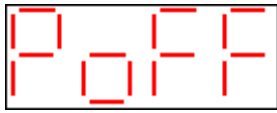
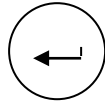
			
Menu level 1 Menu level 2 activation Press for 3 s Menu level 3 activation Press for 7 s	Switch printer off/on	Personal identification input	"Seal check" activation
Menu level 2 Sealing temperature input	Temperature value + 1	Temperature value -1	Confirm input
Menu level 3 3.1 Sealing parameters view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

3.4 Machine settings

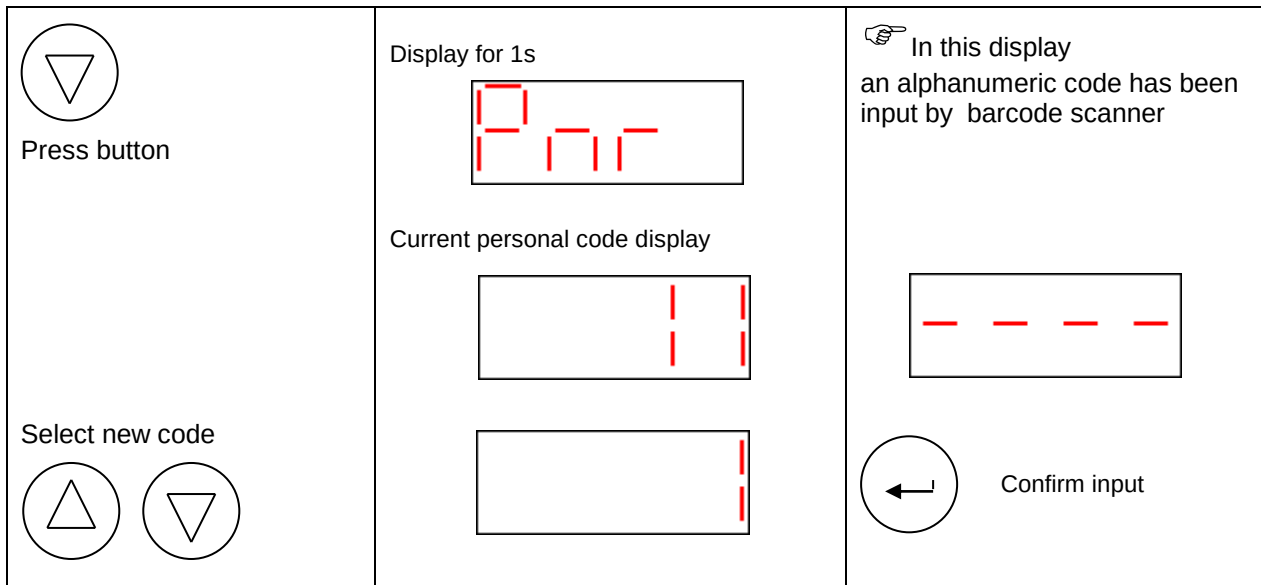
3.4.1 Sealing temperature input

<div data-bbox="183 286 287 392">  </div> <p>Press button for 3s</p> <p>Change set value</p> <div data-bbox="175 750 399 851">   </div>	<p>Display for 1s</p> <div data-bbox="635 358 912 470">  </div> <p>Current temperature set value display</p> <div data-bbox="635 600 912 712">  </div> <div data-bbox="635 743 912 855">  </div>	<div data-bbox="1040 743 1144 844">  </div> <p>Confirm input</p>
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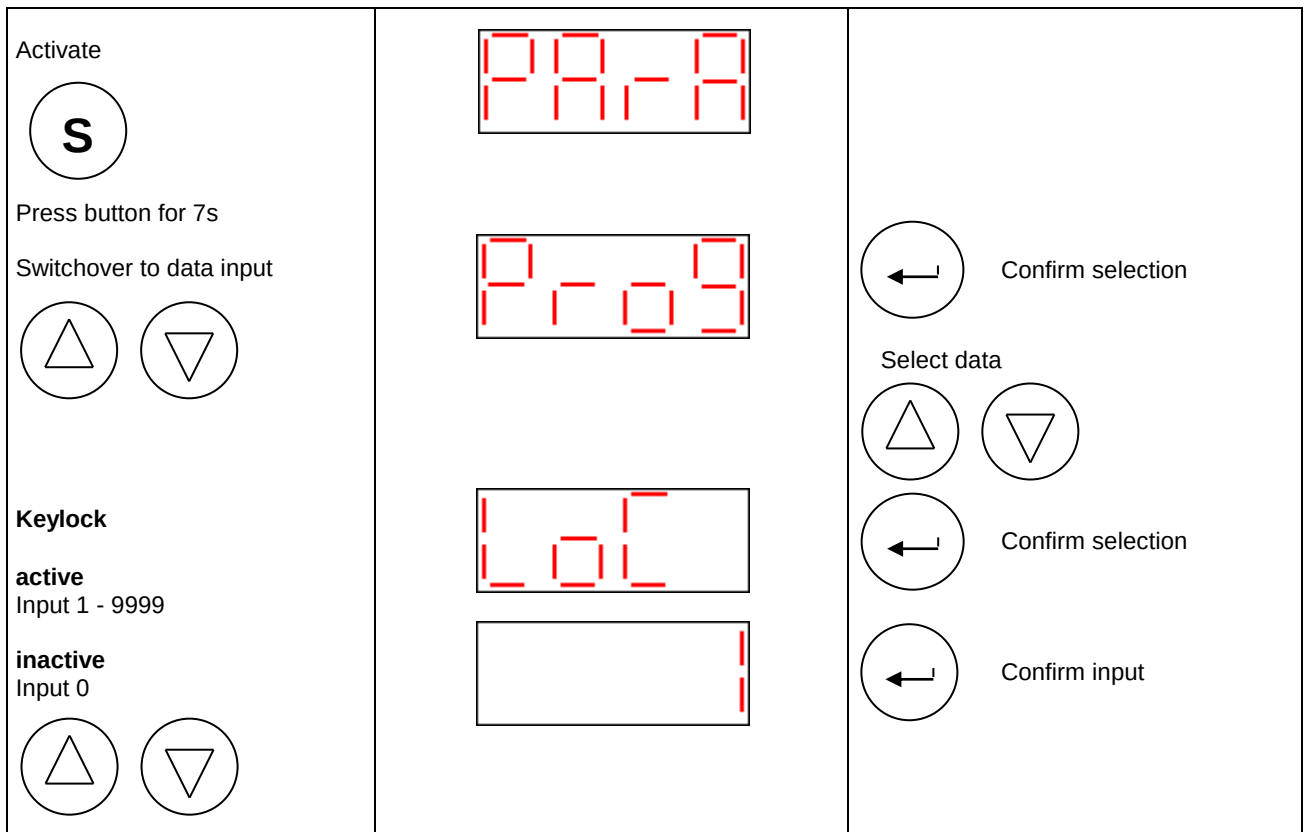
3.4.2 Switch printer off and on

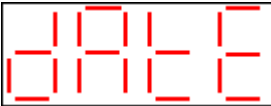
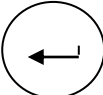
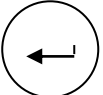
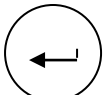
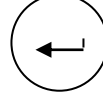
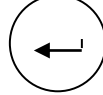
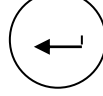
<div data-bbox="175 1046 279 1146">  </div> <p>Press button</p> <p>Switch printer off or on</p> <div data-bbox="175 1482 399 1583">   </div>	<p>Display for 1s</p> <div data-bbox="635 1113 912 1225">  </div> <p>Current setting display</p> <p>Printer switched on</p> <div data-bbox="635 1344 912 1456">  </div> <p>Printer switched off</p> <div data-bbox="635 1505 912 1617">  </div>	<div data-bbox="1016 1516 1120 1617">  </div> <p>Confirm input</p>
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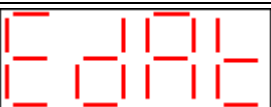
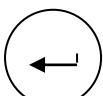
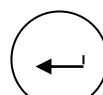
3.4.3 Personal code input

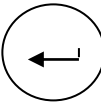
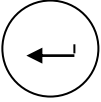
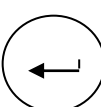
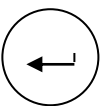


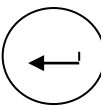
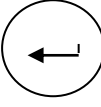
3.4.4 Data input

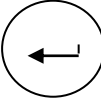
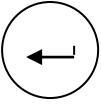


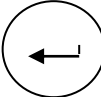
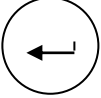
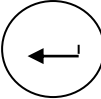
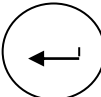
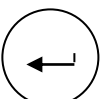
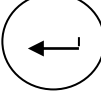
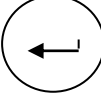
<p>Date and time</p> <p>Day input</p> <p>Month input</p> <p>Year input</p> <p>Hour input</p> <p>Minute input</p>	     	<p> Confirm selection</p> <p> Confirm input</p> <p> Confirm input</p> <p> Confirm input</p> <p> Confirm input</p> <p> Confirm input</p>
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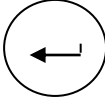
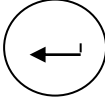
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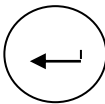
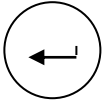
<p>Batch Input 0000 - 9999</p> <div data-bbox="225 595 448 696">   </div>	<div data-bbox="635 165 911 271">  </div> <div data-bbox="635 595 911 701">  </div>	<div data-bbox="1023 165 1123 266">  </div> <p>Confirm selection</p> <p data-bbox="1023 300 1401 405">  In this display an alphanumeric code has been input by barcode scanner </p> <div data-bbox="1070 454 1347 560">  </div> <div data-bbox="1023 595 1123 696">  </div> <p>Confirm input</p>
<p>Pack content quantity Input 0 - 99</p> <div data-bbox="177 925 400 1025">   </div>	<div data-bbox="635 772 911 878">  </div> <div data-bbox="635 909 911 1014">  </div>	<div data-bbox="1023 772 1123 878">  </div> <p>Confirm selection</p> <div data-bbox="1023 909 1123 1014">  </div> <p>Confirm input</p>

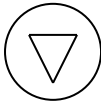
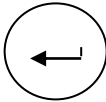
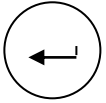
<p>Sterilization type</p> <p>Sterilization type selection</p> <div style="display: flex; justify-content: space-around;">   </div>	<div style="display: flex; flex-direction: column; align-items: center;"> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div style="margin-left: 10px;">Steam</div> </div> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div style="margin-left: 10px;">Ethylene oxide</div> </div> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div style="margin-left: 10px;">Formaldehyde</div> </div> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div style="margin-left: 10px;">Plasma</div> </div> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div style="margin-left: 10px;">Dry heat</div> </div> <div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Ionising radiation</div> </div> </div>	<div style="display: flex; flex-direction: column; align-items: center; justify-content: space-around;"> <div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm selection</div> </div> <div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm selection</div> </div> </div>
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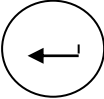
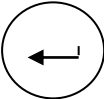
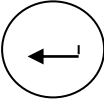
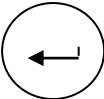
<p>Personal code input</p> <p>Select new code</p> <div style="display: flex; justify-content: space-around;">   </div>	<div style="display: flex; flex-direction: column; align-items: center;"> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div style="margin-left: 10px;">Current personal code display</div> </div> <div style="display: flex; align-items: center; margin-bottom: 10px;">  </div> <div style="display: flex; align-items: center;">  </div> </div>	<div style="display: flex; flex-direction: column; align-items: center; justify-content: space-around;"> <div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm selection</div> </div> <div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm input</div> </div> </div>
---	---	---

<p>Batch counter Input 0 - 9999</p>   <p>Counting direction selection</p> <p>If counting direction down has been selected, an alarm sounds when the value 0 is reached</p> <p>Switch off batch counter</p>	 <p>Counting direction up</p>  <p>Counting direction down</p>  <p>Switch off batch counter</p> 	 Confirm selection  Confirm input  Confirm selection
<p>Standby Input 0 – 60min</p>   <p>If the motor was not started before reaching the set time, then the temperature is set automatically to 50°C / 122°F.</p>	  <p>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</p>	 Confirm selection  Confirm input
<p>Operating data View of the operating hours and the absolute batch counter</p> <p>View selection</p>  	<p>Operating hours</p>  <p>Absolute batch counter</p> 	 Confirm selection  Confirm selection

<p>Units of measurement</p> <p>Units of measurement selection</p> <div style="display: flex; justify-content: space-around;">   </div> <p>Europe Temperature in °C Sealing speed in m/min</p> <p>USA Temperature in °F Sealing speed in inch/mm</p>	<div style="border: 1px solid black; padding: 5px; text-align: center;">  </div> <p>Units of measurement Europe</p> <div style="border: 1px solid black; padding: 5px; text-align: center;">  </div> <p>Units of measurement USA</p>	<div style="text-align: center;">  Confirm selection </div> <div style="text-align: center; margin-top: 20px;">  Confirm selection </div>
--	--	---

<p>Character width</p> <div style="display: flex; justify-content: space-around;">   </div> <p>Input 0 - 2</p> <p>In accordance with the setting selected, the characters are printed in various widths</p> <p>Input A Automatic setting of the character width, depending on the width of the packaging and the length of the print line.</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px; text-align: center;"> PNR </div> <div style="border: 1px solid black; padding: 5px; margin-top: 5px; text-align: center;"> PNR </div>	<div style="border: 1px solid black; padding: 5px; text-align: center;">  </div> <div style="border: 1px solid black; padding: 5px; text-align: center; margin-top: 10px;">  </div>	<div style="text-align: center;">  Confirm selection </div> <div style="text-align: center; margin-top: 20px;">  Confirm input </div>
---	---	--

<p>Monitoring Personal number Input 0 – 60min</p> <div data-bbox="177 398 399 499">   </div> <p>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</p> <p>Once the set time is reached, the personal number is automatically set to 0</p> <p>If the personal number is 0000 and a package is inserted, a command prompt appears</p> <p>By inputting a personal number of 1-9999, the lock of the drive motor is disabled and the command prompt disappears</p>	<div data-bbox="635 226 909 331">  </div> <div data-bbox="635 367 909 472">  </div> <div data-bbox="657 801 914 1057">  </div> <div data-bbox="730 1162 831 1263">  </div>	<div data-bbox="1021 230 1126 331">  </div> <p>Confirm selection</p> <div data-bbox="1021 371 1126 472">  </div> <p>Confirm input</p>
--	---	---

<p>Date format</p> <p>Date format selection</p> <div style="display: flex; justify-content: space-around;">   </div> <ol style="list-style-type: none"> 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 	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;">  </div> <div style="border: 1px solid black; padding: 5px;">  </div>	<div style="display: flex; align-items: center; margin-bottom: 20px;">  <div style="margin-left: 10px;">Confirm selection</div> </div> <div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm selection</div> </div>
<p>Time format</p> <p>Time format selection</p> <div style="display: flex; justify-content: space-around;">   </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 40px;">24</div> <div>13:26</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 40px;">12</div> <div>01:26 PM</div> </div>	<p>Time format 24h</p> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;">  </div> <p>Time format 12h</p> <div style="border: 1px solid black; padding: 5px;">  </div>	<div style="display: flex; align-items: center; margin-bottom: 20px;">  <div style="margin-left: 10px;">Confirm selection</div> </div> <div style="display: flex; align-items: center;">  <div style="margin-left: 10px;">Confirm selection</div> </div>

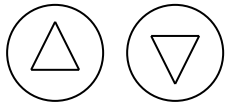
3.4.5 Print data selection

Activate



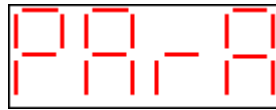
Press button for 7s

Switchover to print data

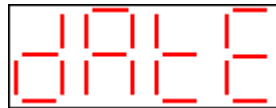


The print sequence is predefined.
Activated print data is always printed in this sequence

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



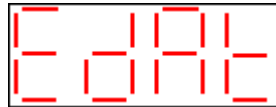
Sterilization date



Time



Expiry date



Batch number



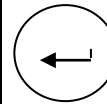
Personal identification



Batch counter

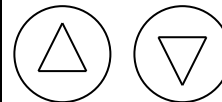
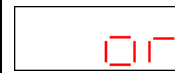
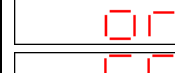
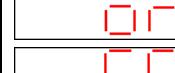
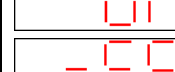
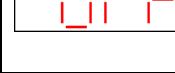


Sterilization type



Confirm selection

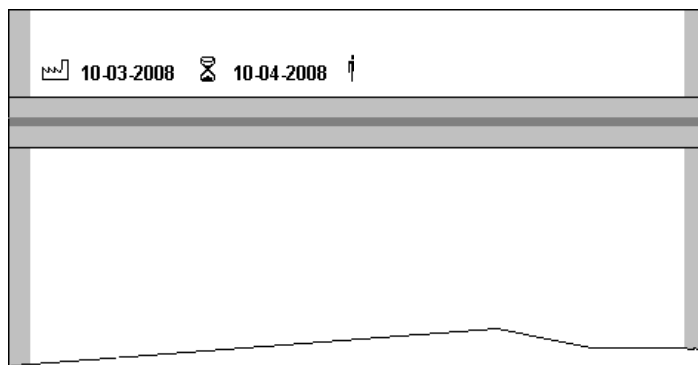
Select data to be printed



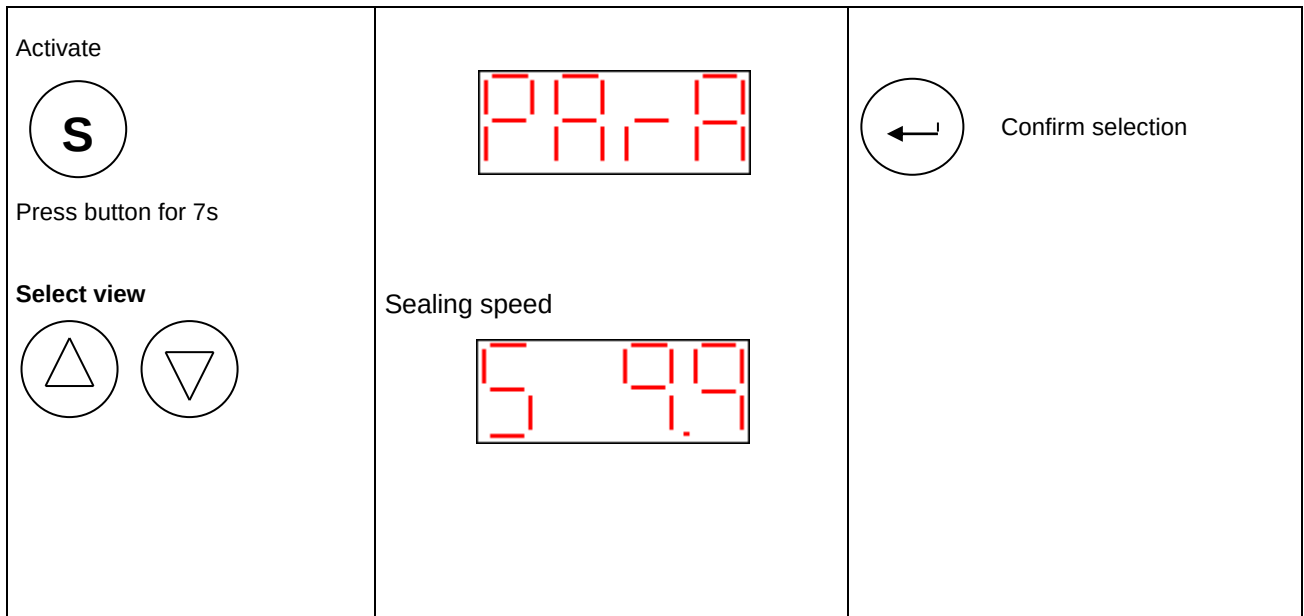
	Pack content quantity					
	Text					

Example

Printing the sterilization date and the expiry date



3.4.6 View of sealing parameter sealing speed



3.4.7 IntelligentScan, connection of a barcode scanner

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

Inputs and functions via the controller or using the barcode scanner

Inputs

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

Functions

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

Inputs and functions only with the barcode scanner

Inputs

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

Functions

Switching the batch counter off or on



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



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.

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 $\frac{3}{4}$ full (DIN 58953-7). The limited filling prevents a load that is too large from being placed on the sealing seams.



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

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

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

* see the DGSV guideline for validation of the sealing process

3.6 Sealing seam test – "Seal Check"

Testing of the critical process parameters temperature and sealing speed (dwell) with "SEAL CHECK".

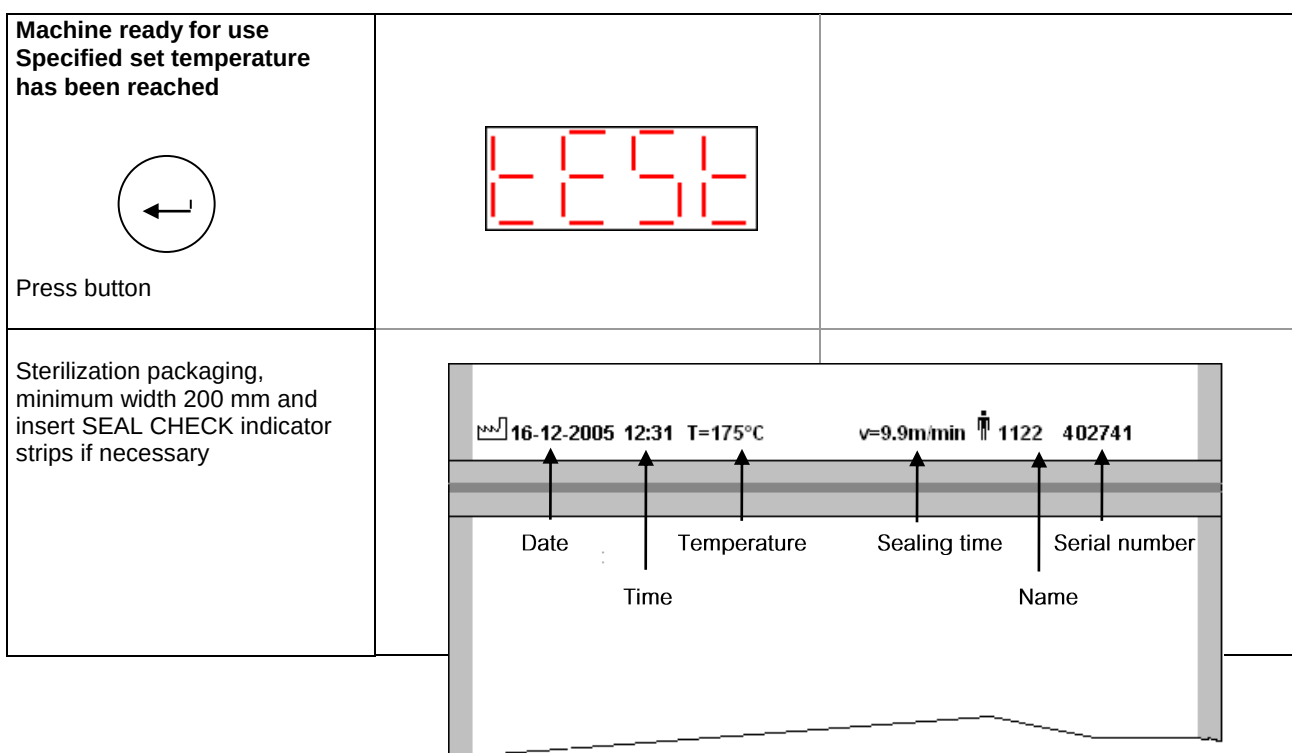


Seal Check seal indicators are not suitable for packaging with side folds

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.



4 Troubleshooting and servicing

4.1 Troubleshooting checklist



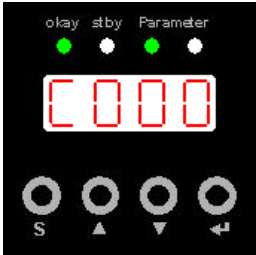
The trouble shooting suggestion marked with a * may only be carried out by a service partner authorised by the manufacturer.

Malfunction	Possible cause	Troubleshooting
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 13)
	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
No feed	SST Module defective	Replace SST Module*
	Conveyor belt - damaged - no feed	Replace conveyor belt Check belt tension
	Front flap not closed	Close front flap
	Motor - sensor	Replace light barrier*
	Front flaps - sensor	Replace front flap sensor*
	Motor	Replace motor*
	Temperature controller defect	Replace Temperature controller*

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 Alarm functions and error displays

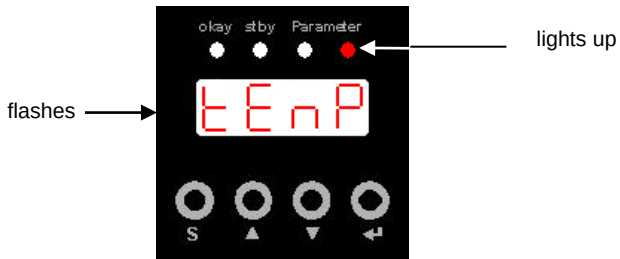
4.2.1 Alarm functions

<p>Batch counter, set to count down, has reached the value 0</p>	<p>flashes →</p> 				
	<table border="1"> <tr> <td data-bbox="550 616 949 660"></td><td data-bbox="949 616 1449 660">Canceling the Alarm</td></tr> <tr> <td data-bbox="550 660 949 873"></td><td data-bbox="949 660 1449 873"> Set batch counter to a value > 0 or Set batch counter direction to up see page 19 </td></tr> </table>		Canceling the Alarm		Set batch counter to a value > 0 or Set batch counter direction to up see page 19
	Canceling the Alarm				
	Set batch counter to a value > 0 or Set batch counter direction to up see page 19				

4.2.2 Error displays



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

Sealing temperature outside tolerance		
	Possible cause	Troubleshooting
	Temperature sensor defective	Replace temperature sensor*
	Temperature Controller defective	Replace controller*
	SST module defective	Replace SST module*
Sealing speed outside tolerance		
	Possible cause	Troubleshooting
	Motor defective	Replace motor*

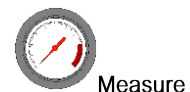
4.3 Servicing / calibration



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 annually						

Legend:



4.4 Parts Service

Please contact your local sales representative for further information.

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:

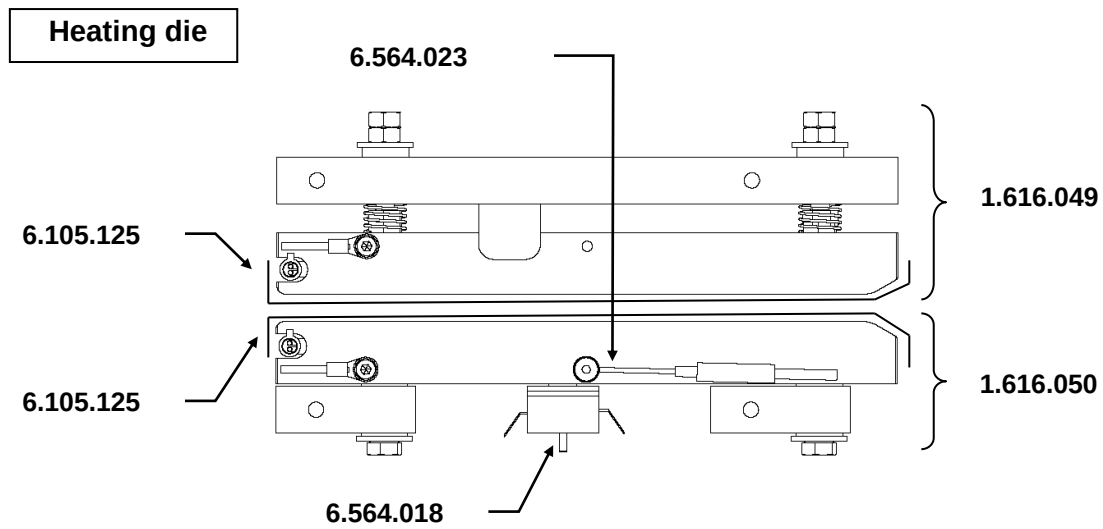
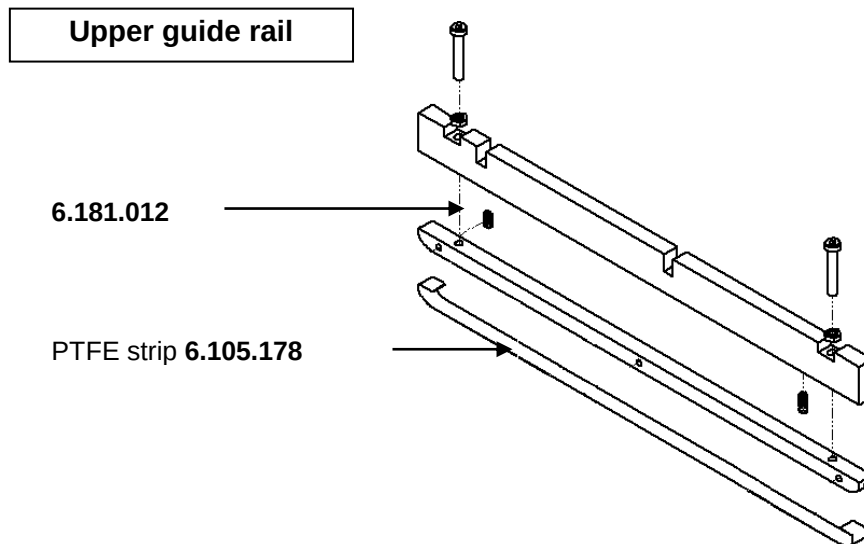
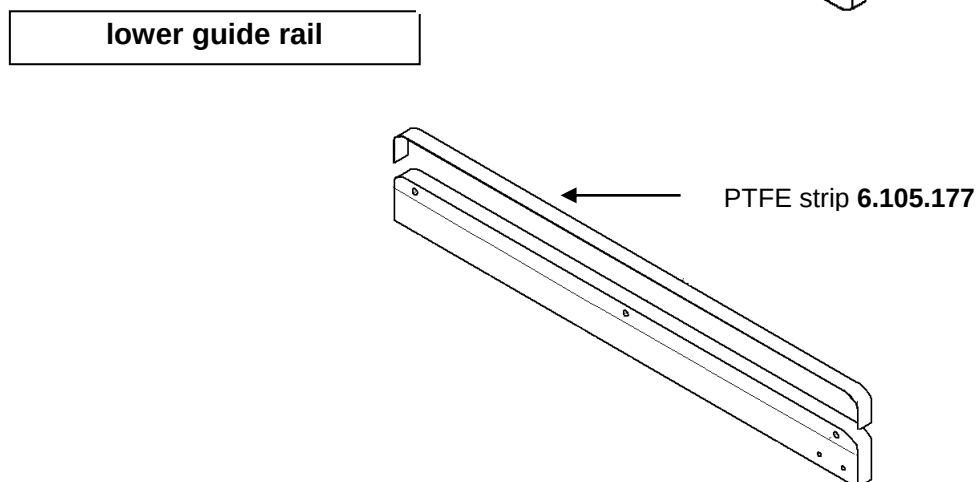
Sender:

Fax No.

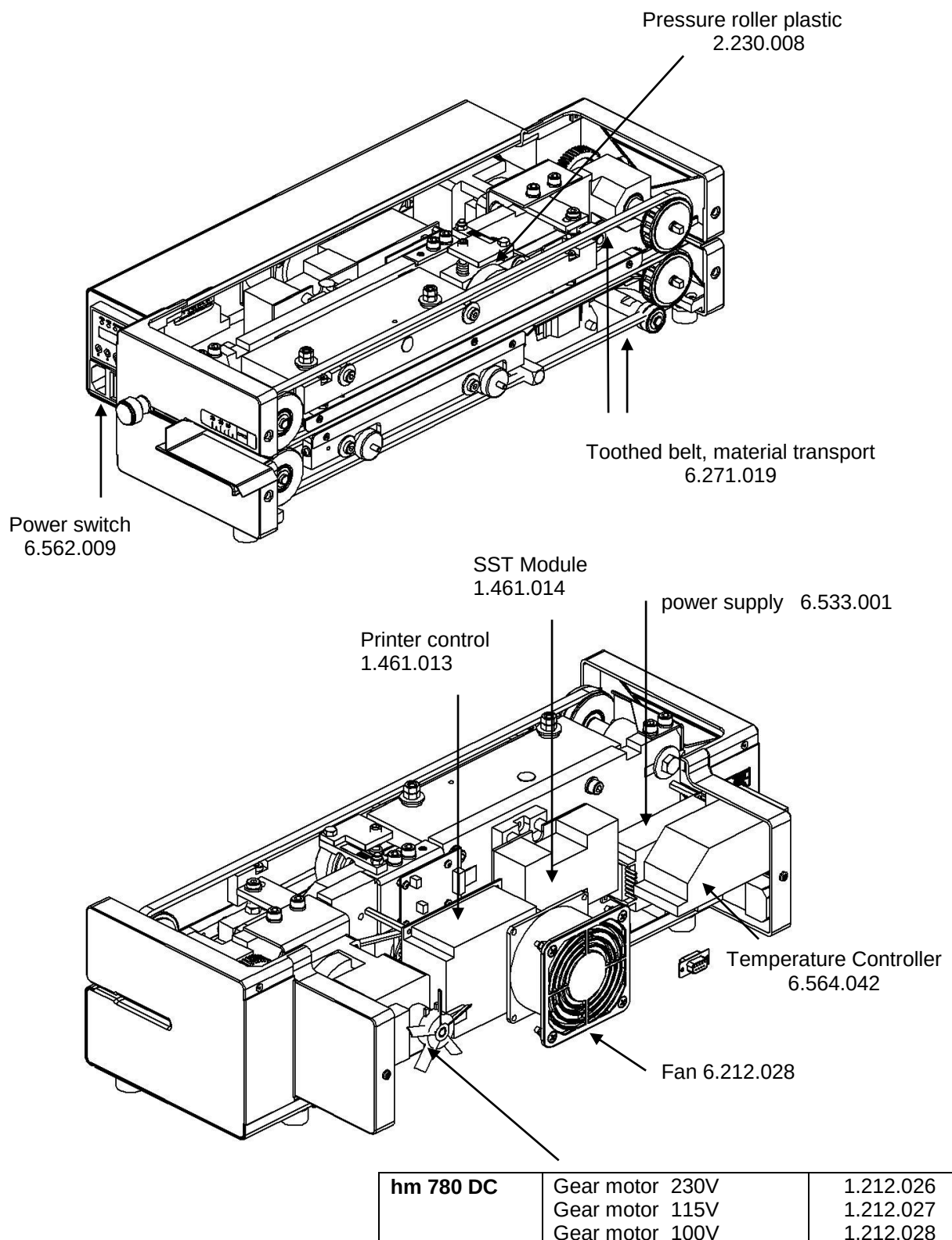
Your order no.: _____		Date _____	
Machine Model _____		Serial number _____	
☒	Designation	Part No	qty
☐	Temperature control 100 - 245V	6.564.042	
☐	Printer control	1.461.013	
☐			
☐	SST Module	1.461.014	
☐	Switched –mode power supply	6.533.001	
☐	Light barrier printer	1.561.003	
☐	Light barrier motor	1.561.010	
☐	hm 780 DC		
☐	Gear motor 230V	1.212.026	
☐	Gear motor 115V	1.212.027	
☐	Motor ink ribbon	1.212.012	
☐	Temperature limit switch	6.564.018	
☐	Thermocouple	6.564.023	
☐	Fan 24V	6.212.028	

Signature _____

4.5 Replacement part orders- allocation of article numbers



4.6 Spare part ordering – Complete overview



4.7 Information about replacing wearing and spare parts

! Please use only genuine replacement parts

Replacing ink ribbon

→ Switch off machine

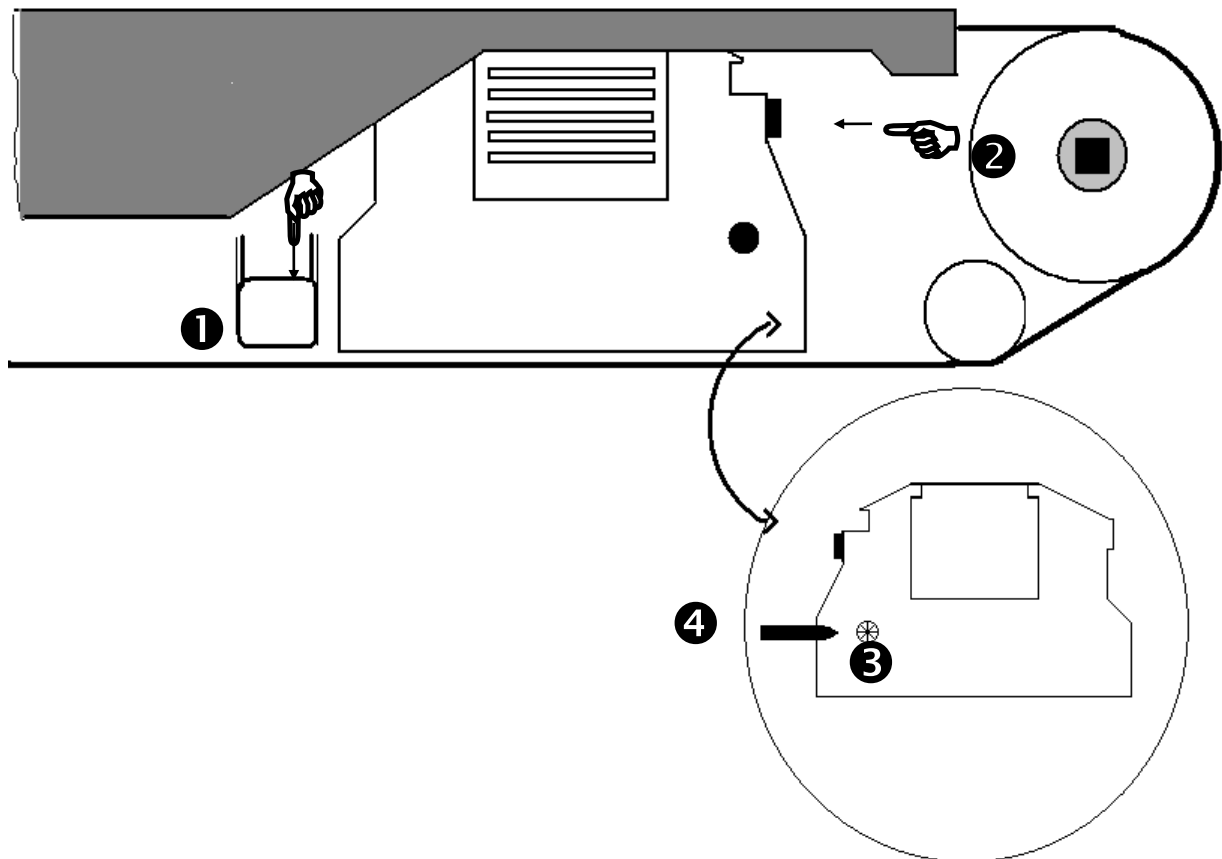
- Open front flap, set in feed section to 0 if appropriate
- Press lever for ink ribbon holder **1** down with left hand.
- Press holder for ink ribbon cassette **2** to side and remove cassette.
- Insert new ink ribbon cassette



Always ensure that the transport opening **3** in the cassette is attached to the transport shaft **4**.

- Press ink ribbon cassette toward rear until holder **2** catches
- Close front flap

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



Maintenance Information

! Please use only genuine replacement parts

Replacing PTFE strip on guide rail

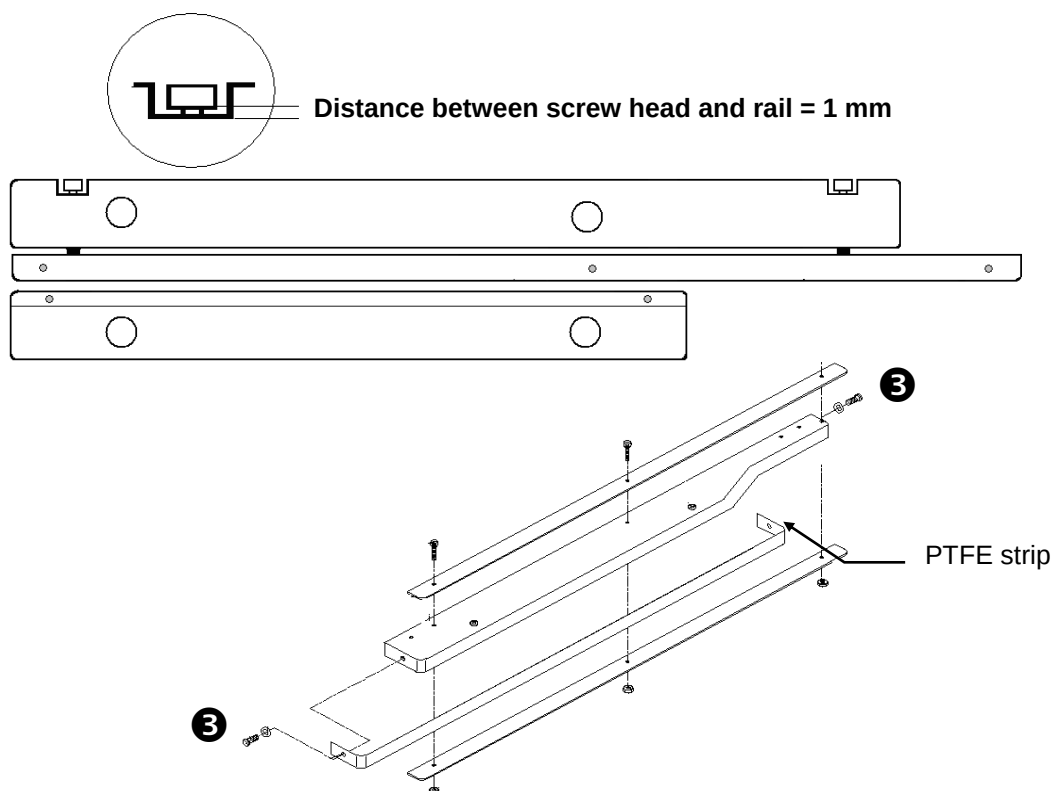
➔ **Switch off machine and DISCONNECT POWER PLUG !**

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



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

- Close housing



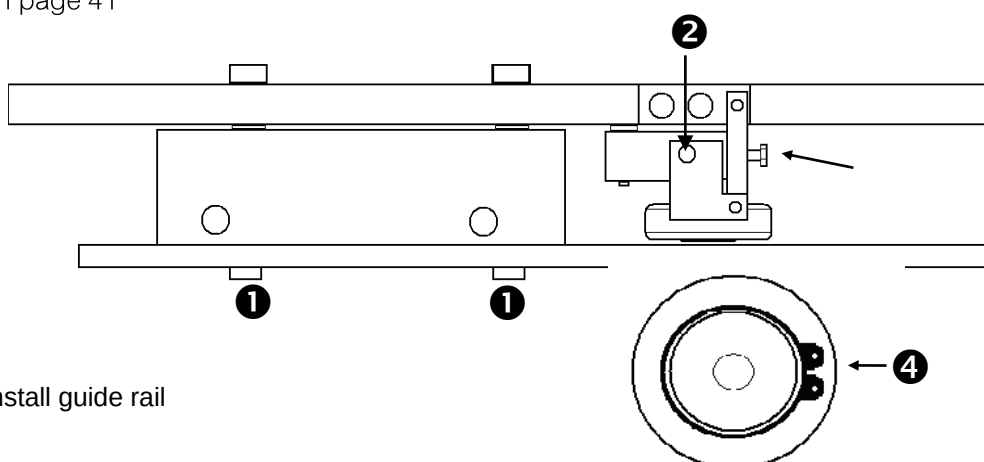
Maintenance Information

! Please use only genuine replacement parts

Replacing pressure roller

→ Switch off machine and DISCONNECT POWER PLUG !

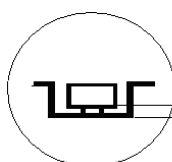
- Open housing
- Remove mounting screws **1** for upper guide rail and remove guide rail.
- Unscrew pressure adjustment screw **2** approx. 5 mm
- Loosen mounting screw **3** and pull pressure roller completely out of holder
- Detach snap ring **4** and remove pressure roller
- Install new pressure roller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



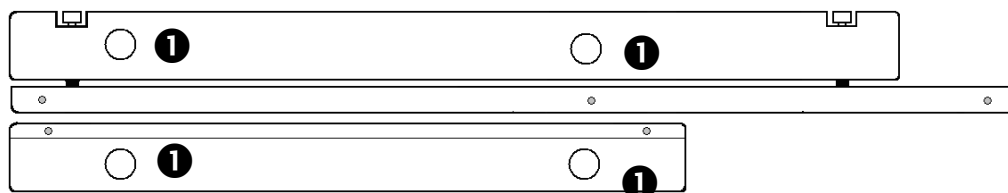
- Install guide rail



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



Distance between screw head and rail = 1mm



- Close housing

4.8 Process parameters adjustment

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

4.8.1 Temperature control



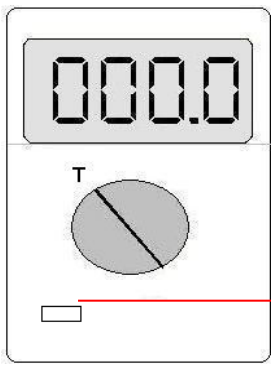
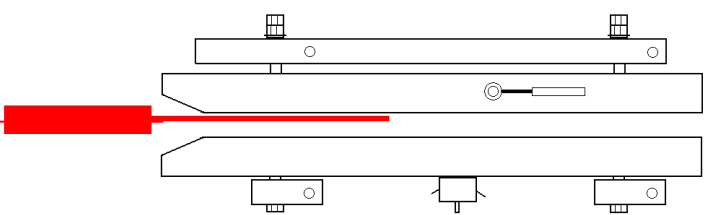
The temperature control adjustment should always be carried out after replacing a heating element, after replacing the temperature sensor and after replacing the temperature control

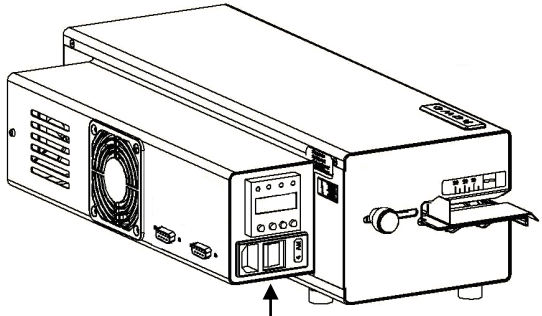
The temperatures **120 °C and 200 °C** are measured consecutively and the difference between set and actual value corrected.

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

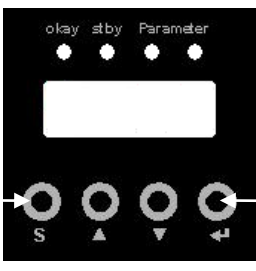
Insert the temperature sensor of a temperature measuring machine from the inflow side on the left, between the sealing units

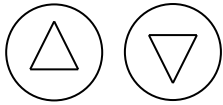


Power Switch

Press both buttons simultaneously and switch on the machine.



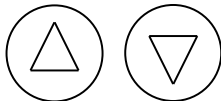
Select temperature adjustment



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

After reaching that temperature the stabilizing time starts

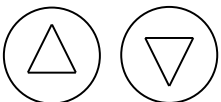
After expiry of that time input the temperature measured with the measuring device



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



120

120

120

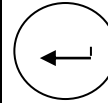
120

120

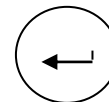
200

120

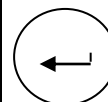
200



Confirm selection



Confirm input



Confirm input

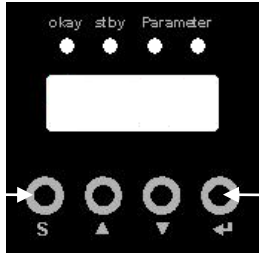
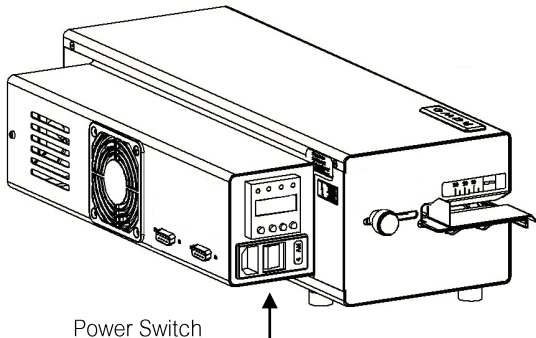
4.8.2 Motor monitoring configuration



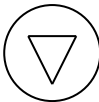
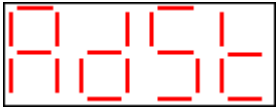
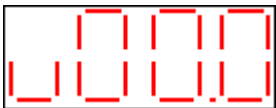
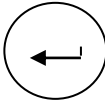
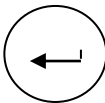
Motor monitoring configuration should always be done after replacing the temperature control, after replacing the motor and after replacing the tachogenerator

Only then is the motor monitoring active

Press both buttons simultaneously and switch on the machine

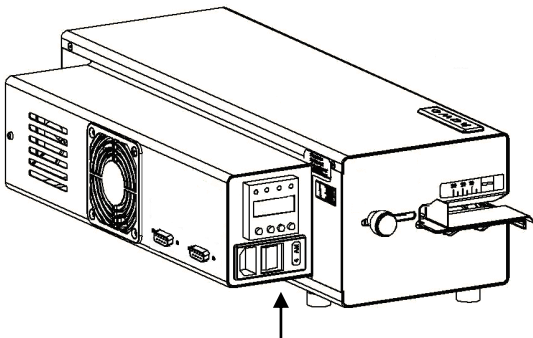
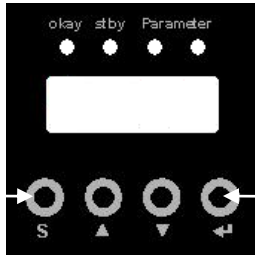



Power Switch

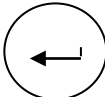
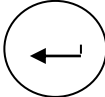
<p>Select motor monitoring configuration</p> <div style="display: flex; justify-content: space-around;">   </div> <p>Select motor power frequency</p> <div style="display: flex; justify-content: space-around;">   </div> <p>The motor is started and for 5s the measured sealing speed is displayed</p>	<div style="text-align: center;">   </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="width: 30%;"> <p>50Hz</p>  <p>60Hz</p>  </div> <div style="width: 65%;"> <p>Display motor hm 780 DC-V</p>  <p>Display motor hm 780 DC</p>  </div> </div>	<div style="text-align: center;">  <p>Confirm selection</p> </div> <div style="text-align: center; margin-top: 20px;">  <p>Confirm selection</p> </div>
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4.8.3 Setting the transmission rate (baud rate) of the serial interface

Press both buttons simultaneously and switch on the machine

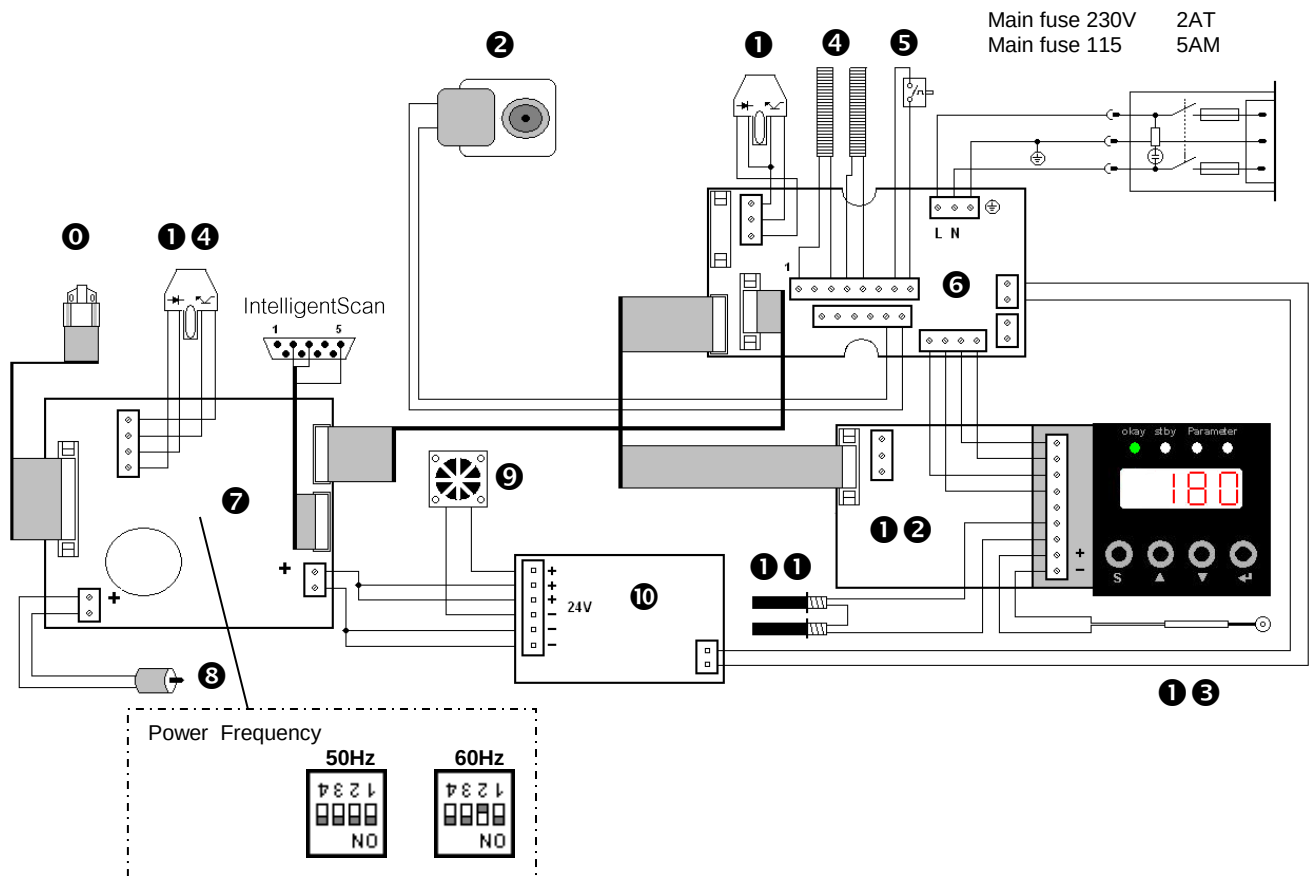



Power Switch

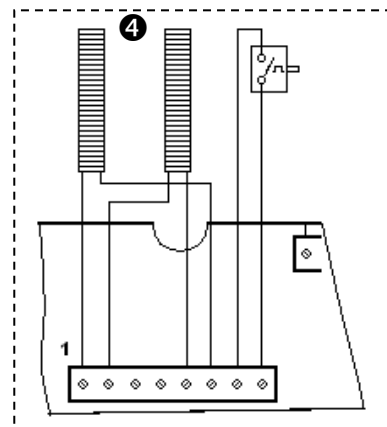
<p>Select baud rate setting</p> <div style="display: flex; justify-content: space-around;">   </div> <p>Select baud rate</p> <p>9600Bd – 57600Bd</p> <div style="display: flex; justify-content: space-around;">   </div>	  <p>Example: Baud rate 57600Bd</p> 	<div style="text-align: center; margin-bottom: 20px;">  <p>Confirm selection</p> </div> <div style="text-align: center;">  <p>Confirm selection</p> </div>
---	--	--

5 Technical Data

5.1 Circuit and Wiring Diagram



Heating elements connection at 115V



0	Print head	1.653.002
1	Light barrier motor	1.561.010
2	Gear motor 230V	1.212.026
	Gear motor 115V	1.212.027
3		
4	Heating cartridge	6.536.024
5	Temperature limit switch	6.564.018
6	SST Module	1.461.014
7	Printer control	1.461.013
8	Motor ink ribbon	1.212.012
9	Fan	6.212.028
10	Switched-mode power supply	6.533.001
11	Reed contact	6.543.011
12	Temperature control	6.564.042
13	Thermocouple	6.564.023
14	Light barrier printer	1.561.003

5.2 Specifications

Connection data

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

Mechanic

Dimension	Length Width Height	[mm]	560 250 145
Housing cover			Steel AISI 304
Housing bottom			Steel AISI 304
Weight		[kg]	14
Sealed edge infinitely adjustable		[mm]	0 – 35
Sealing seam width		[mm]	12 +/- 0,5
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 bar code scanner and PC	yes
Datea rate (Baudrate)	[Baud]	Bar Code Scanner 9600 PC 9600 - 57600
Protection class		1

Environmental parameter

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

6 Declarations of Conformity

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaración de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade	9.696.162C																																																						
Gültig ab: 23.11.2021 Valid from:	Seite 1/1 Version 1.01																																																							
<p>Hiermit erklären wir, dass die Folienschweissmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: 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:</p> <p style="text-align: center;">INNOQ SEAL 200</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: correspondent aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <table border="0"> <tr> <td>EG - Maschinenrichtlinie</td> <td>2006/42/EG</td> <td></td> </tr> <tr> <td>Machinery directive</td> <td></td> <td></td> </tr> <tr> <td>Directive "CE" rel. aux machines</td> <td></td> <td></td> </tr> <tr> <td>Directiva de Maquinaria de la CE</td> <td></td> <td></td> </tr> <tr> <td>Direttiva CE sulle macchine nella versione</td> <td></td> <td></td> </tr> <tr> <td>Directiva da UE relativa a maquinaria</td> <td></td> <td></td> </tr> <tr> <td>EMV-Richtlinie</td> <td>EMC-directive</td> <td>2014/30/EU</td> </tr> <tr> <td>Directive CEM</td> <td>Directiva de CEM</td> <td></td> </tr> <tr> <td>Direttiva CEM</td> <td>Directiva CEM</td> <td></td> </tr> <tr> <td>WEEE-Richtlinie</td> <td>WEEE-directive</td> <td>2012/19/EU</td> </tr> <tr> <td>Directive WEEE</td> <td>Directiva da WEEE</td> <td></td> </tr> <tr> <td>Direttiva WEEE</td> <td>Directiva WEEE</td> <td></td> </tr> <tr> <td>RoHS-Richtlinie</td> <td>RoHS-directive</td> <td>2015/863/EU</td> </tr> <tr> <td>Directive RoHS</td> <td>Directiva de RoHS</td> <td></td> </tr> <tr> <td>Direttiva RoHS</td> <td>Directiva RoHS</td> <td></td> </tr> <tr> <td>Harmonisierte Normen</td> <td>Harmonized standards</td> <td>EN ISO 12100:2010 EN 60204-1:2018</td> </tr> <tr> <td>Standard harmonise</td> <td>Las normas armonizadas</td> <td>EN ISO 13857:2019 EN IEC 61000-6-1:2019</td> </tr> <tr> <td>Norme armonizzate</td> <td>Normas harmonizadas</td> <td>EN IEC 63000:2018 EN 61000-6-3:2007+A1:2011</td> </tr> </table> <p>Verantwortliche Person für die Technischen Unterlagen siehe unten Responsible person for technical documentation see below La personne responsable pour la documentation technique est mentionnée au-dessous</p>			EG - Maschinenrichtlinie	2006/42/EG		Machinery directive			Directive "CE" rel. aux machines			Directiva de Maquinaria de la CE			Direttiva CE sulle macchine nella versione			Directiva da UE relativa a maquinaria			EMV-Richtlinie	EMC-directive	2014/30/EU	Directive CEM	Directiva de CEM		Direttiva CEM	Directiva CEM		WEEE-Richtlinie	WEEE-directive	2012/19/EU	Directive WEEE	Directiva da WEEE		Direttiva WEEE	Directiva WEEE		RoHS-Richtlinie	RoHS-directive	2015/863/EU	Directive RoHS	Directiva de RoHS		Direttiva RoHS	Directiva RoHS		Harmonisierte Normen	Harmonized standards	EN ISO 12100:2010 EN 60204-1:2018	Standard harmonise	Las normas armonizadas	EN ISO 13857:2019 EN IEC 61000-6-1:2019	Norme armonizzate	Normas harmonizadas	EN IEC 63000:2018 EN 61000-6-3:2007+A1:2011
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<div style="text-align: center;">  hawa GmbH 74847 Obrigheim/Germany Torsten Ehrhardt T + 49 (0) 6261 / 9770-0 info@hawa.com Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany </div>																																																								
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9.910.007 Version 2.01



INNOQ SEAL 300
ROTARY SEALER
OPERATING INSTRUCTIONS



ENGLISH

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1 Introduction

1.1 Preface

First of all we would like to thank you for purchasing the sealing 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 (SBS¹).

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



Please read these operating instructions carefully before commissioning so that you are familiar with the capabilities of the 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.

The Medical Device Directive 93/42/EEC and Medical Device Regulation 2017/745 (MDR) is not applicable to sealing devices.

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 P242A12 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 Cleaning

Before cleaning, disconnect the mains plug from the socket and disconnect the device from the power supply with the plug.

Cleaning the machine "outside"

Clean the machine "outside" with a damp cloth for

Stainless steel suitable cleaning agent. Then allow the machine to dry well and/or dry it off well.

Disinfection

For optional disinfection, the machine can be cleaned with a damp cloth made of disinfectants suitable for stainless steel.

(For example, alcohol-based "isopropanol, spirit, etc.")

Do not allow water to enter the machine.

Attention! Never clean the machine wet!

2.2 Intended use

The device is intended only for commercial and industrial use, and must be used only for the intended purpose and with the following sealable materials.

SEALING MATERIALS

Sealable paper pouches in accordance with EN ISO 11607-1/EN 868-4	x
Sealable pouches and tubes in accordance with EN ISO 11607-1/EN 868-5 made of film and paper as per EN 868-3	x
Sealable pouches and tubes in accordance with ISO EN 11607-1/EN 868-5 made of film and uncoated materials made of polyolefins as per EN 868-9 (e.g. Tyvek ^{®1})	x ¹
Aluminium-laminate film	x ²
Sealable pouches and tubes in accordance with ISO 11606-1/EN 868-5 made of PP fleece or PP non-woven	x ²

NON-SEALABLE MATERIALS

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

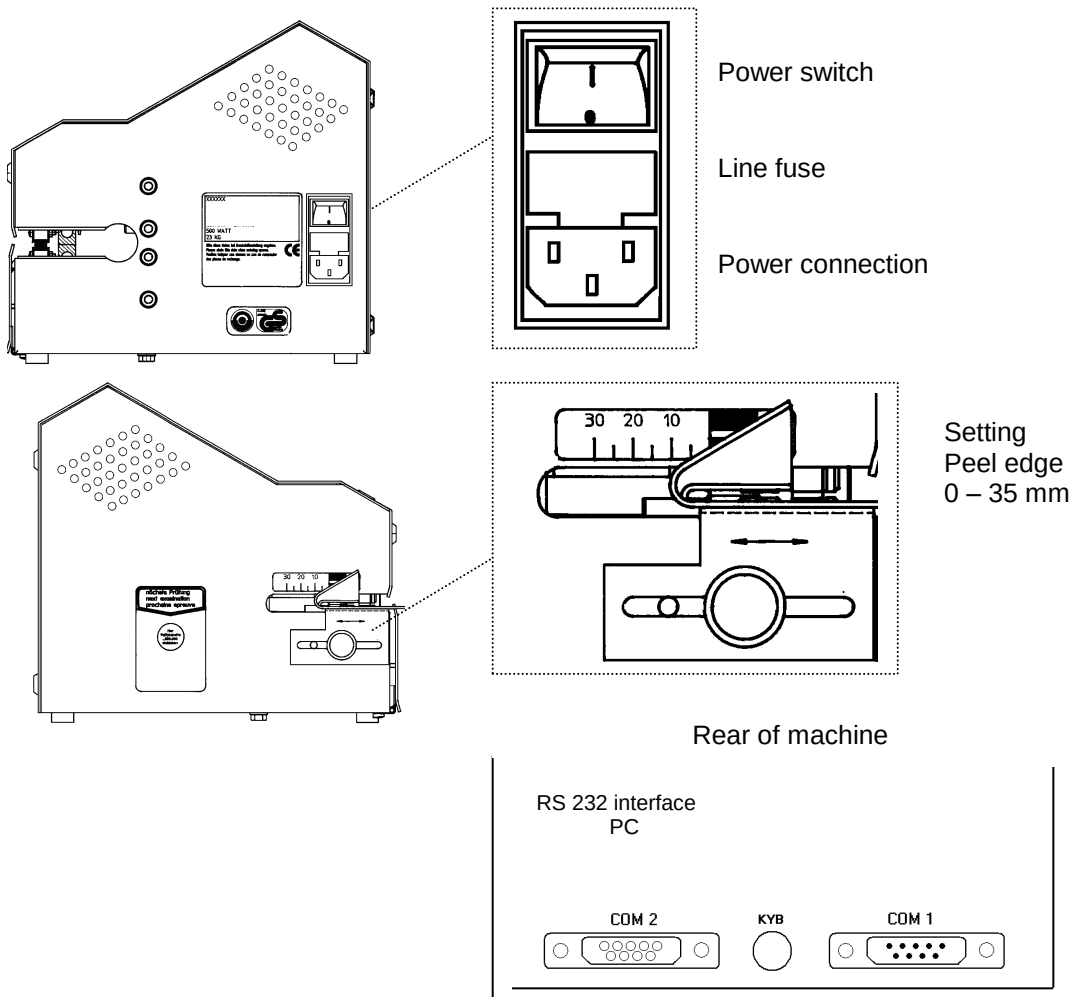
The correct sealing temperature for the packaging materials being used must be identified by means of test sealings (DIN 58953-7).

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

¹ Tyvek[®] is a registered trademark of E.I. du Pont Nemours.

² Release and / or test required

2.3 Design and functions



2.4 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).

2.5 Installation instructions and commissioning

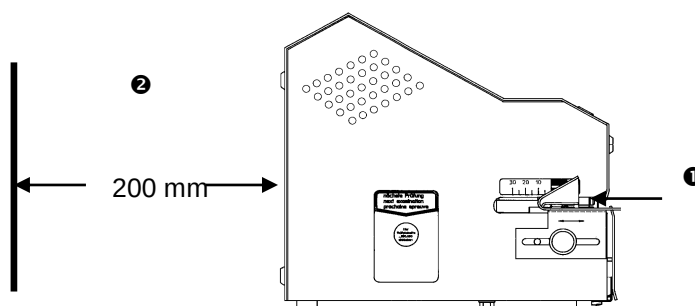


Prior to installation, read the safety instructions in chapter 1.4

2.5.1 Installation

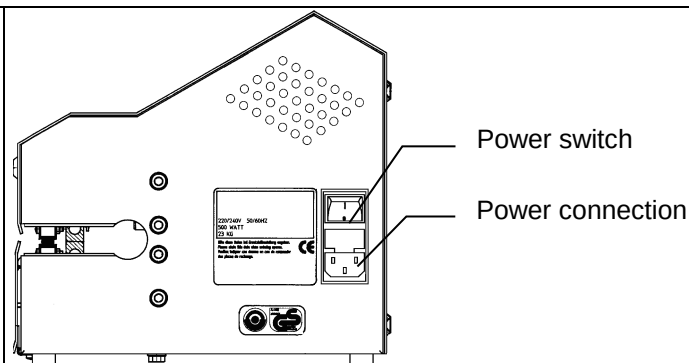
Place the machine on a horizontal surface.

- 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.



2.5.2 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

<p>Switch on machine Self-test runs for approx. 30s</p> <p>Default settings When the machine is switched on for the very first time, the following defaults must be undertaken:</p> <p>Language</p> <p>Unit of measurement</p> <p>Date and time</p> <p>Display for approx. 5 s Program version P242A06 Serial number 440001</p> <p>Display of</p> <table border="0"> <tr> <td>Date and time</td> <td>d,t</td> </tr> <tr> <td>Nominal temperature</td> <td>Tn</td> </tr> <tr> <td>Actual temperature</td> <td>Ta</td> </tr> </table> <p>The set nominal temperature is reached after about 3 - 4 min, and the machine is ready</p> <p>Maintenance note If this display appears, please refer to the maintenance notes on page 27</p>	Date and time	d,t	Nominal temperature	Tn	Actual temperature	Ta	<div style="text-align: right; border: 1px solid black; padding: 2px; margin-bottom: 10px;">hm 850 DC-V</div> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="text-align: center;"> <div>⬆</div> <div>⬇</div> </div> <div> <p>Language selection: D,GB,F,I,E,SF S,PL,CZ,TR</p> </div> <div style="text-align: right;"> <div>Language</div> <div>D</div> <div>OK</div> </div> </div> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-top: 10px;"> <div style="text-align: center;"> <div>⬆</div> <div>⬇</div> </div> <div> <p>EU Temperature [°C] Pressure applied [N] Throughput rate [m/min]</p> <p>US Temperature [°F] Pressure applied [lbf] Throughput rate [ft/min]</p> </div> <div style="text-align: right;"> <div>units of measure</div> <div>EU</div> <div>OK</div> </div> </div> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-top: 10px;"> <div style="text-align: center;"> <div>⬆</div> <div>⬇</div> </div> <div> <p>Change date or time</p> </div> <div style="text-align: right;"> <div>DD-MM-YY hh:mm</div> <div>18-02-10 14:43</div> <div>OK</div> </div> </div> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-top: 10px;"> <div></div> <div> <p>Control P242A06 440001</p> </div> <div style="text-align: right;"> <div>OK</div> </div> </div> <div style="text-align: center; margin-top: 20px;"> <div> <div>d</div> <div>↓</div> </div> <div> <div>t</div> <div>↓</div> </div> <div> <div>Ta</div> <div>↓</div> </div> </div> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 5px auto; width: 150px;"> 17-02-10 14:30 025 °C Nominal temp 180 °C </div> <div style="text-align: center; margin-top: 5px;"> <div>↑</div> <div>Tn</div> </div> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 5px auto; width: 150px;"> 17-02-10 14:30 180 °C </div> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-top: 20px;"> <div> <p>Pressing the OK button makes it possible to continue working with the machine</p> </div> <div style="text-align: right;"> <div>MAINTENANCE</div> <div>OK</div> </div> </div>
Date and time	d,t						
Nominal temperature	Tn						
Actual temperature	Ta						

3.2 Programming aids

Cursor control e.g. Press right arrow key once	<div> <div>  Cursor left </div> <div> Cursor right  </div> </div> <div> 1x  </div>	<div> <div> 100°C ▲ Cursor flashes in 1st position </div> <div> 100°C ▲ Cursor flashes in 2nd position </div> </div>
Change numbers and letters e.g. Press Position +1 key once	<div> <div>  Position +1 </div> <div> Position -1  </div> </div> <div> 1x  </div>	<div> <div> 100°C ▲ </div> <div> 110°C ▲ </div> </div>
Input is not activated, return to previous menu		
Input is activated		
Deletes character Batch counter to 0		

3.3 Data input

3.3.1 Sealing temperature entry

 <p>It is possible to enter 3 different sealing temperatures</p> <p>Temperature ranges</p> <p>1 80 - 220 °C / 302 - 428 °F</p> <p>2 80 - 220 °C / 302 - 428 °F</p> <p>3 80 - 220 °C / 302 - 428 °F</p>		1. Press key	nominal temp. 180°C +-5°C	
		2. Select temperature number for example Temperature 2	nominal temp. 180°C +-5°C	2 OK
				
		3. Enter temperature for example 135°C	nominal temp. 135°C +-5°C	2 OK
			17-02-10 14:43 135°C	

3.3.2 Expiry date entry

 <p>It is possible to enter 3 different dates</p> <p>Factory setting:</p> <p>1 = today's date + 1 month</p> <p>2 = today's date + 3 months</p> <p>3 = today's date + 6 months</p> <p> The date is printed automatically</p>		1. Press key	 17-03-10	
		2. Select date number for example Date 2	 17-05-10	2 OK
				
		3. Enter new date for example 17-04-10	DD-MM-YY 17-04-10	2 OK
			17-02-10 14:43 135°C  17-04-2010	

3.3.3 User name entry

 <p>It is possible to enter 20 alphanumerical characters</p> <p> The user name is printed automatically</p>		1. Press key		
		2. Enter name	 MILLER	OK
			17-02-10 14:43 135°C  MILLER	

3.3.4 Batch data entry

<div data-bbox="339 226 405 286" data-label="Text"> <div>LOT</div> <div>CHARGE</div> </div> <p>It is possible to enter 10 alphanumerical characters</p> <div data-bbox="188 421 252 454" data-label="Image"> </div> <p>The batch data is printed automatically</p>	<div data-bbox="587 226 652 286" data-label="Text"> <div>LOT</div> <div>CHARGE</div> </div> <ol style="list-style-type: none"> 1. Press key 2. Enter batch data <div data-bbox="587 315 659 383" data-label="Image"> </div> <div data-bbox="587 398 659 465" data-label="Image"> </div>	<div data-bbox="1082 248 1345 309" data-label="Text"> <div>LOT</div> </div> <div data-bbox="1082 338 1345 398" data-label="Text"> <div>LOT</div> <div>AB123</div> </div> <div data-bbox="1082 427 1345 488" data-label="Text"> <div>17-02-10 14:43 135 °C</div> <div>LOTAB123</div> </div> <div data-bbox="1385 338 1449 398" data-label="Text"> <div>OK</div> </div>
--	---	---

3.3.5 Set batch counter

<div data-bbox="339 604 405 665" data-label="Text"> <div>1.2.3.</div> <div>COUNT</div> </div> <p>7 numbers can be entered</p> <div data-bbox="188 763 252 797" data-label="Image"> </div> <p>The batch counter is printed automatically</p>	<div data-bbox="587 604 652 665" data-label="Text"> <div>1.2.3.</div> <div>COUNT</div> </div> <div data-bbox="687 604 751 665" data-label="Text"> <div>OK</div> </div> <ol style="list-style-type: none"> 1. Press keys one after another 2. Set batch counter, e.g. to 0001000 <div data-bbox="587 689 659 757" data-label="Image"> </div> <div data-bbox="587 772 659 840" data-label="Image"> </div>	<div data-bbox="1082 622 1345 683" data-label="Text"> <div>piece counter</div> </div> <div data-bbox="1082 712 1345 772" data-label="Text"> <div>piece counter</div> <div>0001000</div> </div> <div data-bbox="1082 801 1345 862" data-label="Text"> <div>17-02-10 14:43 135 °C</div> <div>0001000</div> </div> <div data-bbox="1385 712 1449 772" data-label="Text"> <div>OK</div> </div>
---	---	--

3.3.6 Set batch counter to zero

<div data-bbox="339 981 405 1041" data-label="Text"> <div>1.2.3.</div> <div>COUNT</div> </div> <div data-bbox="188 1176 252 1209" data-label="Image"> </div> <p>The batch counter is printed automatically</p>	<div data-bbox="587 981 652 1041" data-label="Text"> <div>1.2.3.</div> <div>COUNT</div> </div> <div data-bbox="659 981 751 1041" data-label="Text"> <div>→</div> <div>OK</div> </div> <div data-bbox="587 1070 659 1131" data-label="Text"> <div>c</div> </div> <ol style="list-style-type: none"> 1. Press keys one after another 2. Set batch counter to 0000000 	<div data-bbox="1082 1003 1345 1064" data-label="Text"> <div>piece counter</div> </div> <div data-bbox="1082 1093 1345 1153" data-label="Text"> <div>piece counter</div> <div>0000000</div> </div> <div data-bbox="1082 1182 1345 1243" data-label="Text"> <div>17-02-10 14:43 135 °C</div> <div>0000000</div> </div> <div data-bbox="1385 1093 1449 1153" data-label="Text"> <div>OK</div> </div>
--	--	--

3.3.7 CE information entry

<div data-bbox="288 1357 443 1429" data-label="Text"> <div>></div> <div>c</div> </div> <p>It is possible to enter 20 alphanumerical characters</p> <div data-bbox="188 1556 252 1590" data-label="Image"> </div> <p>The CE information is printed automatically</p>	<div data-bbox="587 1357 751 1429" data-label="Text"> <div>></div> <div>→</div> <div>c</div> </div> <ol style="list-style-type: none"> 1. Press keys one after another 2. Enter CE information <div data-bbox="587 1444 659 1512" data-label="Image"> </div> <div data-bbox="587 1527 659 1594" data-label="Image"> </div>	<div data-bbox="1082 1379 1345 1440" data-label="Text"> <div>CE- info</div> </div> <div data-bbox="1082 1469 1345 1529" data-label="Text"> <div>CE- info</div> <div>EN 294</div> </div> <div data-bbox="1082 1559 1345 1619" data-label="Text"> <div>17-02-10 14:43 135 °C</div> <div>CE EN 294</div> </div> <div data-bbox="1385 1469 1449 1529" data-label="Text"> <div>OK</div> </div>
--	---	---

3.3.8 Text entry

<div data-bbox="336 219 408 293" data-label="Image"> </div> <p>It is possible to enter 20 alphanumerical characters</p> <div data-bbox="188 427 245 456" data-label="Image"> </div> <p>The text is printed automatically</p>	<div data-bbox="587 219 659 293" data-label="Image"> </div> <p>1. Press key</p> <div data-bbox="587 309 659 383" data-label="Image"> </div> <p>2. Enter text</p> <div data-bbox="587 398 659 472" data-label="Image"> </div>	<div data-bbox="1082 237 1345 304" data-label="Text"> <p>text input</p> </div> <div data-bbox="1082 327 1345 394" data-label="Text"> <p>text input Text</p> </div> <div data-bbox="1082 416 1345 483" data-label="Text"> <p>17-02-10 14:43 135°C Text</p> </div> <div data-bbox="1382 327 1453 394" data-label="Text"> <p>OK</p> </div>
--	--	---

3.4 Operator logon, Machine settings

3.4.1 Display contrast

Press the keys one after another  → 	 Contrast ↑  Contrast ↓	<div>display - contrast</div> <div>OK</div>
---	--	---

3.4.2 Language selection

Press the keys one after another  →  1x 	 Language selection: D,GB,F,I,E,SF S,PL,CZ,TR 	<div>set language GB</div> <div>OK</div>
--	---	--

3.4.3 Indication of standard print data

Press the keys one after another  →  2x 	 Yes Indication for date, expiry, batch Operators are printed as a symbol acc. to EN 980	<div>pictogramm YES</div>  <div>OK</div>
	 No Identification for date, expiry, batch. Operators are printed as text	<div>pictogramm NO</div> <div>OK</div>

3.4.4 Selection of unit of dimension

Press the keys one after another  →  3x 	 EU Temperature [°C] Pressure applied [N] Throughput rate [m/min]	<div>unit of measure EU</div> <div>OK</div>
	 US Temperature [°F] Pressure applied [lbf] Throughput rate [ft/min]	<div>unit of measure US</div> <div>OK</div>

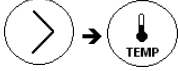
3.4.5 Selection of date format

Press the keys one after another  → 	 Selection of date format: 	<div>format date & time DD-MM-YYYY</div> <div>OK</div>
	1 dd-mm-yyyy 2 mm-dd-yyyy 3 yyyy-mm 4 mm-yyyy 5 yyyy 6 yyyy-mm-dd	<div>OK</div>

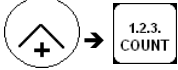
3.4.6 Change of date or time

<p>Press the keys one after another</p> 	<p>Change date or time</p>  	<div style="border: 1px solid black; padding: 5px;"> DD-MM-YY hh:mm 18 -02-10 14:43 </div> 
---	--	---

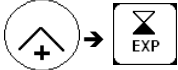
3.4.7 Sealing temperature switch-off tolerance entry

<p>Press the keys one after another</p>  <p>Allocation of a temperature tolerance limit which, if violated, results in the motor being stopped automatically.</p> <p>Range $\pm 2^{\circ}\text{C}$ to $\pm 5^{\circ}\text{C}$ Factory setting $\pm 5^{\circ}\text{C}$</p>		<p>1. Select temperature number for example Temperature 2</p>	<div style="border: 1px solid black; padding: 5px;"> tolerance limit 180°C $\pm 5^{\circ}\text{C}$ </div>	
		<p>2. Enter tolerance limit for example $\pm 3^{\circ}$</p>	<div style="border: 1px solid black; padding: 5px;"> Nominal temperature 135°C $\pm 5^{\circ}\text{C}$ 2 </div>	
		<p>tolerance limit</p>	<div style="border: 1px solid black; padding: 5px;"> 135°C $\pm 3^{\circ}\text{C}$ 2 </div>	
		<p>tolerance limit</p>	<div style="border: 1px solid black; padding: 5px;"> 135°C $\pm 3^{\circ}\text{C}$ 2 </div>	

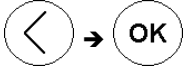
3.4.8 Display of absolute batch counter

<p>Press the keys one after another</p> 	<div style="border: 1px solid black; padding: 5px;"> absolute p. counter 0000020 </div> 
---	--

3.4.9 Display of operating hours

<p>Press the keys one after another</p> 	<div style="border: 1px solid black; padding: 5px;"> operating time 000010 h 38 min </div> 
---	---

3.4.10 Selection of sterilisation kind include SBS System

<p>Press the keys one after the other</p>  <p>IRRAD STEAM EO FORM VH2O2 DRY</p>	<p>Selection of sterilisation type</p>   <p>SSBS SSBS with PPI SSBS with PPO DSBS None</p>	<div style="border: 1px solid black; padding: 5px;"> Sterilisationsart IRRAD </div>  <p>Single SBS System Single SBS System with protective packaging inside Single SBS System with protective packaging outside Double SBS System</p>
--	--	--

3.5 Printer settings

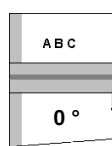
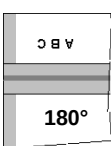
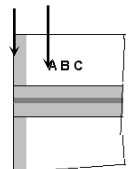
3.5.1 Print data

<p>The sequence of print data is set and cannot be changed</p> <p>The individual items of information are always printed in this sequence:</p> <p>Date of manufacture, time</p> <p>Expiry date</p> <p>Operator name</p> <p>Batch counter or</p> <p>Absolute batch counter</p> <p>Text</p> <p>CE information</p> <p>Machine number</p> <p>Batch data</p>	<p>For example, printout of sterilisation date, expiry date, personnel number</p> <div><div><div><div><div></div><div></div><div></div></div><div>17-02-2010</div><div></div><div>17-03-2010</div><div></div><div>Miller</div></div></div></div>																																								
<p>Date of manufacture</p> <p>Expiry date</p> <p>Batch data</p> <p>Operator name</p> <p>Batch counter</p> <p>Absolute batch counter</p> <p>Machine number</p> <p>Text</p> <p>CE information</p>	<table><tr><th colspan="2">Print</th><th colspan="2">Do not print</th></tr><tr><td><div><div><div></div><div>DAT</div></div></div></td><td><div>OK</div></td><td><div><div><div></div><div>18-02-10</div></div></div></td><td><div><div><div></div><div>DAT</div></div></div><div>DEL</div></td></tr><tr><td><div><div><div></div><div>EXP</div></div></div></td><td><div>OK</div></td><td><div><div><div></div><div>17-04-10</div></div></div></td><td><div><div><div></div><div>EXP</div></div></div><div>DEL</div></td></tr><tr><td><div><div><div></div><div>LOT</div><div>CHARGE</div></div></div></td><td><div>OK</div></td><td><div><div><div></div><div>AB123</div></div></div></td><td><div><div><div></div><div>LOT</div><div>CHARGE</div></div></div><div>DEL</div></td></tr><tr><td><div><div><div></div><div>PERS</div></div></div></td><td><div>OK</div></td><td><div><div><div></div><div>MILLER</div></div></div></td><td><div><div><div></div><div>PERS</div></div></div><div>DEL</div></td></tr><tr><td><div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div></td><td><div>2x</div><div>OK</div></td><td><div><div><div></div><div>piece counter</div><div>0000001</div></div></div></td><td><div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div><div>OK</div><div>DEL</div></td></tr><tr><td><div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div></td><td><div>1x</div><div><div><div></div><div>+</div></div></div><div>OK</div></td><td><div><div><div></div><div>absolute p. counter</div><div>0000020</div></div></div></td><td><div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div><div>DEL</div></td></tr><tr><td><div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div></td><td><div>2x</div><div><div><div></div><div>+</div></div></div><div>OK</div></td><td><div><div><div></div><div>serial number</div><div>440001</div></div></div></td><td><div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div><div>DEL</div></td></tr><tr><td><div><div><div></div><div>▽</div></div></div></td><td><div>OK</div></td><td><div><div><div></div><div>text input</div><div>Text</div></div></div></td><td><div><div><div></div><div>▽</div></div></div><div>DEL</div></td></tr><tr><td><div><div><div></div><div>c</div></div></div></td><td><div>OK</div></td><td><div><div><div></div><div>CE- info</div><div>EN 294</div></div></div></td><td><div><div><div></div><div>c</div></div></div><div>DEL</div></td></tr></table>	Print		Do not print		<div><div><div></div><div>DAT</div></div></div>	<div>OK</div>	<div><div><div></div><div>18-02-10</div></div></div>	<div><div><div></div><div>DAT</div></div></div> <div>DEL</div>	<div><div><div></div><div>EXP</div></div></div>	<div>OK</div>	<div><div><div></div><div>17-04-10</div></div></div>	<div><div><div></div><div>EXP</div></div></div> <div>DEL</div>	<div><div><div></div><div>LOT</div><div>CHARGE</div></div></div>	<div>OK</div>	<div><div><div></div><div>AB123</div></div></div>	<div><div><div></div><div>LOT</div><div>CHARGE</div></div></div> <div>DEL</div>	<div><div><div></div><div>PERS</div></div></div>	<div>OK</div>	<div><div><div></div><div>MILLER</div></div></div>	<div><div><div></div><div>PERS</div></div></div> <div>DEL</div>	<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div>	<div>2x</div> <div>OK</div>	<div><div><div></div><div>piece counter</div><div>0000001</div></div></div>	<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div> <div>OK</div> <div>DEL</div>	<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div>	<div>1x</div> <div><div><div></div><div>+</div></div></div> <div>OK</div>	<div><div><div></div><div>absolute p. counter</div><div>0000020</div></div></div>	<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div> <div>DEL</div>	<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div>	<div>2x</div> <div><div><div></div><div>+</div></div></div> <div>OK</div>	<div><div><div></div><div>serial number</div><div>440001</div></div></div>	<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div> <div>DEL</div>	<div><div><div></div><div>▽</div></div></div>	<div>OK</div>	<div><div><div></div><div>text input</div><div>Text</div></div></div>	<div><div><div></div><div>▽</div></div></div> <div>DEL</div>	<div><div><div></div><div>c</div></div></div>	<div>OK</div>	<div><div><div></div><div>CE- info</div><div>EN 294</div></div></div>	<div><div><div></div><div>c</div></div></div> <div>DEL</div>
Print		Do not print																																							
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<div><div><div></div><div>PERS</div></div></div>	<div>OK</div>	<div><div><div></div><div>MILLER</div></div></div>	<div><div><div></div><div>PERS</div></div></div> <div>DEL</div>																																						
<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div>	<div>2x</div> <div>OK</div>	<div><div><div></div><div>piece counter</div><div>0000001</div></div></div>	<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div> <div>OK</div> <div>DEL</div>																																						
<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div>	<div>1x</div> <div><div><div></div><div>+</div></div></div> <div>OK</div>	<div><div><div></div><div>absolute p. counter</div><div>0000020</div></div></div>	<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div> <div>DEL</div>																																						
<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div>	<div>2x</div> <div><div><div></div><div>+</div></div></div> <div>OK</div>	<div><div><div></div><div>serial number</div><div>440001</div></div></div>	<div><div><div></div><div>1.2.3.</div><div>COUNT</div></div></div> <div>DEL</div>																																						
<div><div><div></div><div>▽</div></div></div>	<div>OK</div>	<div><div><div></div><div>text input</div><div>Text</div></div></div>	<div><div><div></div><div>▽</div></div></div> <div>DEL</div>																																						
<div><div><div></div><div>c</div></div></div>	<div>OK</div>	<div><div><div></div><div>CE- info</div><div>EN 294</div></div></div>	<div><div><div></div><div>c</div></div></div> <div>DEL</div>																																						

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

<p>Activate settings Press the keys one after another</p> <p>    1x  </p>	
<p>Representation of print format</p>	<div>   <div>   </div> <div> <div>Printer config. YES</div> <div>Print format 0°</div> <div>OK</div> </div> </div>
<p>Margin adjustment Positioning of the print data on the package 0 –99 mm from the edge of the package</p>	<div>  <div>   </div> <div> <div>distance 02 0-99</div> <div>OK</div> </div> </div>
<p>Standard character size Printout of print data in 6 different widths</p>	<div> <div>   </div> <div> <div>character width 0 0-5</div> <div>OK</div> </div> </div>
<p>Character pitch 5 different pitches between the individual characters</p>	<div> <div>   </div> <div> <div>character distance 0 0-5</div> <div>OK</div> </div> </div>

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 $\frac{3}{4}$ full (DIN 58953-7). The limited filling prevents a load that is too large from being placed on the sealing seams.



The correct sealing temperature must be identified by means of 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

	Sealing temperature	Sealing time	Serial number
	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;">  16-12-2005 12:31h T: 150°C F: 100N t: 2.8s </div> <div style="text-align: right;">  Miller [402741] </div> </div>		
	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> <div style="text-align: right;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> </div>		
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	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> <div style="text-align: right;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> </div>		
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	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> <div style="text-align: right;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> </div>		
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	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> <div style="text-align: right;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> </div>		
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	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> <div style="text-align: right;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> </div>		
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	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> <div style="text-align: right;"> <div style="border-bottom: 2px solid black; width: 100%;"></div> </div> </div>		
	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> <div style="border-bottom: 2px solid black; width: 100%;"></div></div></div>		

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.*
Machine fails to heat up	Indicator card	Exchange indicator card*
	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.*
No transport	Heating cartridge	Check heating cartridges and replace if necessary*
	Control board	Replace control board*
	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
Uneven material feed or loud running noise	Motor	Replace motor*
	Control board	Replace control board*
	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	Increased temperature
	Contact pressure too low	Readjust pressure of the sealing roller or replace sealing roller*
	Sealing die - Distance between the sealing dies too large	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	Reprogram print start (see pg. 21)
	Ink ribbon	Ink ribbon not inserted properly Replace ink ribbon.(see pg. 31)
	Print head	Replace print head
	Control board	Replace control board*
Printing too faint	Ink ribbon	Replace ink ribbon
	Print head	Readjust print head
	Paper pressure roller	Adjust paper pressure roller
No keyboard function	Keyboard	- Check keyboard plug for contact - Renew keyboard
	Indicator card	Exchange indicator card*
	Control board	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

Sealing temperature out of tolerance	flashing →	<div data-bbox="986 353 1410 439"> 17-02-10 14:30 180 °C nominal temp. 186 °C </div>
	Possible cause Temperature sensor defective Control board defective	Remedy Replace temperature sensor* Replace control board*
Contact pressure out of tolerance	flashing →	<div data-bbox="986 633 1410 707"> 17-02-10 14:30 180°C contact pressure </div>
	Possible cause DMS module not calibrated DMS module defective Control board defective	Remedy Recalibrate DMS module* Replace DMS module* Replace control board*

4.3 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	 Pressing the OK button makes it possible to continue working with the machine	<div>MAINTENANCE</div> <div>OK</div>
Maintenance date reached		

4.4 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

4.5 Parts service

Please contact your local sales representative for further information.

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:

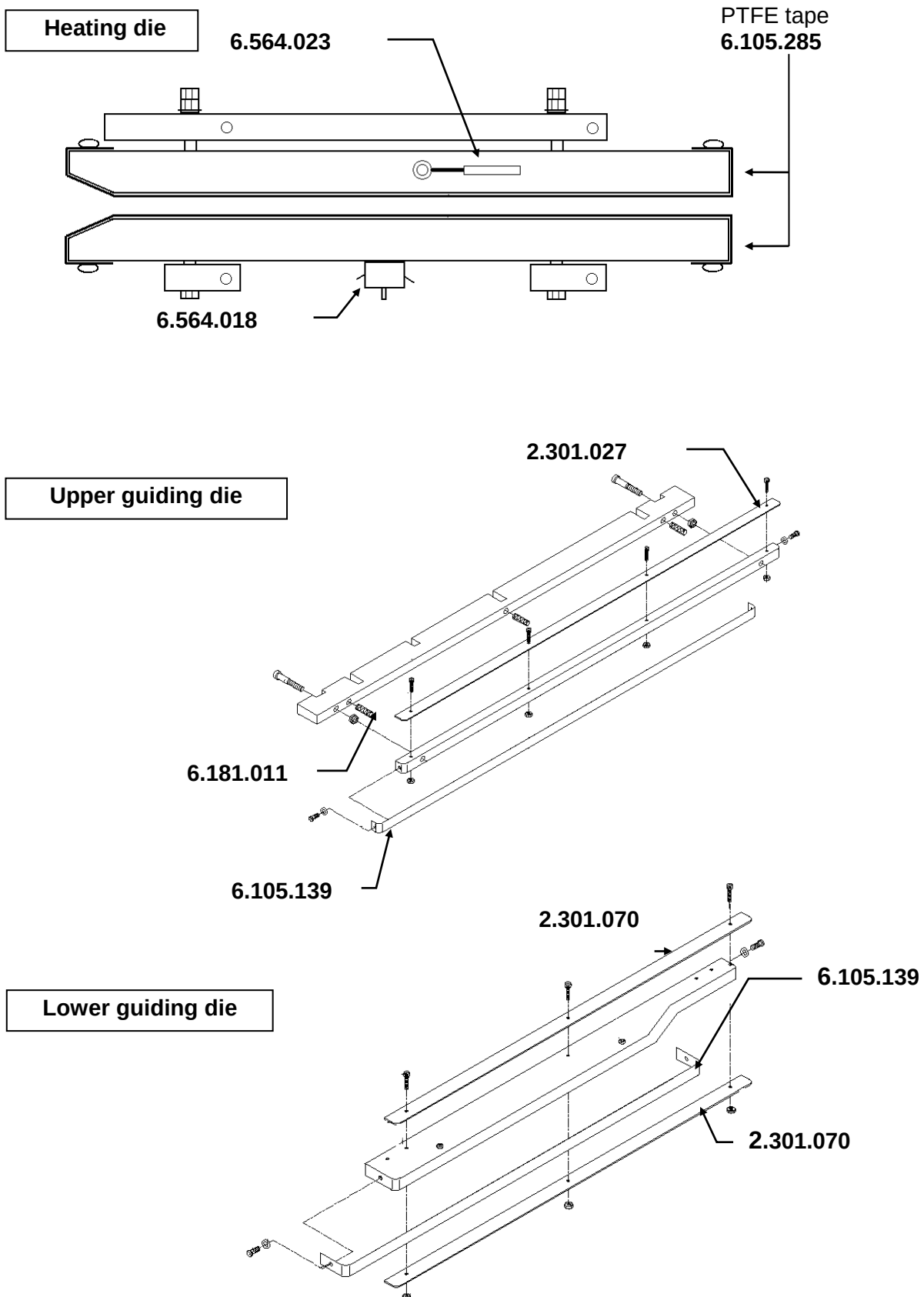
Sender:

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 _____

4.6 Replacement parts order – allocation of article numbers



4.7 Information about replacing wearing and spare parts

4.7.1 Replacing ink ribbon

➔ Switch off the machine

- Open front flap
- Press lever for ink ribbon holder ❶ down with left hand
- Press holder for ink ribbon cassette ❷ to side and remove cassette
- Insert new ink ribbon cassette

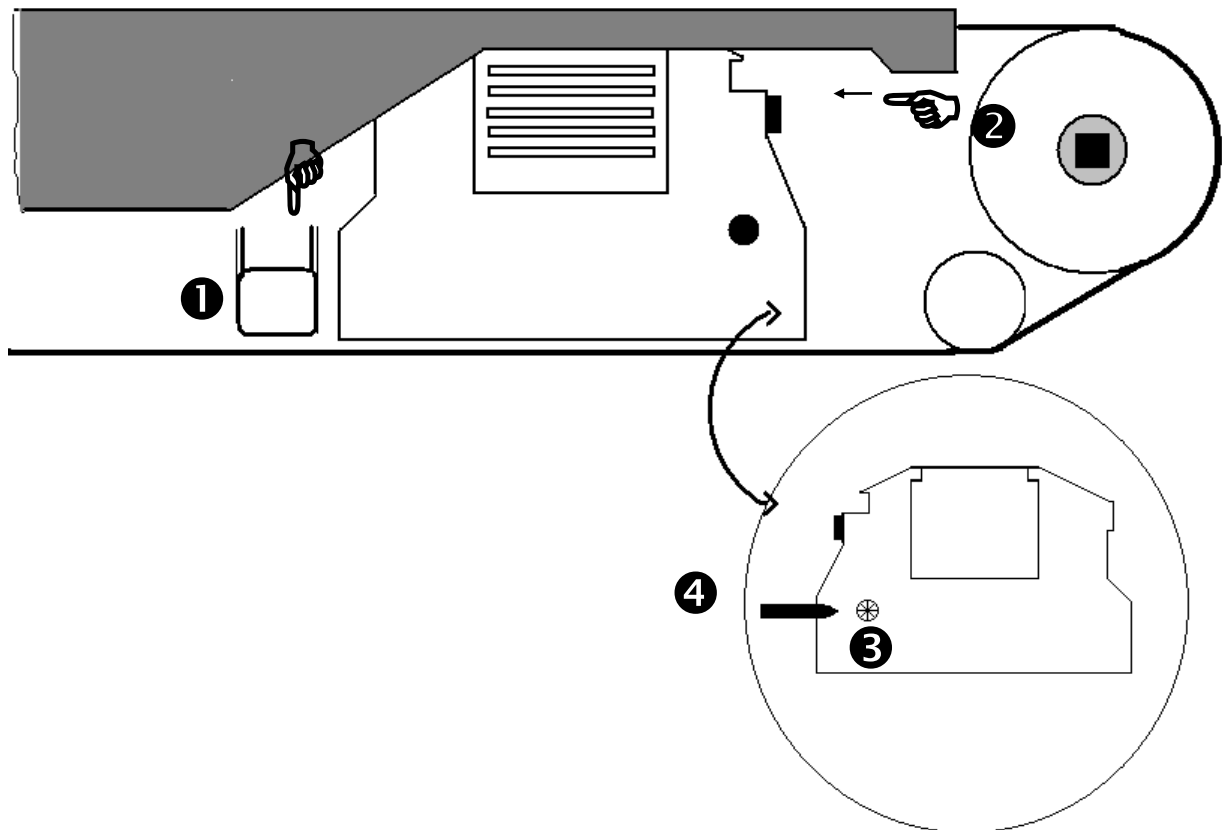
! Please use **only genuine replacement parts**



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**

4.7.2 Replacing PTFE strip on guide rail

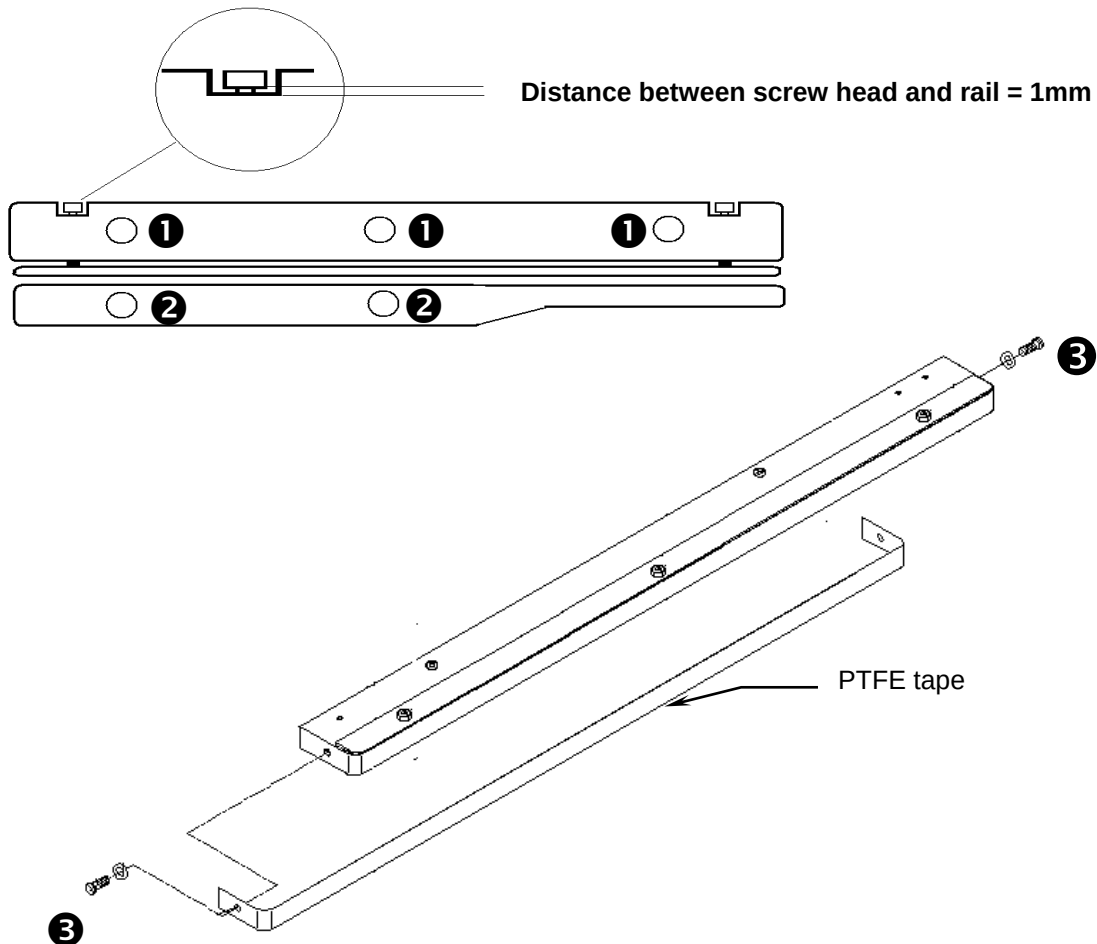
➔ Switch off machine and DISCONNECT POWER PLUG!

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



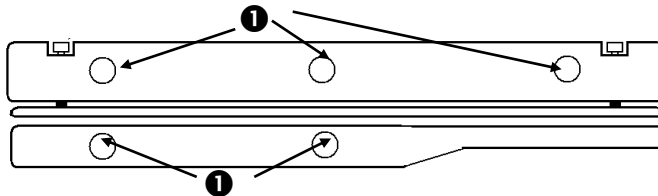
Maintenance information

! Please use **only genuine replacement par**

4.7.3 Replacing PTFE strip for upper and lower heating die

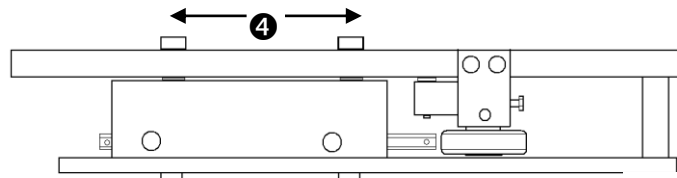
➔ Switch off machine and DISCONNECT POWER PLUG!

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

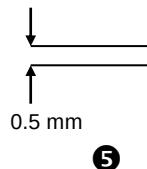


- Disconnect electrical connections for heating die
- Remove fastening screws ❷
- Remove top or bottom heating die
- Unscrew mounting screw ❸ and detach PTFE strip

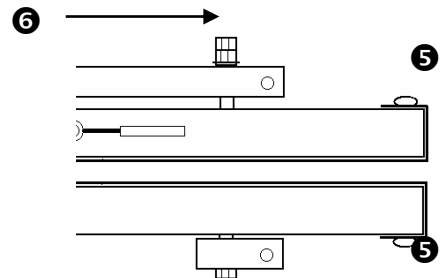
- Remove backing foil on new PTFE strip and glue new PTFE strip on straight and without wrinkles
- Fasten PTFE strip with screws ❹
- Install heating die
- Fasten fastening screws ❷ of the heating die
- Reconnect electrical connections to heating die



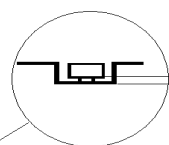
- Detach nuts ❺
- Set distance between the sealing dies to 0.5 mm
- Fasten nuts ❺



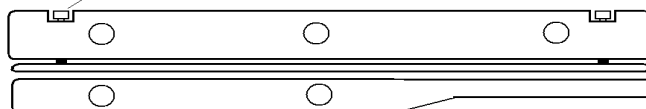
- Install guide rail.



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

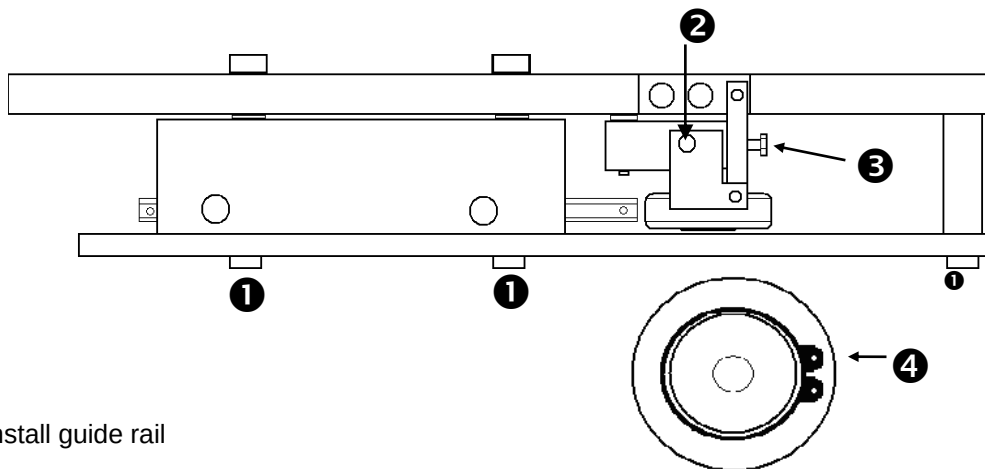
Maintenance information

! Please use **only genuine replacement parts**

4.7.4 Replacing pressure roller

➔ Switch off machine and DISCONNECT POWER PLUG!

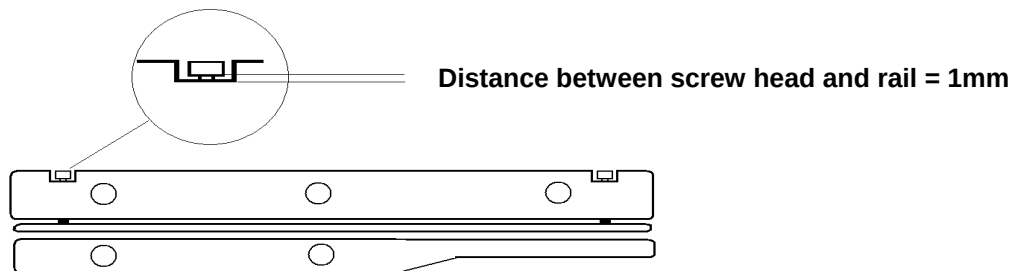
- Open housing
- Remove mounting screws **1** for upper guide rail and remove guide rail.
- Unscrew pressure adjustment screw **2** approx. 5 mm
- Loosen mounting screw **3** and pull pressure roller completely out of holder
- Detach snap ring **4** and remove pressure roller
- Install new pressure roller and fasten with snap ring **4**
- Insert pressure roller fully into holder, align centrally with the lower roller
- Tighten mounting screw **3**
- Adjust contact pressure by screwing in adjustment screw **2** according to calibration instructions on page 39



- Install guide rail



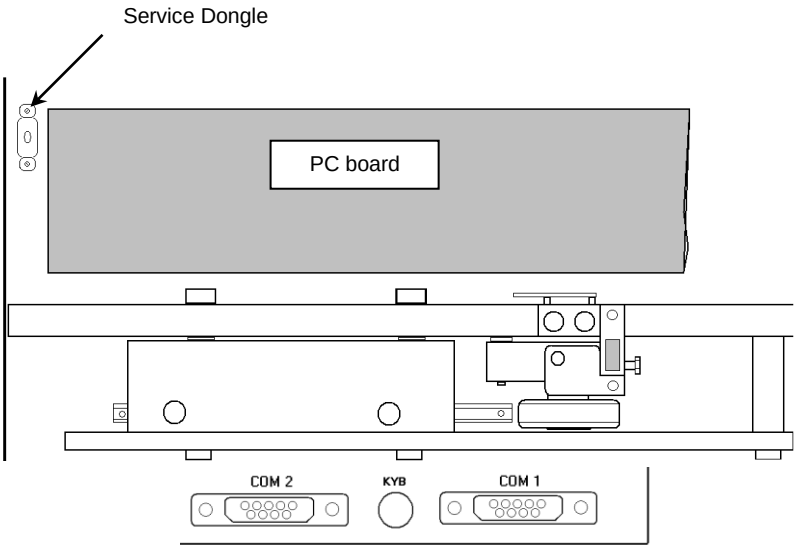
When installing the upper guide rail before fastening, push the die down so that the interval between the screw head and rail is 1mm on both sides. This ensures the correct contact pressure for the guide rail.



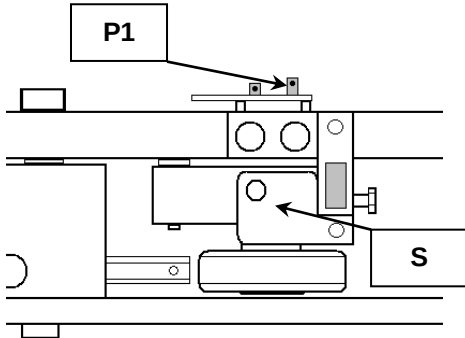
- Close housing

4.8 Service settings

4.8.1 Activate service menu

<ol style="list-style-type: none"> 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 	
	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> language GB </div>

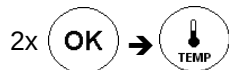
4.8.2 Adjusting contact pressure

<p>Press key after activating the Service menu</p> <div style="text-align: center; margin: 10px 0;">  </div> <ol style="list-style-type: none"> 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 	<div style="text-align: center; margin-bottom: 20px;">  </div> <div style="display: flex; flex-direction: column; align-items: center;"> <div style="margin-bottom: 10px;"> <div style="border: 1px solid black; padding: 2px 10px; margin-bottom: 5px;">M</div> <div style="text-align: center;">↓</div> <div style="border: 1px solid black; padding: 2px 10px;">contact pressure range: 00N</div> </div> <div style="margin-bottom: 10px;"> <div style="border: 1px solid black; padding: 2px 10px; margin-bottom: 5px;">M</div> <div style="text-align: center;">↓</div> <div style="border: 1px solid black; padding: 2px 10px;">contact pressure range: 05N</div> </div> <div style="margin-bottom: 10px;"> <div style="border: 1px solid black; padding: 2px 10px; margin-bottom: 5px;">M</div> <div style="text-align: center;">↓</div> <div style="border: 1px solid black; padding: 2px 10px;">contact pressure range: 100N</div> </div> <div style="margin-top: 10px; text-align: right;">  </div> </div>
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4.8.3 Adjusting temperature control

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

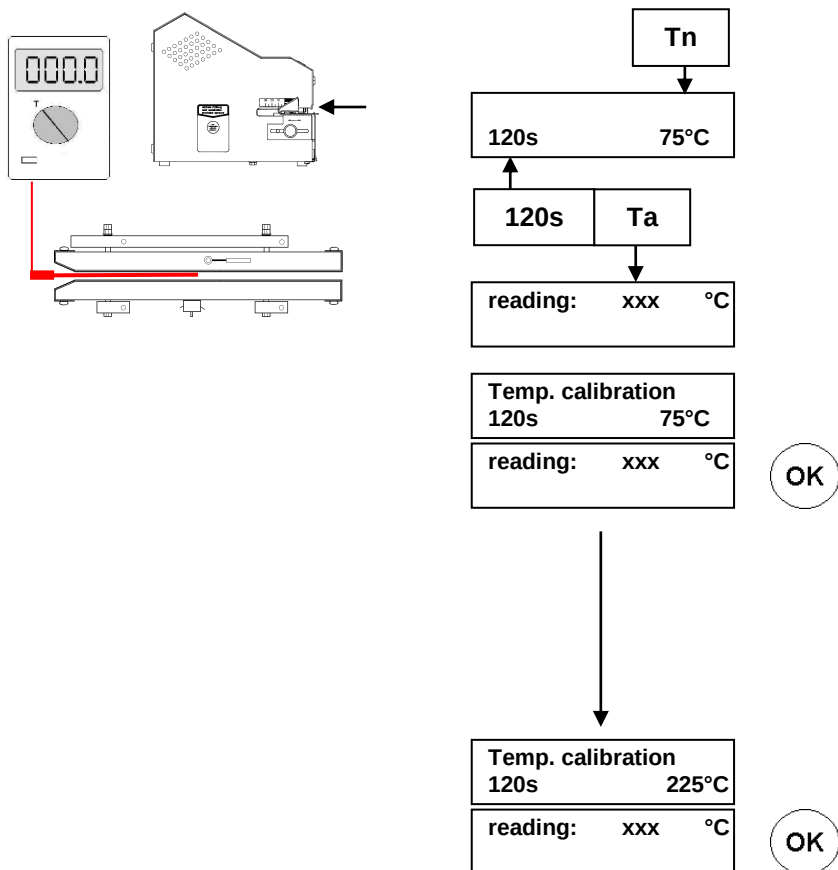
2. Activate the service menu and press the keys one after another



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

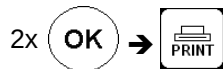
After a set temperature has been reached it is stabilized for 120s.

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



4.8.4 Setting the margin

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



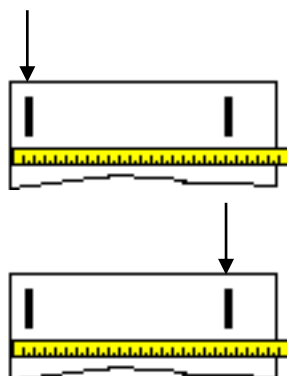
2. Insert package, dimension > 150 mm.

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



printer calibration
test print

printer calibration
test print

OK

printer calibration
distance 1 25mm

OK

printer calibration
distance 1 125mm

OK

4.8.5 Maintenance date entry

<p>1. Activate the service menu and press the keys one after another</p> <p>2x  → </p> <p>2. Enter date for the next maintenance reminder</p>	<div style="border: 1px solid black; padding: 5px; display: inline-block;">DD-MM-YY 12-11-10</div> <div style="margin-left: 20px;"></div>
---	--

4.8.6 Setting of the standby function

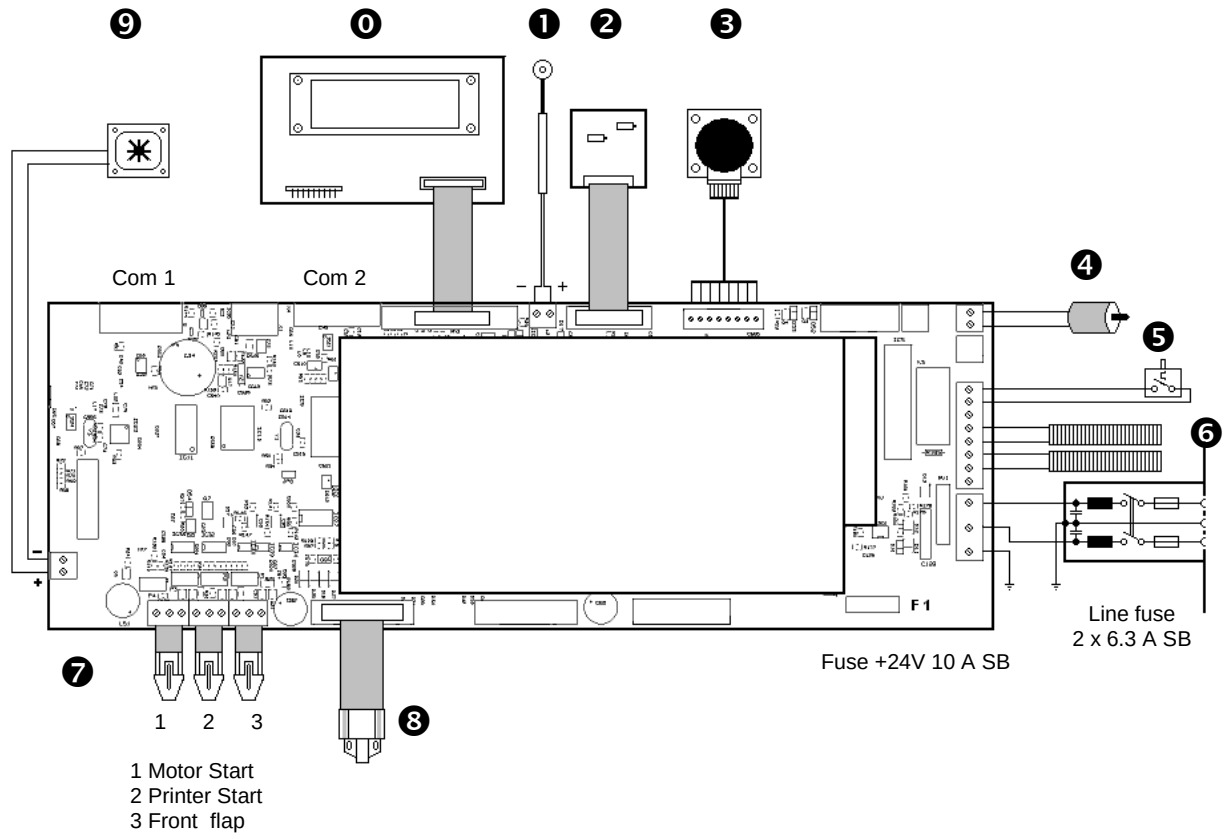
<p>1. Activate the service menu and press the keys one after another</p> <p>2x  → </p> <p>2. Enter the time for starting the standby function 0-120 min</p> <p>3. Activate or deactivate standby function</p>	<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 40%;"> <p> Yes If no sealings are performed, the set sealing temperature is reduced to 60°C after the entered time expires</p> <p> No Standby function not active</p> </div> <div style="width: 50%;"> <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-bottom: 10px;">stand by after 010 min</div> <div style="margin-left: 20px;"></div> <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-bottom: 10px;">stand by activate YES</div> <div style="margin-left: 20px;"></div> <div style="border: 1px solid black; padding: 5px; display: inline-block;">standby activate NO</div> <div style="margin-left: 20px;"></div> </div> </div>
---	---

4.8.7 Activation of default settings

<p>1. Activate the service menu and press the keys one after another</p> <p>2x  → </p> <p>2. Activate or deactivate default settings</p>	<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 40%;"> <p> 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</p> <p> No No default setting needs to be performed after the very first switch-on.</p> </div> <div style="width: 50%;"> <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-bottom: 10px;">very first time YES</div> <div style="margin-left: 20px;"></div> <div style="border: 1px solid black; padding: 5px; display: inline-block;">very first time NO</div> <div style="margin-left: 20px;"></div> </div> </div>
--	--

5 Technical data

5.1 Circuit diagram and wiring diagram



0	Indicator card	1.410.017
1	Temperature sensor	6.564.023
2	DMS module	1.410.018
3	Gear motor	1.212.011
4	Ink ribbon motor	1.212.012
5	Temperature switch	6.564.018
6	Heating cartridges 115V/200W	6.536.032
7	Optosensors	1.561.003
8	Print head	1.653.002
9	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	Length	[mm]	710
including infeed section	Width		260
	Height		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 +/-1
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		±10
Sealing speed	[%]	
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)		9.600
Serial interface PC		
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

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaración de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade	9.696.163C														
Gültig ab: 23.11.2021 Valid from:		Seite 1/1 Version 1.01														
<p>Hiermit erklären wir, daß die Folienschweissmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: 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:</p> <p style="text-align: center;">INNOQ SEAL 300</p> <p>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 disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <table border="0"> <tr> <td>EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle macchine nella versione Directiva da UE relativa a maquinaria</td> <td>2006/42/EG</td> </tr> <tr> <td>EMV-Richtlinie Directive CEM Direttiva CEM</td> <td>EMC-directive Directiva da CEM Directiva CEM</td> </tr> <tr> <td>WEEE-Richtlinie Directive WEEE Direttiva WEEE</td> <td>WEEE--directive Directiva da WEEE Directiva WEEE</td> </tr> <tr> <td>RoHS-Richtlinie Directive RoHS Direttiva RoHS</td> <td>RoHS-directive Directiva de RoHS Directiva RoHS</td> </tr> <tr> <td>Harmonisierte Normen Standard harmonise Norme armonizzate</td> <td>Harmonized standards Las normas armonizadas Normas harmonizadas</td> </tr> <tr> <td></td> <td>EN ISO 12100:2010 EN ISO 13857:2019 EN IEC 63000:2018</td> </tr> <tr> <td></td> <td>EN 60204-1:2018 EN IEC 61000-6-1:2019 EN 61000-6-3:2007+A1:2011</td> </tr> </table> <p>Verantwortliche Person für die Technischen Unterlagen siehe unten Responsible person for technical documentation see below La personne responsable pour la documentation technique est mentionnée au-dessous</p> <p style="text-align: center;">  hawa GmbH 74847 Obrigheim / Germany Torsten Ehrhardt Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany </p>			EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle macchine nella versione Directiva da UE relativa a maquinaria	2006/42/EG	EMV-Richtlinie Directive CEM Direttiva CEM	EMC-directive Directiva da CEM Directiva CEM	WEEE-Richtlinie Directive WEEE Direttiva WEEE	WEEE--directive Directiva da WEEE Directiva WEEE	RoHS-Richtlinie Directive RoHS Direttiva RoHS	RoHS-directive Directiva de RoHS Directiva RoHS	Harmonisierte Normen Standard harmonise Norme armonizzate	Harmonized standards Las normas armonizadas Normas harmonizadas		EN ISO 12100:2010 EN ISO 13857:2019 EN IEC 63000:2018		EN 60204-1:2018 EN IEC 61000-6-1:2019 EN 61000-6-3:2007+A1:2011
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hawa GmbH Obere Au 2-4 74847 Obrigheim / Germany	T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 9770-69 info@hawa.com www.hawa.com	Amtsgericht Mannheim: HRB 441011 Geschäftsführer: Christian Wolf Firmensitz: Obrigheim This document and the contents hereof are considered proprietary and confidential information of hawa and disclosure to unauthorized individuals or dissemination, publication, or copying is prohibited without prior written consent by hawa GmbH, 74847 Obrigheim, Germany.														

9.910.007 Version 2.01

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

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration de Conformité Declaración de conformidad Dichiarazione di conformità - Declaração de conformidade	9.696.163D
Gültig ab: 23.11.2021 Valid from:	Seite 1/1 Version 1.01	
<p>Hiermit erklären wir, daß die Folienschweissmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: 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:</p> <p style="text-align: center;">INNOQ SEAL 300</p> <p>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 disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>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)</p> <p>Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens Packaging for terminally sterilized medical 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 d'assemblage</p> <p>Sterilisation – Sterilgutversorgung – Teil 7: Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und –schläuchen Sterilization – Sterile supply – Part 7: Use of 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 stérilisation, de matériaux d'enveloppe en non-tissé, matériaux textiles tissés, de sacs en papier, de sachets et gaines scellables</p> </div> <div style="width: 45%;"> <p>KRINKO / BfArM Bundesgesundheitsblatt 2012 55:1244-1310</p> <p>ISO 11607-2:2019</p> <p>DIN 58953-7:2020</p> </div> </div> <div style="text-align: center; margin-top: 20px;">  hawa GmbH 74847 Obrigheim/Germany T + 49 (0) 6261 / 9770-0 info@hawa.com Torsten Ehrhardt Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany </div>		
hawa GmbH Obere Au 2-4 74847 Obrigheim / Germany	T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 9770-69 info@hawa.com www.hawa.com	Amtsgericht Mannheim: HRB 441011 Geschäftsführer: Christian Wolf Firmensitz: Obrigheim
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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 $\pm 5\text{ °C}$ ($\pm 9\text{ °F}$) according to DIN 58953-7.

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

Transparent packages according to EN 868-5:	170 – 190 °C
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)



INNOQ SEAL 400 ROTARY SEALER OPERATING INSTRUCTIONS

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1 Introduction

1.1 Preface

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

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

The sealing device is a microprocessor controlled rotary sealer with a printer for packaging sealable transparent pouches and reels (SBS = sterile barrier system).

The sealing device meets the requirements of DIN 58953-7, DIN EN ISO 11607-2 and the resulting DGSV (German Society for Sterile Supply) guideline for validating the sealing process.



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



Always keep these instructions close to the device.

1.2 Important notice



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

The Medical Device Directive 93/42/EEC and Medical Device Regulation 2017/745 (MDR) is not applicable to sealing devices.

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.

Note

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

These operating instructions apply to products from software version OS 5.00.07 onwards

1.3 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.
	A hand symbol indicates important information.
	Select function
	Press the button
	Press and hold down the button
	Press the button several times
	Select data by swiping up or down

1.4 Safety instructions



Our products are in a flawless condition in terms of safety technology when they leave the plant.

To maintain this condition, the contents of these safety instructions as well as type plates, labelling and safety instructions attached to the device must be observed while handling the device (transport, storage, installation, commissioning, operation and maintenance).

This device is suitable for processing laminated films in the heat-sealing process. See also chapter 1.6 "Intended use".

Please check the packaging, and lodge a complaint for any damage with the carrier or parcel service immediately, before installing the device.

Before commissioning, ensure that the device does not show any evidence of damage. In case of doubt, contact the manufacturer or a service partner authorised by the manufacturer.

Do not operate the device if the power cable or the power plug is damaged. Do not use the device if it does not operate correctly or it is damaged in any way. If the mains cable or the device have been damaged, the device must be repaired by the manufacturer or by one of the manufacturer's authorised service partners.

The device must be connected using the mains cable included in the scope of delivery to a protective contact socket with a stable voltage. Operation on IT networks is not permitted.

Place the device on a stable base.

The device must not be installed or operated in potentially explosive areas.

If the sealing device is brought directly from a cold environment into a warm environment, condensation may form. Wait until temperature equalisation has taken place.

Repairs and the replacement of spare parts must be performed only by the manufacturer or by one of the manufacturer's authorised service partners.

Switch off the device when it is not in use, or remove the power plug from the socket.



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

Do not insert items into the louvres of the device. You might receive an electric shock or the device could be damaged.

Do not use the device if you have any doubts about its safety.

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

The device must not be operated unsupervised.

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



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



The device contains valuable materials that can be recycled and reused.
The device should therefore be disposed of at a public disposal facility near you.
The device has been labelled in accordance with Directive 2012/19/EU (WEEE) on waste electrical and electronic equipment.
This directive governs the return and recycling of scrap equipment within the EU.

1.5 Cleaning

Before cleaning, disconnect the mains plug from the socket and disconnect the device from the power supply with the plug.

Cleaning the machine "outside"

Clean the machine "outside" with a damp cloth for Stainless steel suitable cleaning agent.
Then dry it off well.

Disinfection

For optional disinfection, the machine can be cleaned with a damp cloth made of disinfectants suitable for stainless steel. After disinfection dry it off well.
(For example, alcohol-based "isopropanol, spirit, etc.")

Do not allow water to enter the machine.

Attention! Never clean the machine wet!

1.6 Intended use

The device is intended only for commercial and industrial use, and must be used only for the intended purpose and with the following sealable materials.

SEALING MATERIALS

Sealable paper pouches in accordance with EN ISO 11607-1/EN 868-4	x
Sealable pouches and tubes in accordance with EN ISO 11607-1/EN 868-5 made of film and paper as per EN 868-3	x
Sealable pouches and tubes in accordance with ISO EN 11607-1/EN 868-5 made of film and uncoated materials made of polyolefins as per EN 868-9 (e.g. Tyvek ^{®1})	x ¹
Aluminium-laminate film	x ²
Sealable pouches and tubes in accordance with ISO 11606-1/EN 868-5 made of PP fleece or PP non-woven	x ²

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 sealings (DIN 58953-7).

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

¹ Tyvek[®] is a registered trademark of E.I. du Pont Nemours.

² Release and / or test required

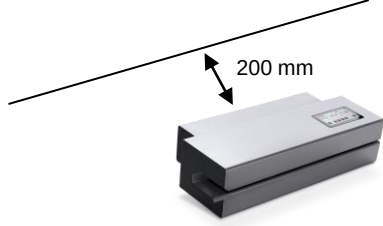
2 Commissioning

2.1 Commissioning the sealing device

2.1.1 Step 1 Inspection of the device

<p>After opening the packaging and the air-conditioning bag, check the device and its accessories for damage and completeness.</p>	<div> Sealing device  </div> <div> Power supply  </div> <div> Power cable (EU; US; UK)  </div> <div> Operating instructions </div> <div> Test report(s) </div> <div> Replacement ink ribbon </div>
--	---

2.1.2 Step 2 Setting up the device

<p>Set up the device on a flat surface and make sure that there is at least a 200 mm spacing between the device and the wall!</p>	
---	---

2.1.3 Step 3 Connect the device

Insert the 24V cable of the power supply **1** into the device

Connect the mains cable **2** to the power supply **3** and insert the mains plug **4** into the socket



Top keyway



2.1.4 Step 4

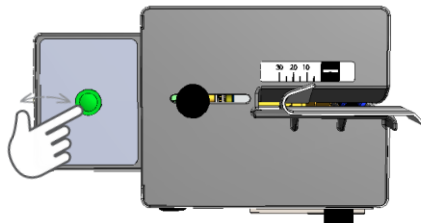
Switch on the device

Press the Power button

The colour changes from red to green.

The device operating system is loaded.

When the device is turned on for the first time, the date, time, date format and languages can be reset.

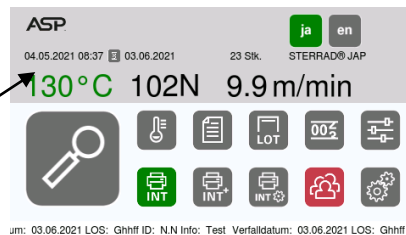
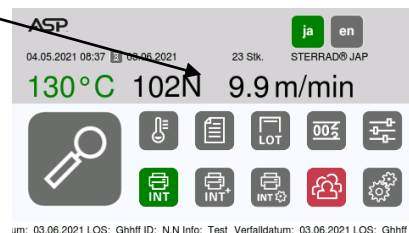


2.1.5 Step 5 Checking of the sealing parameter sensors

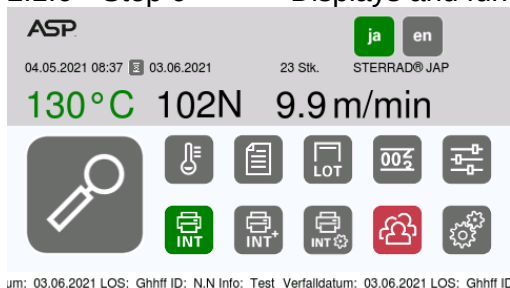
After switch-on, the device heats up to the default sealing temperature of 135°C. The process variables temperature, contact pressure and throughput speed are checked.

If their safe function is guaranteed, the main menu is displayed and the device heats up to the default set value. The heating process is also indicated by an alternating display of the temperature and information in the bottom line.

Once the sealing temperature has been reached, the device is ready for operation.

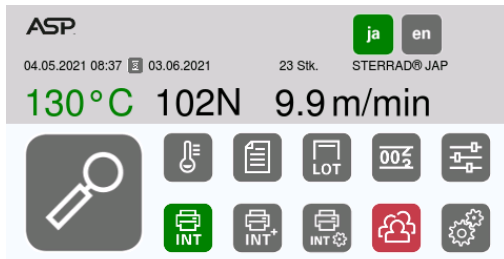


2.1.6 Step 6 Displays and functions of the main menu



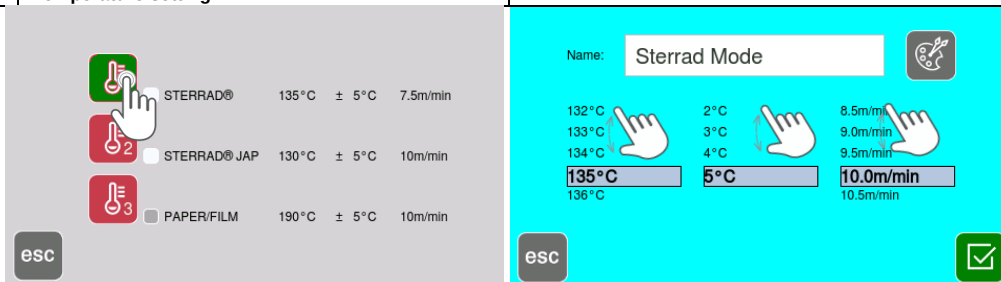
Symbol	Function	Note
130°C	Displays the current sealing temperature	
102 N	Displays the current pressing force	
9.9 m/min	Displays the current throughput speed	Value > 0 only when motor is running
	Settings	
	Control centre	Check of the functions heating, DMS module and motor as well as the device operating data and the mode change
	Display of the preselected languages	For better operation, the device can be switched to different languages using the three buttons during operation. A change is possible at any time via level 7 Settings / System configuration / Language . (See data input 3)
8 pcs.	Display of the absolute batch counter / the set quantity	

2.1.6.1 Main screen

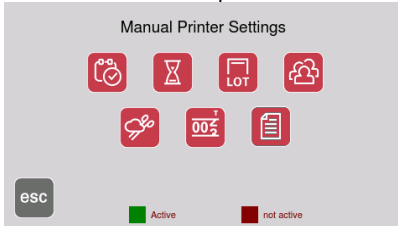
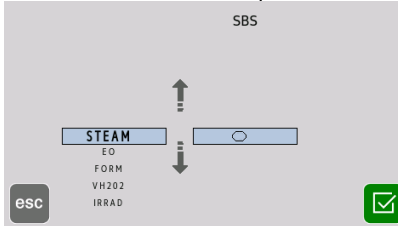


um: 03.06.2021 LOS: Ghff ID: N.N Info: Test Verfalldatum: 03.06.2021 LOS: Ghff IC

Symbol	Function	Note
	Seal Check	
	Temperature setting	Press and hold the one of the temperature setting buttons 1,2 or 3 and select the necessary process parameters.
	Temperature selected	One temperature must be selected
	Temperature not selected	
	Colour selection for the different temperatures Temperature setting	After every pressing of the button, the colour will change.



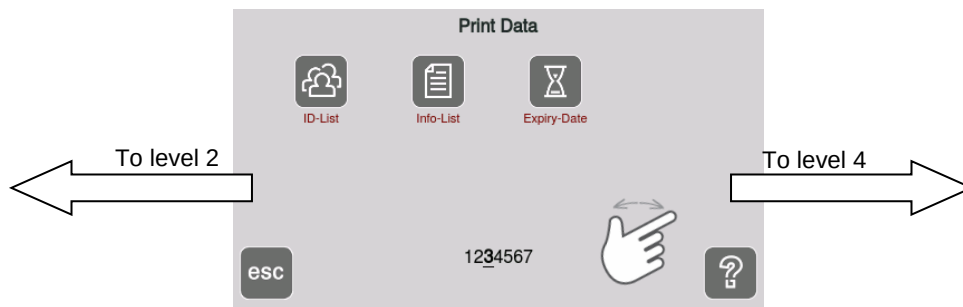
Symbol	Function	Note
	List with information	Device designations, department names
	List with batch data	Batch name, batch numbers The number is overwritten after each new entry
	Batch counter	Setting the batch counter for counting up/down
	Printer on / off	

Symbol	Function	Note
	Printer setting	Pre-select the desired print out information 
 	Print / not Print packaging date Internal Printer setting	
 	Print / not Print expiry date Internal Printer setting	Select expiry date as month or day for print out 
 	Print / not Print LOT number Internal Printer setting	
 	Print / not Print user name Internal Printer setting	
 	Print / not Print sterilisation kind Internal Printer setting	Select sterilisation kind for print out and SBS symbol 
 	Print / not Print piece counter Internal Printer setting	
 	Print / not Print list info Internal Printer setting	
	Accept	
	Abort	

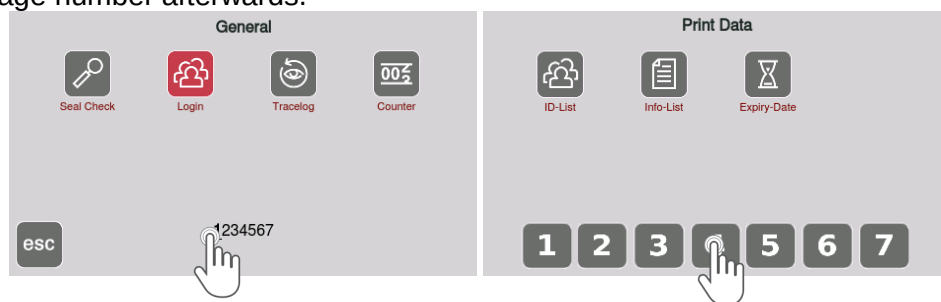
2.1.7 Step 7 Switch of the individual menu levels

→ Press the button settings in the start screen.

To switch to another menu level, swipe across the display in the desired direction.



Alternatively, a quick page change selection can be made by pressing the page numbers and the respective page number afterwards.

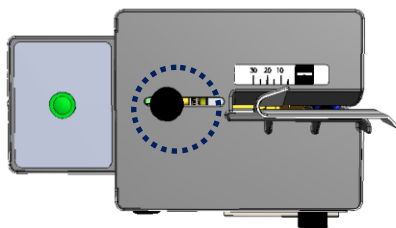


2.1.8 Step 8 The first sealing process

The default sealing temperature is 190°C and the throughput speed is 10 m/min. This ensures pouches and reels are sealed in accordance with EN 868-5 and EN ISO 11607-1.

The internal printer is "active" in delivery mode, but without print data.

-  The material to be sealed must be sealed according to the manufacturer's instructions. Sealable pouches and reels must only be filled to $\frac{3}{4}$ full (DIN 58953-7). The limited filling prevents too great a load being placed on the sealing seams.



Setting the peel edge

After releasing the locking device, the peel edge can be steplessly adjusted by between 0 mm and 35 mm by moving the infeed section.

-  A sufficient overhang must be present between the sealing seam and the reel interface on the extraction side (in accordance with DIN 58953-7 min. 10 mm).

The med. 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 med. package and leave briefly to cool.



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

2.1.9 The individual levels of the device

2.1.9.1 Level 1 General

Symbol	Function	Note
	Seal Check	Performing a routine test (see Chapter 2.2.1) SealCheck, InkTest or peel test
	Login	User login/logoff
	TraceLog	Recording of all process-related data, changes, errors and settings made during operation
	Batch counter	Setting the batch counter for counting up/down

2.1.9.2 Layer 2 Printer

Symbol	Function	Note
	printer settings	printer configuration

2.1.9.3 Level 3 Print data

Symbol	Function	Note
	Name list	Creating, editing and deleting users
	Info list	Creating, editing and deleting stored texts
	Expiry date	Setting the expiry date

2.1.9.4 Level 4 Standby

Symbol	Function	Note
	Standby	After the selected time, the device reduces the heat output and cools down to 80°C.
	User standby	After a selected time, a logged-in user is logged off automatically.

2.1.9.5 Level 5 Process monitoring

Symbol	Function	Note
	Test intervals	Setting different intervals for SealCheck, InkTest and peel test.
	DataMatic	Selection of individual DataMatic data Date, time, temperature, contact pressure, sealing speed, total batch counter and serial number are fixed values set by default.

2.1.9.6 Level 6 Advanced settings

Symbol	Function	Note
	Scanner	Assign the scanned data to other functions. The scanner data is assigned to the batch number by default (see Chapter 7.2.2).

2.1.9.7 Level 7 System settings

Symbol	Function	Note
	Date/time	Setting the current date and time
	Date formats	Changing date formats dd.mm.yyyy ● mm.dd.yyyy ● yyyy.mm ● mm.yyyy ● yyyy ● month.dd.yyyy
	Unit of measurement	Conversion of the units of measurement from si T[°C] ● F[N] ● v[m/min] fps T[°F] ● F[lbf] ● v[ft/min]
	Default	Resetting the device to default settings (Password-protected settings)
	Language	Setting the three languages that can be preselected via the start menu The printout of country-specific characters is only possible with a 24 stylus print head! (special equipment)
	IP	Password-protected menu level for setting the IP address
	Config.	password-protected menu for the service
	Update	Performing software updates via USB stick (for more details see technical data)

2.2 The sealing seam test

Testing of the process variables temperature, contact pressure and sealing time by means of the sealing seam test. This test should be performed and documented before and after the daily work process and/or before/after each lot (EN ISO 11607-2).

The sealing parameters are displayed during the tests.

Activating and starting the sealing seam test

1. If a user has been created in the name list, a user code must be entered before a test is carried out.
→ Otherwise this is not necessary.
2. Activate the sealing seam test
3. Select the type of sealing seam test
 - 3.1 Seal check
 Cannot be used for packages with a side fold!
Place the indicator strips inside the package.
 - 3.2 Ink test
Place the disposable cartridge inside the package
 - 3.3 Peel test
Cut out the test strips after sealing
4. Insert med. packaging, width min. 200 m.

This key is used to cancel the function

esc

um: 03.06.2021 LOS: Ghff ID: N.N Info: Test Verfalldatum: 03.06.2021 LOS: Ghff IC

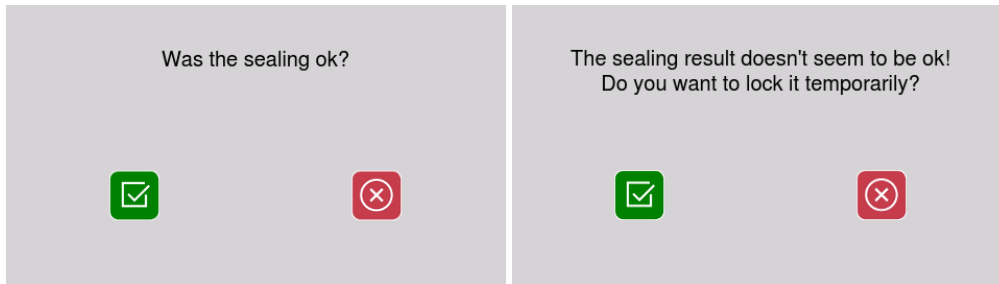
2.2.1 Blocked device due to failed seal check tests

As soon as a seal check has not been evaluated as passed after two tests, the device asks for a possible lock.

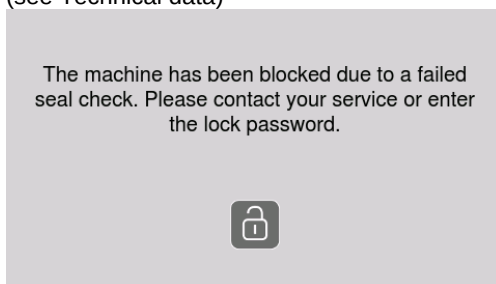
Seal check evaluation

Notification after two messages rated as not OK

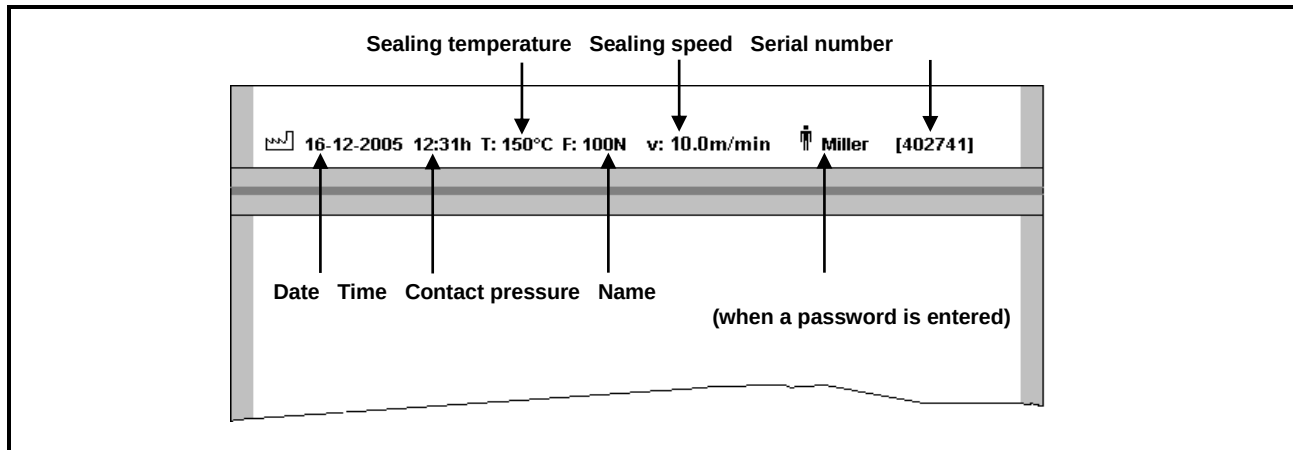
Seal check



If the screen has been locked due to a faulty seal check, it can be unlocked again by entering the lock password.
(see Technical data)



2.2.2 Printing of the test parameters on a package



3 Data Input

3.1 Creating data for different languages

When entering data, it should be noted that lists, names and all freely editable texts are only printed correctly after they have been created in the selected language and if the printer is activated.

The corresponding language in the start menu must also be selected.

This means that a text created in Japanese, for example, can only be printed correctly in a packing list if the language in the start screen has been changed to Japanese and the Japanese keyboard has been used to enter the text.

The same applies to all other languages.

3.2 The name list

The names and passwords of users who will be operating the device are entered into the user list. The users on the list can/must log in to the device before starting their task via the password entered into the list, i.e. they can also log out when their task is complete.

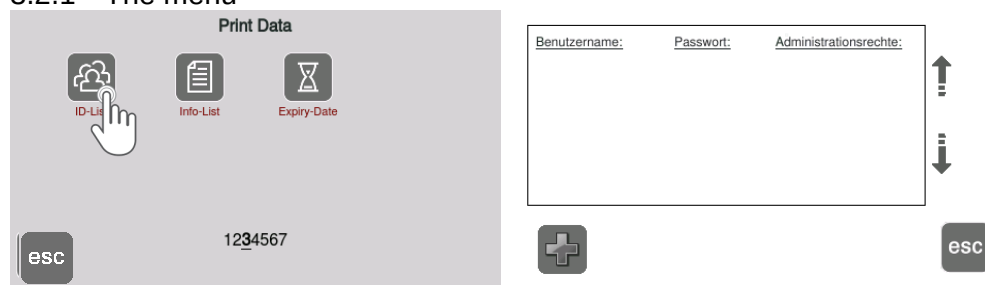
If the **User standby** function was activated in the **Settings menu**, the user is automatically logged out after a set time after which no sealing process has taken place.



A logged in user is automatically printed on the packaging when using the **"Test"** function.

It is possible to record the user name with each sealing process using the **DataMatic** function.

3.2.1 The menu



Key	Function	Note
	Delete an entry	Only visible when the user has already been created.
	Re-enter an entry	Length of name: max. 8 alphanumeric characters Length of a password: max. 5 digits Number of names: max. 50, individual entry or one after another
	Activate or deactivate administrator right	A so-called administrator right can be assigned to one or more users. This authorises him/her to block or release certain functions.
	Exit menu level	
	Edit created name	Only visible when the user has already been created.

3.2.3 Removing administrator rights

1. Select a name, e.g. "User"

2. Press the symbol to edit selected name.

3. Remove the administrator data and confirm by pressing the  key.

Administrator rights inactive



 it this menu level

Name:	Passwort:	Administrationsrechte:
User	12345	1

esc + + - [edit icon] [checkmark]

Name:	Passwort:	Administrationsrechte:
User	12345	

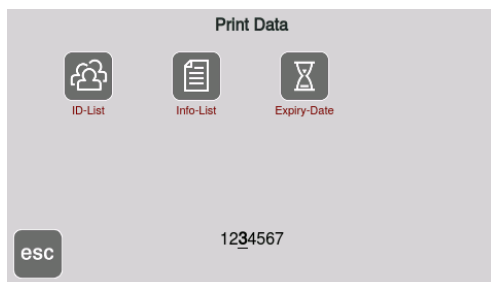
esc [checkmark]

Name:	Passwort:	Administrationsrechte:
User	12345	1

esc + + - [edit icon] [checkmark]

3.3 Data lists

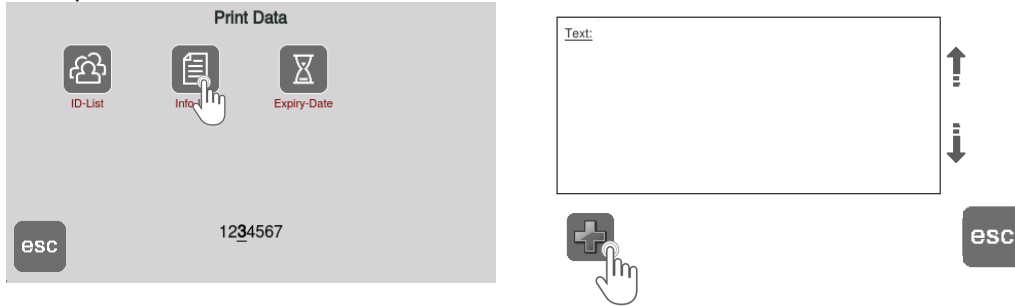
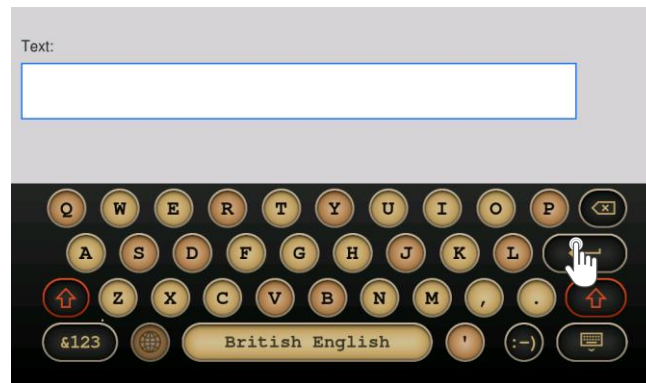
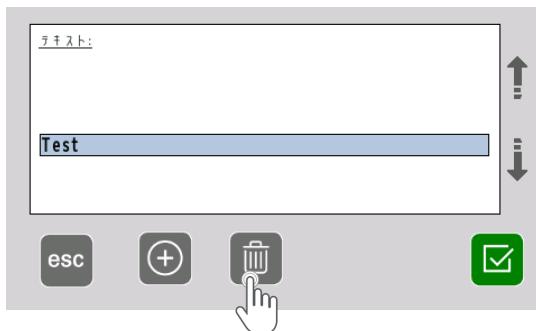
3.3.1 The selection menu



Key	Function	Example	Note
	List with names		Length of user data: Name: 20 alphanumeric characters Password: 5 numbers Number of user entries: 50, individual entry or one after another
	List with information	Device designations, department names	Length of list texts: 20 alphanumeric characters Number of list texts: 500, individual entry or one after another
	Selection of the expiry date		
	Exit menu level		

3.3.2 The Processing menu

Example of an information list



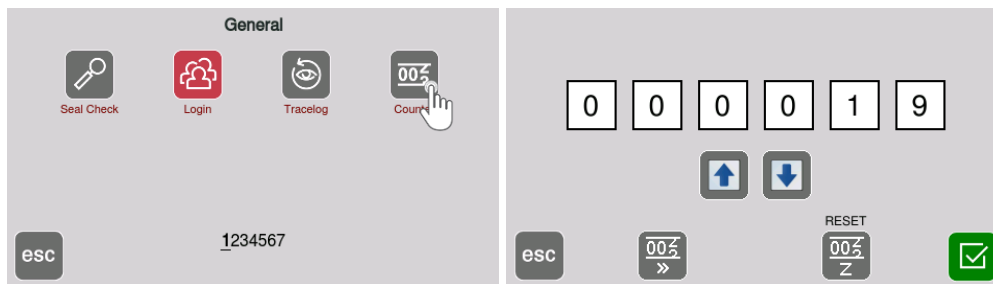
Key	Function
	Re-enter information
	Delete information
	Confirm/activate
	Exit menu level

4 Device configuration

4.1.1.1 Batch counter

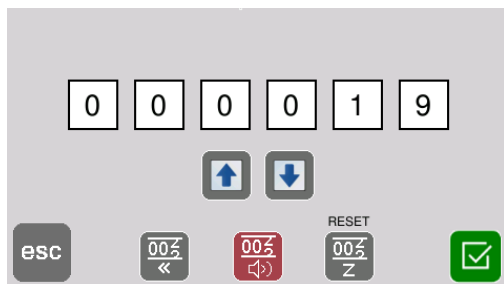
4.1.1.1.1 Batch counter functions

Counting forwards



Key	Function	Note
	0 0 0 0 1 9	Displays the current value
	Switches the counter to forwards counting	
	Sets the counter to 000000	
	Confirms the settings	

Counting backwards



Key	Function	Note
	0 0 0 0 1 9	Displays the current value
	0 0 0 0 1 0	Select the individual digits of the batch counter; the respective number is highlighted in blue and the desired quantity can be set using the ↑ and ↓ arrow keys (e.g.: 10 items)
	Switches the counter to backwards counting	
	Switch on, off signal tone after reaching the set batch counter	
	Confirms the settings	

5 Data recording

5.1 DataMatic

If any formatted USB stick is plugged into a free USB slot and the stick is detected, a message will appear on the display indicating that the DataMatic has been activated, if it is confirmed with "yes". If you confirm this prompt with "no", no data will be written to the USB stick. However, the activation can still be carried out later in the menu/DataMatic.

The data is written in *.csv format to the USB stick, and can be displayed in the device display, using a text editor such as the Windows Text Editor or Windows WordPad, or using a spreadsheet program such as Windows Excel.

If the DataMatic function is activated, a sealing process can only be started if a USB stick is also plugged in!

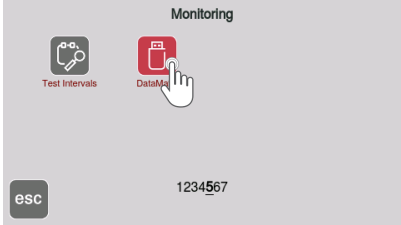
The DataMatic data are output automatically via the RS 232 and Ethernet interfaces with each seal, even if the USB stick is not plugged in!

5.1.1 Activating DataMatic

1. Insert a USB Stick into a free USB slot

2. After inserting the stick, you will be asked to activate DataMatic.

If this prompt is answered with "NO", DataMatic can also be activated later in the DataMatic menu .



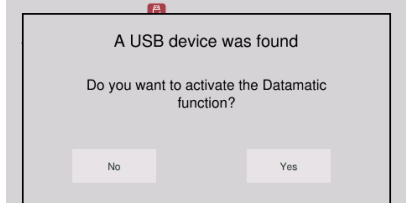
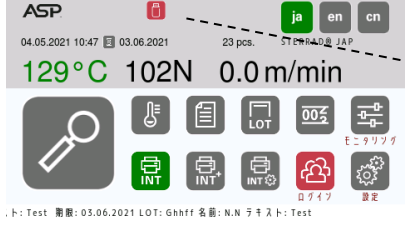


Inactive



Active after long pressing

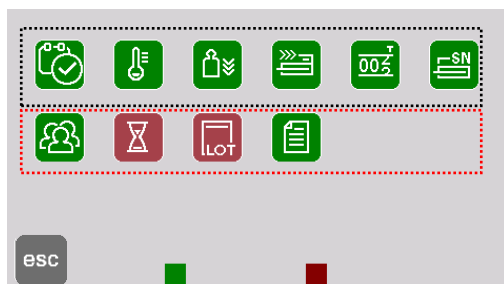
→ If DataMatic has been activated, a seal can only be started with the USB stick inserted.


5.1.2 Rebooting with „DataMatic“

Once the machine has been restarted, the USB stick must be unplugged once and then plugged in again for the DataMatic function to work properly. Otherwise the USB stick may not be recognised after the machine has been restarted and the data may not be recorded.

5.1.3 Configuring DataMatic data

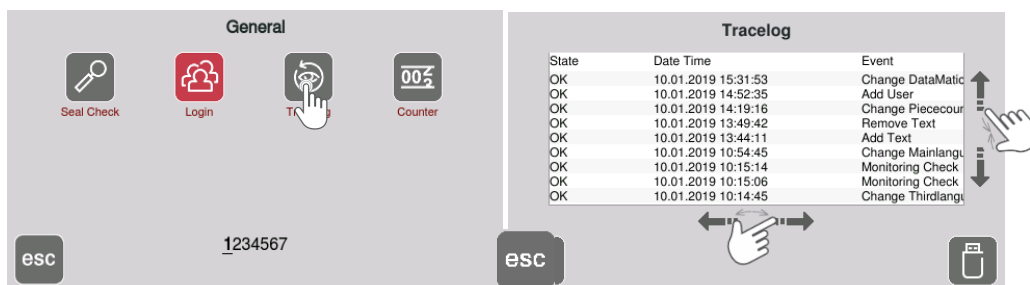


Keys	Data	Note
	Date and time Sealing temperature Contact pressure Throughput speed Unit counter TOTAL Device serial number	Fixed recording data
	Name Expiry date Batch number Info	Optional recording data

5.1.4 Show the DataMatic data on the device display

Only possible with a contacted USB stick containing recorded data!

5.1.4.1 The display menu

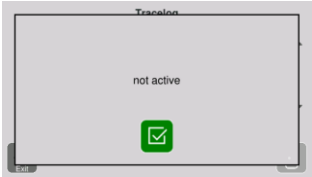


Key	Function	Display	Function
	Recorded TraceLog (logbook) data	10/01/2019	Date of the recording
	Scroll up and down	0 – 9	Data counter
	Scroll left and right		
	Exit menu level		
	Read the DataMatic data		

5.1.4.2 View the recordings on the USB stick

1. Activate the **TraceLog** menu

2. Activate the USB memory data view



Appears when there is no USB stick.



Confirm

3. Select the USB slot where the stick was inserted



Confirm

3. Select the year of the recordings, such as 2019

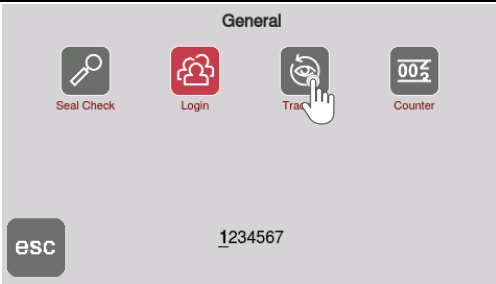
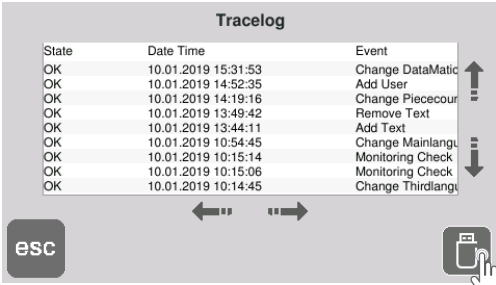
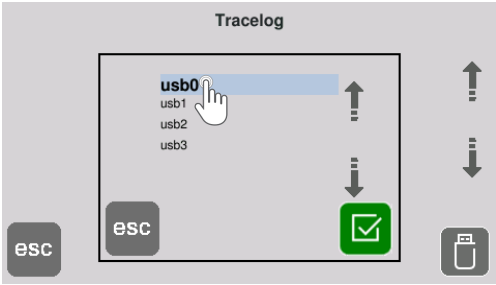
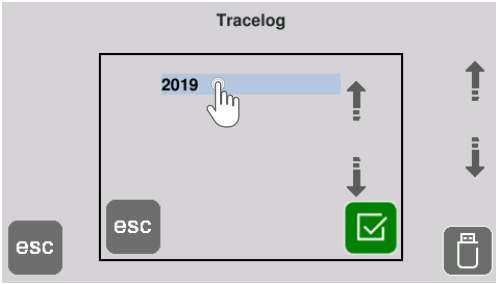
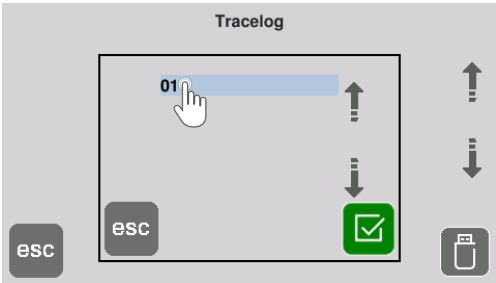


Confirm

4. Select the month of the recordings, such as January



Confirm

5. Select the day of the recordings, such as the tenth



Confirm

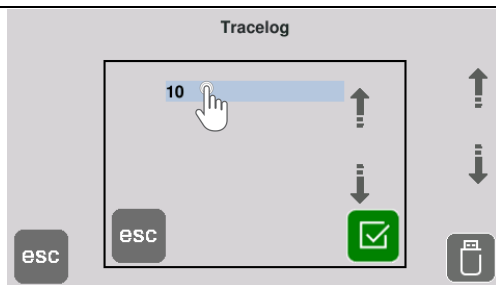
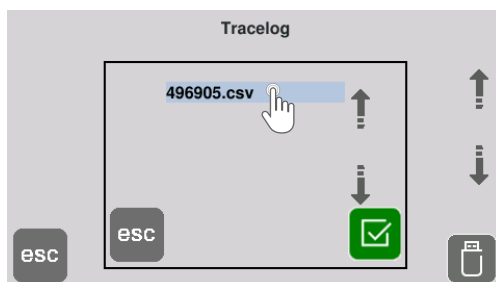
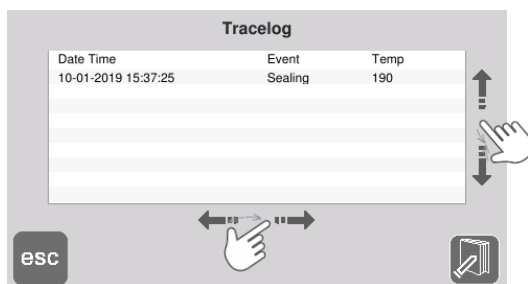
5. Select the serial number of the recordings, such as



Confirm

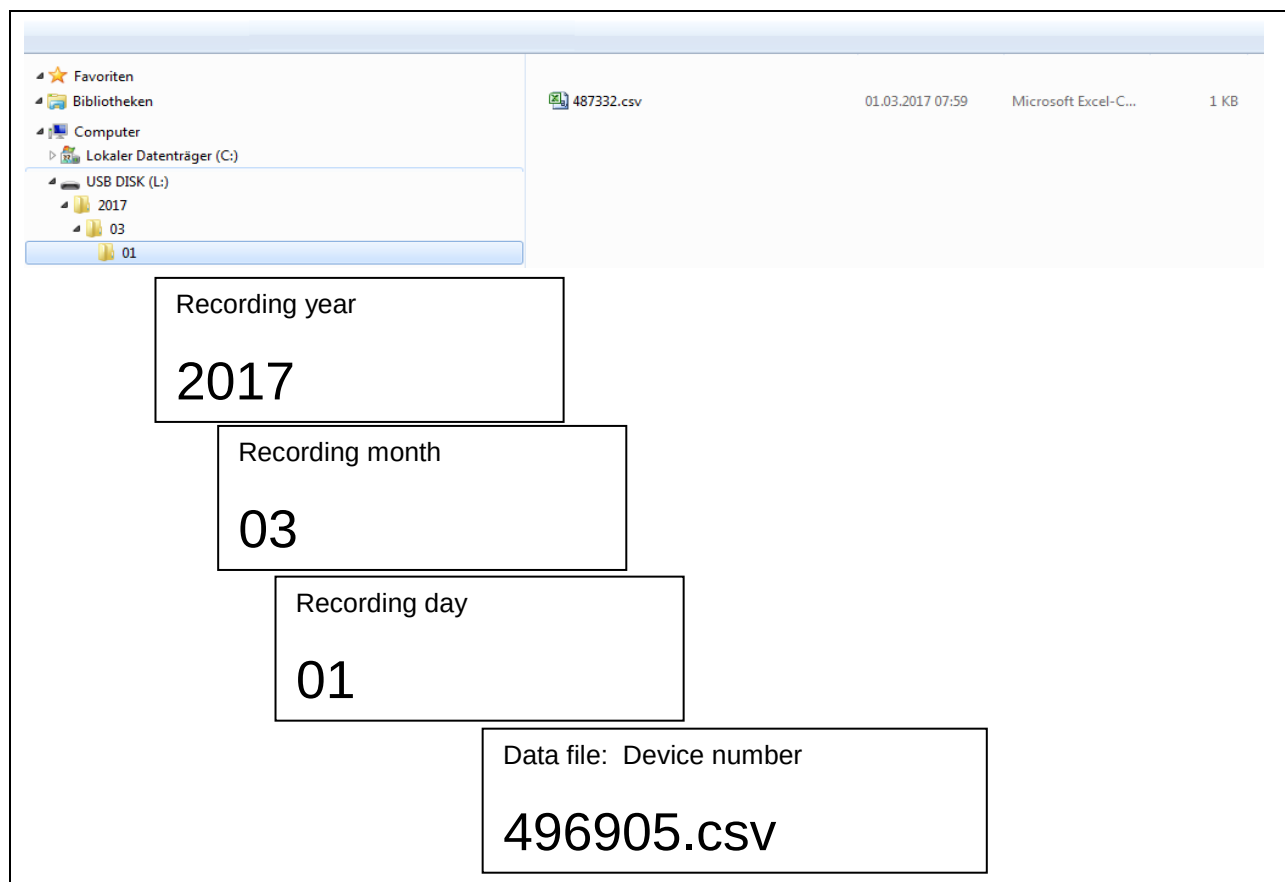
→ Change display by swiping

Status of the event
Date and time
Event
Sealing temperature
Contact pressure
Throughput speed
Batch counter
Selected packaging
Names
Expiry date
Batch data
Info



5.1.5 Show the DataMatic data on a PC

USB stick directory with the recording data (for example: PC with Windows 7)



Display of a standard DataMatic recording, e.g. using Windows Excel

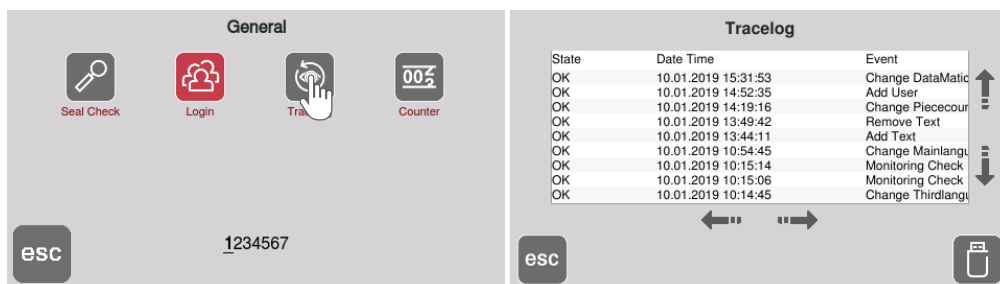
5.2 TraceLog (logbook)

This logbook contains the temporary recording of various completed actions, events and faults that have occurred on the device.

These recordings are only viewable while the device is switched on, however if a USB stick is connected for the DataMatic function, the data are stored as an add-on to the DataMatic data on it in the event of a date change and during the switch-off process.

 For reliable data transfer, the device must switch itself off after pressing the Power off button and once the shut-down period of one minute has elapsed.
No "EMERGENCY STOP" must be carried out by holding the Power off button!

5.2.1.1 The display menu



5.2.1.2 Interpretation of entries

State	Date and time	Event	T	F	v
OK	10/01/2019 15:31:53	Change DataMatic	Sealing temperature at this time	Contact pressure at this time	Throughput speed at this time
OK	10/01/2019 14:52:35	Add User			
OK	10/01/2019 14:19:16	Change Piece Counter			
OK	10/01/2019 13:49:42	Remove Text			
OK	10/01/2019 13:44:11	Add Text			
OK	10/01/2019 10:54:45	Change Mains Language			

5.3 Data readout via Ethernet

If an address is assigned to the device in the Settings / System Configuration / IP menu, the corresponding CSV file of DataMatic can be read out via network connection and saved on the PC.

Caution: A direct connection between the device and PC is not possible. The device needs to be on a computer network for this.

5.4 External keyboard for data entry

A country-specific, external keyboard can be connected to enter packaging designations and the data for the various lists

<p>Insert the keyboard into a free USB slot</p> <p><u>Optional:</u> 6.561.028 wireless keyboard or 6.561.029 medical keyboard</p>	
---	--

5.5 Display

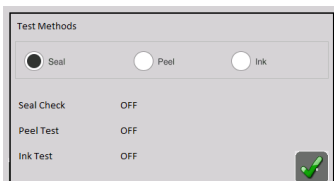
5.5.1 Standby

<p>Standby is active, the sealing temperature returns to the ambient temperature</p> <p>Reactivate device function</p>	<p>The display is darker and the device cools down to the default set temperature of 80°C.</p>
--	--

5.5.2 Counter status 0

<p>If the batch counter was configured to count backwards and the quantity reaches 000000, a message appears, a signal tone sounds and the drive is inactive.</p> <p>For further use, the counter must be reset or the counting direction must be changed to count forward by pressing the "Stop counter" key.</p>	
--	--

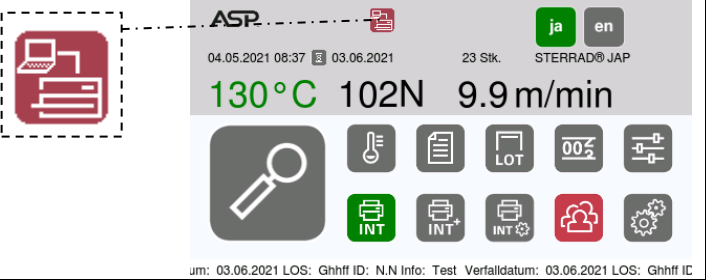
5.5.3 Display of the set test interval

<p>This symbol only appears if a test interval was selected</p>	<p>An individual date can be set for each test interval. See level 4 "Test intervals".</p> 
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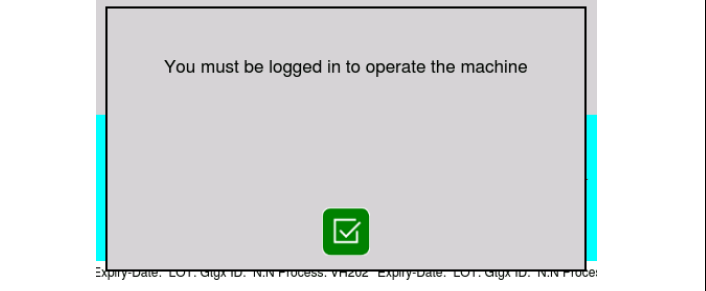
5.5.4 Maintenance indicator

<p>This symbol appears 30 days before the set maintenance cycle with information about the remaining days until the maintenance deadline or the days already exceeded after the maintenance deadline.</p> <p>Default setting: 12 months.</p> <p>Customer setting via the Service menu (see device technical manual)</p>	
--	---

5.5.5 RS 232 data interface active display

<p>This symbol appears if an external PC has made contact with the sealing device via the RS 232 data interface</p> <p>(More details in the interface description 6.594.039)</p>	
--	--

5.5.6 Display of password startup interlock

<p>This symbol appears when the password startup interlock is active</p> <p>This means that the motor will only start if a previously listed password has been entered</p> <p>This function can only be activated or deactivated in service mode!</p> <p>(see device's Technical manual)</p>	
--	--

6 The barcode scanner (1.490.029)

 The barcode scanner is an optional accessory and not part of the sealing device scope of delivery! A connected barcode scanner that has not been approved by the device manufacturer can cause the device to fail!

6.1 Commissioning the barcode scanner

6.1.1 Step 1 Unpack the barcode scanner

<p>Open the packaging</p> <p>Check to ensure that all parts are there and undamaged.</p>	<p>Barcode scanner with USB connection cable Art. No.: 1.490.029</p> 
--	--

6.1.2 Step 2 Connect the barcode scanner

1. Switch off the device

2. Connect the barcode scanner's connection cable to a free USB slot

2. Switch on the device



6.2 Recording data using the barcode scanner



The capture of data with a barcode scanner is only possible if the language German or English has been set!

6.2.1 Data of a created barcode list

Only the print data of the internal printer can also be changed with a barcode scanner, provided they are activated in their print sequence.

The data read in with the scanner are not saved. They are only current while the device is switched on!

Print data	Data source	Note
 Info	Scan list with information	Assignment of general barcode data possible
 Batch data	Scan list with batch data	Assignment of general barcode data possible

6.2.2 General barcode data

Data	Data source	Note
 General data	All alphanumerically readable data	If not changed, they are always read in as a batch number.

6.2.2.1 Assignment of general barcode data

All data collected by the scanner is assigned to the previously selected function.

This means that data captured by the scanner can be scanned and updated independently of editing the packaging list

7 Switch off the device

Briefly press the Power button

then, confirm the switch-off of the machine or cancel the switch-off procedure by pressing the relevant key



Confirm

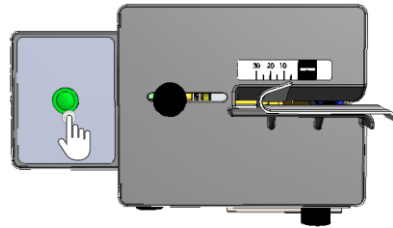


Cancel

By holding the Power button down, the device is switched off directly

Do not use if a USB stick is connected!
Data loss!

The colour of the Power button changes from green to red



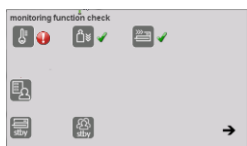
≈5 s

8 Troubleshooting and maintenance

8.1 Troubleshooting checklist



The malfunction corrections highlighted in grey may only be performed by authorised service technicians!

Malfunction	Possible display	Possible cause	Possible malfunction correction
Open the front flap		Front flap open display	Close front flap
		Front flap sensor defective	Replace defective component <i>Inform Service</i>
Monitoring function check The sealing temperature is not reached after switch-on or it is outside of the set tolerance limit		Temperature sensor defective Control board faulty Heating cartridge defective	Replace defective component <i>Inform Service</i>
Monitoring function check After switch-on the contact pressure is outside of the set tolerance limit		DMS module faulty Control board faulty	Replace defective component <i>Inform Service</i>
Monitoring function check After switch-on the throughput speed is outside of the set tolerance limit		Optical sensor "Motor Start" defective Control board faulty Motor faulty	Replace defective component <i>Inform Service</i>

8.2 Maintenance

Like all technical devices, your device is subject to technical wear.

In order to guarantee continuous operational readiness, your device should be inspected regularly by a competent person and cleaned, serviced and calibrated at least once per year by the manufacturer or by one of the manufacturer's authorised service partners.

8.3 Spare part service

Please contact your local sales representative for further information.

To:		Sender:	
E-mail:			
Fax no.:			
Your order No.:		Date:	
Device type:		Serial number:	
☒	Designation	Art. No	Qty.
☐	Device printer ink ribbon	6.813.104	
☐	Device printer ink ribbon, red	6.813.224	
☐			

8.4 Replacing the sealing device ink ribbon cassette

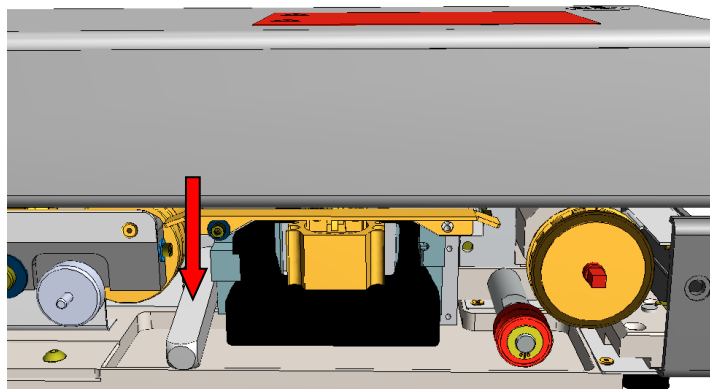


Switch off the device and DISCONNECT THE POWER SUPPLY

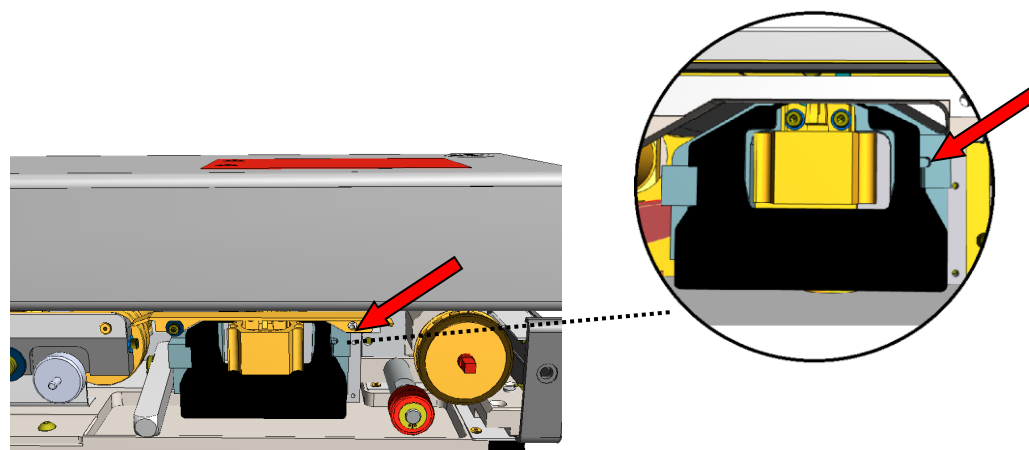
Step 1 Switch off the machine and remove the mains plug from the socket

Step 2 Open the front flap from the machine

Step 3 Press and hold the lever down



Step 4 Remove the ink ribbon by pressing the lock on the ink ribbon

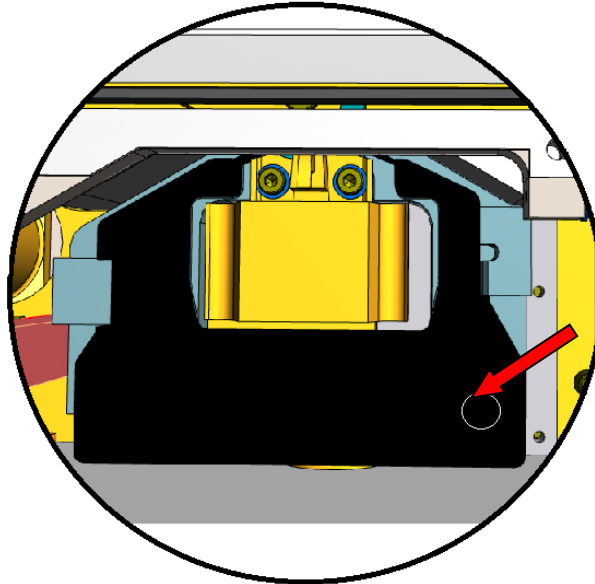


Step 5

Press the lever down and insert a new ink ribbon until it clicks into place.

Step 6

Once the ink ribbon is correctly engaged, it should not be possible to turn the wheel on the ink ribbon.



Step 7

Close the front flap

9 Technical data

9.1 Specifications

Connection data

Mains connection	[V]	100 - 240
Mains frequency	[Hz]	50 / 60
Power consumption	max. [W]	200

Mechanical system

Dimensions	Length [mm]	560
Including	Width	250
Infeed section	Height	145
Housing cover		Stainless steel AISI 304
Housing bottom		Stainless steel / Aluminium
Weight	[kg]	14
Seal distance from edge	[mm]	0 – 35
Sealing seam width	[mm]	12 +/-0,5
Sealing system		SealPeak
Sealing seam length	[mm]	Unlimited
Distance from medical product	[mm]	>30 (as per DIN 58953-7)

Process variables/sealing parameters

Sealing temperature	max. [°C]	210
Tolerance for sealing temperature	[°C]	± 2 – ±5 (adjustable)
Contact pressure	[N]	100
Contact pressure deactivation tolerance	[%]	±20
Throughput speed	[m / min]	5 -13
Switch-off tolerance		±10
Throughput speed	[%]	
Temperature ranges		1
Temperature standard tolerance	[%]	±2

Electronics and communication systems

System		Microprocessor
Interfaces		RS-232 USB A Ethernet (LAN)
Transfer speed (baud rate)	[Bd]	9,600
Serial RS-232 interfaces and Ethernet		
Electrical protection class		1

Environmental parameters

Ambient temperature	[°C]	5-25
Heat output	[kJ/s]	0.1
Relative humidity	[%]	30-80 non-condensing
Noise intensity acc. to Machinery Directive 2006/42/EC Appendix I 1.7.4.2 u.)	[dB/ A]	<70
Average power consumption ¹	[W]	90
Max. noise development	[db]	65

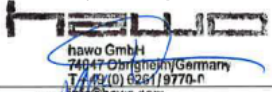
Passwords

Password for unlocking the device for SealCheck		29815
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¹Deviates in the heating process

10 Declarations of conformity

10.1 CE declaration of conformity for sealing device

	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaración de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade	9.696.164C															
Gültig ab: 19.11.2021 Valid from:		Seite 1/1 Version 1.01															
<p>Hiermit erklären wir, daß die Folienschweissmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: 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:</p> <p style="text-align: center;">INNOQ SEAL 400</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: corresponde aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <table border="0"> <tr> <td>EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle macchine nella versione Directiva da UE relativa a maquinaria</td> <td>2006/42/EG</td> <td></td> </tr> <tr> <td>EMV-Richtlinie Directive CEM Direttiva CEM</td> <td>EMC-directive Directiva da CEM Directiva CEM</td> <td>2014/30/EU</td> </tr> <tr> <td>WEEE-Richtlinie Directive WEEE Direttiva WEEE</td> <td>WEEE-directive Directiva da WEEE Directiva WEEE</td> <td>2012/19/EU</td> </tr> <tr> <td>RoHS-Richtlinie Directive RoHS Direttiva RoHS</td> <td>RoHS-directive Directiva de RoHS Directiva RoHS</td> <td>2015/863/EU</td> </tr> <tr> <td>Harmonisierte Normen Standard harmonise Norme armonizzate</td> <td>Harmonized standards Las normas armonizadas Normas harmonizadas</td> <td>EN ISO 12100:2010 EN 60204-1:2018 EN ISO 13857:2019 EN IEC 61000-6-1:2019 EN IEC 63000:2018 EN 61000-6-3:2007+A1:2011</td> </tr> </table> <p>Verantwortliche Person für die Technischen Unterlagen siehe unten Responsible person for technical documentation see below La personne responsable pour la documentation technique est mentionnée au-dessous</p> <p style="text-align: center;">  hawa GmbH 74847 Obrigheim / Germany T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 9770-69 info@hawa.com www.hawa.com </p> <p>Torsten Ehrhardt Prokurist / authorized officer</p> <p>hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany</p>			EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle macchine nella versione Directiva da UE relativa a maquinaria	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	2015/863/EU	Harmonisierte Normen Standard harmonise Norme armonizzate	Harmonized standards Las normas armonizadas Normas harmonizadas	EN ISO 12100:2010 EN 60204-1:2018 EN ISO 13857:2019 EN IEC 61000-6-1:2019 EN IEC 63000:2018 EN 61000-6-3:2007+A1:2011
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10.2 DIN EN ISO 11607-2 / DIN 58953-7 declaration of conformity of sealing device

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration de Conformité Declaración de conformidad Dichiarazione di conformità - Declaração de conformidade	9.696.164D
Gültig ab: 19.11.2021 Valid from:		Seite 1/1 Version 1.01
<p>Hiermit erklären wir, daß die Folienschweissmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: 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:</p> <p style="text-align: center;">INNOQ SEAL 400</p> <p>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 disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <p>Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. KRINKO / BfArM Bundesgesundheitsblatt 2012 55:1244-1310 Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention(KRINKO) beim Robert Koch-Institut(RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte(BfArM)</p> <p>Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: ISO 11607-2:2019 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 d'assemblage</p> <p>Sterilisation – Sterilgutversorgung – Teil 7: DIN 58953-7:2020 Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und –schläuchen Sterilization – Sterile supply – Part 7: Use of sterilization paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels Stérilisation – Approvisionnement en produits stériles – Partie 7: Utilisation de papier pour stérilisation, de matériaux d'enveloppe en non-tissé, matériaux textiles tissés, de sacs en papier, de sachets et gaines scellables</p> <p style="text-align: center;">  hawa GmbH 74847 Obrigheim/Germany T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 9770-69 info@hawa.com www.hawa.com </p> <p>Torsten Ehrhardt Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany</p>		
hawa GmbH Obere Au 2-4 74847 Obrigheim / Germany	T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 9770-69 info@hawa.com www.hawa.com	Amtsgericht Mannheim: HRB 441011 Geschäftsführer: Christian Wolf Firmensitz: Obrigheim

9.610.007, Version 2.01

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CE declaration of conformity for barcode scanner



DECLARATION OF CONFORMITY



EC-053

Rev.: 1

Pag.: 1 di 1

Datalogic Scanning Group Srl
Via S. Vitalino, 13
Lippo di Calderara di Reno (BO)
40012 Italy

dichiara che
declares that the
déclare que le
bescheinigt, daß das Gerät
declare que el

Gryphon D41xx Black and Gryphon D41xx White

e tutti i suoi modelli
and all its models
et tous ses modèles
und seine Modelle
y todos sus modelos

sono conformi alle Direttive del Consiglio Europeo sottoelencate:
are in conformity with the requirements of the European Council Directives listed below:
sont conformes aux spécifications des Directives de l'Union Européenne ci-dessous:
den nachstehenden angeführten Direktiven des Europäischen Rats:
cumple con los requisitos de las Directivas del Consejo Europeo, según la lista siguiente:

2004/108/EC EMC Directive

Basate sulle legislazioni degli Stati membri in relazione alla compatibilità elettromagnetica ed alla sicurezza dei prodotti.
On the approximation of the laws of Member States relating to electromagnetic compatibility and product safety.
Basée sur la législation des Etats membres relative à la compatibilité électromagnétique et à la sécurité des produits.
Über die Annäherung der Gesetze der Mitgliedsstaaten in bezug auf elektromagnetische Verträglichkeit und Produktsicherheit entsprechen.
Basado en la aproximación de las leyes de los Países Miembros respecto a la compatibilidad electromagnética y las Medidas de seguridad relativas al producto.

Questa dichiarazione è basata sulla conformità dei prodotti alle norme seguenti:
This declaration is based upon compliance of the products to the following standards:
Cette déclaration repose sur la conformité des produits aux normes suivantes:
Diese Erklärung basiert darauf, daß das Produkt den folgenden Normen entspricht:
Esta declaración se basa en el cumplimiento de los productos con las siguientes normas:

EN 55022 (CLASS B ITE), SEPTEMBER 1998:
AMENDMENT A1 (CLASS B ITE), OCTOBER 2000:

LIMITS AND METHODS OF MEASUREMENTS OF RADIO DISTURBANCE
CHARACTERISTICS OF INFORMATION TECHNOLOGY EQUIPMENTS

EN 55024, SEPTEMBER 1998:

INFORMATION TECHNOLOGY EQUIPMENT
IMMUNITY CHARACTERISTICS
LIMITS AND METHODS OF MEASUREMENT

Lippo di Calderara, July 7th, 2009

Ruggero Cacioppo
Quality Assurance Manager

