



hm 950

NanoPak

TRANSLATION OF THE ORIGINAL
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 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 5.01.12 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

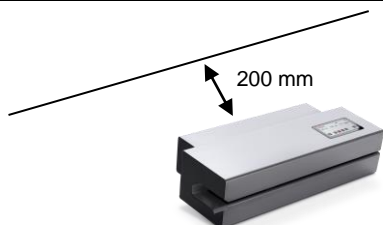
2 Commissioning

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>	<p>Sealing device</p> <p>Power supply</p> <p>Power cable</p> <p>Operating instructions</p> <p>Test report(s)</p> <p>Replacement ink ribbon</p> 
--	--

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 ❶ into the device

Connect the mains cable ❷ to the power supply ❸ and insert the mains plug ❹ into the socket



2.1.4 Step 4

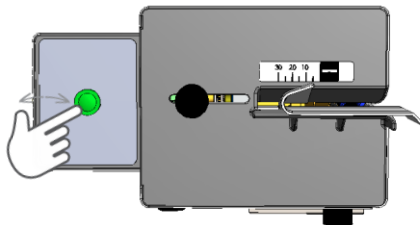
Switch on the device

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.

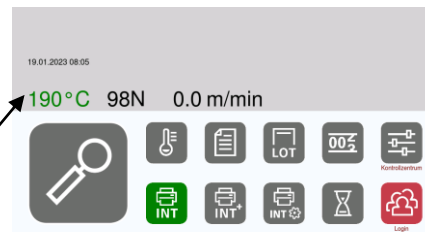
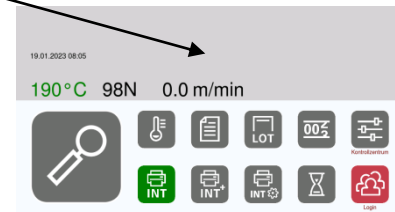
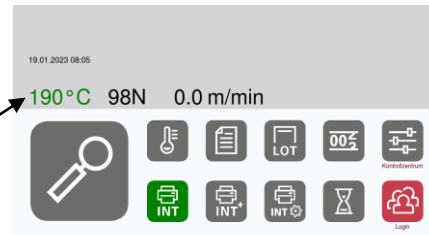


2.1.5 Step 5 Checking of the sealing parameter sensors

After switch-on, the device heats up to the default sealing temperature of 190°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

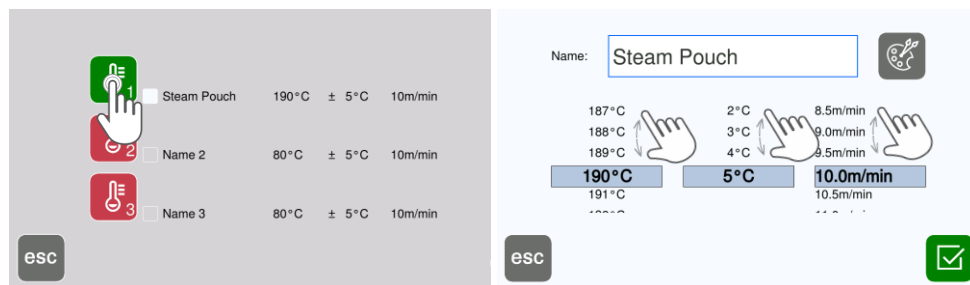


Symbol	Function	Note
189°C	Displays the current sealing temperature	
97 N	Displays the current pressing force	
0.0 m/min	Displays the current throughput speed	Value > 0 only when motor is running
	Login	User login/logoff
	Control centre	Check of the functions heating, DMS module and motor as well as the device operating data and the mode change
de en	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	


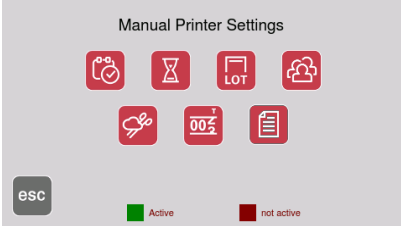




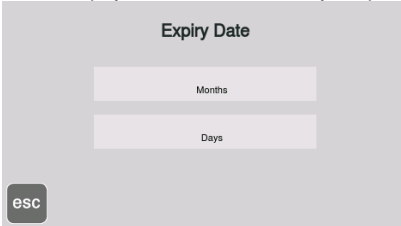






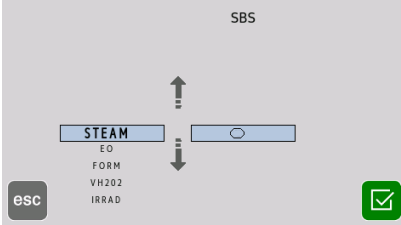






2.1.6.1 Main screen



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.

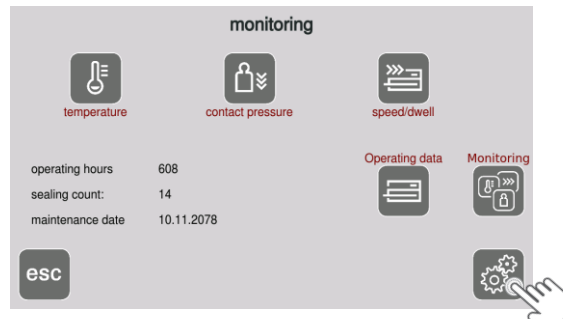


Symbol	Function	Note
	List with information	Device designations, department names
	Batch data	Batch name, batch numbers The number is overwritten after each new entry
	Batch counter	Setting the batch counter for counting up/down
	Printer on / off	

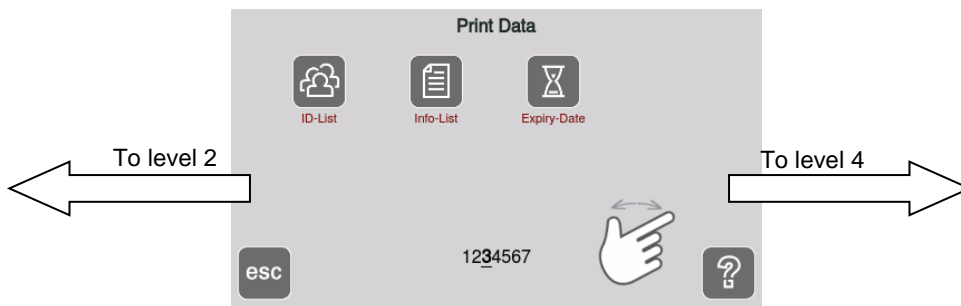
Symbol	Function	Note
	Printer setting	Pre-select the desired print out information 
 	Print / not Print packaging date Internal Printer setting	
 	Print / not Print expiry date Internal Printer setting	Select expiry date as month or day for print out 
 	Print / not Print LOT number Internal Printer setting	
 	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 (more SBS symbols available on the hm 950 DC-VI with 24-needle printer head) 
 	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

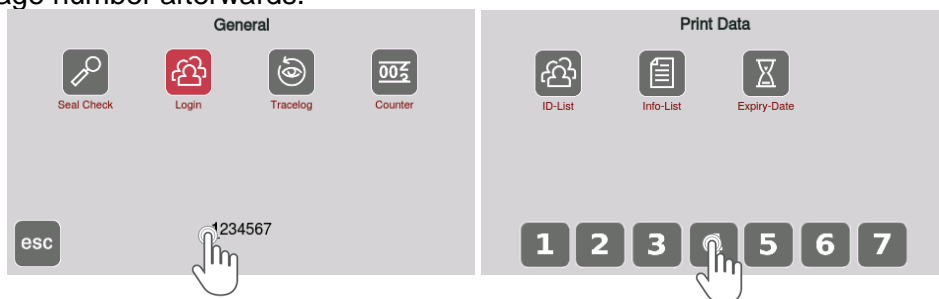
- Press the button control center in the start screen.
- Press the button settings in the monitoring screen.



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.



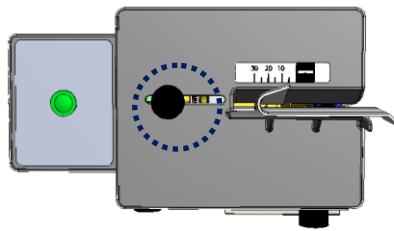
2.1.8 Step 8 The first sealing process

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



The interface shows the following parameters and options:

- Top bar: 19.01.2023 08:37, 14 pcs., 189 °C, 100N, 0.0 m/min
- Menu icons: Seal Check (magnifying glass), Ink Test (pen), Peel Test (scissors)
- Selected option: Seal Check, Please seal
- Parameters: 189 °C, 101 N, 0.0 m/min
- Buttons: esc, Seal Check, Ink Test, Peel Test
- Diagram: A package with a seal strip being applied.

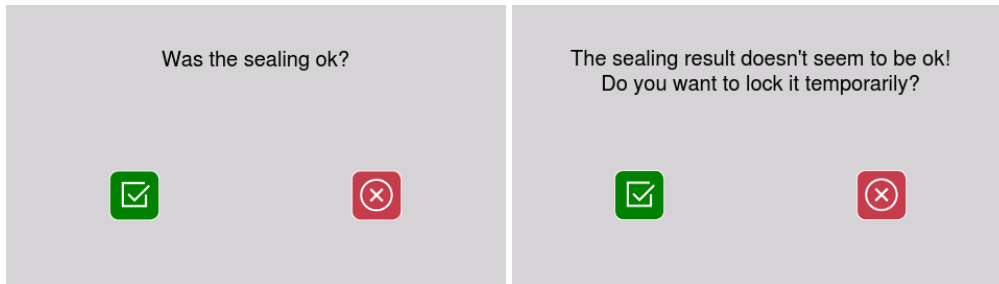
2.2.1 Blocked device due to failed seal check tests

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

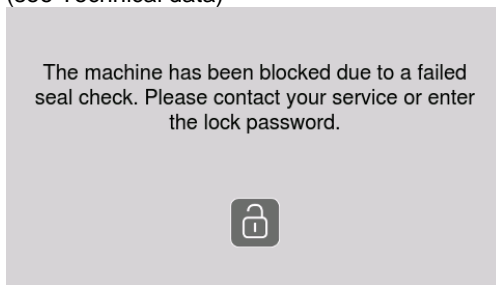
Notification after two messages rated as not OK

Seal check

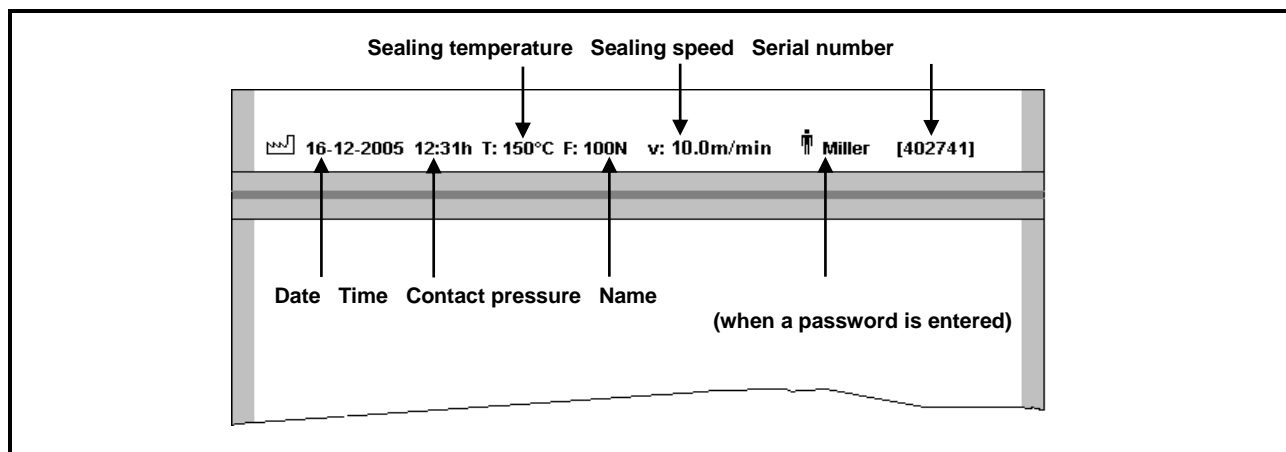


If the screen has been locked due to a faulty seal check, it can be unlocked again by entering the lock password.

(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, make sure that the correct language is activated.

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

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.

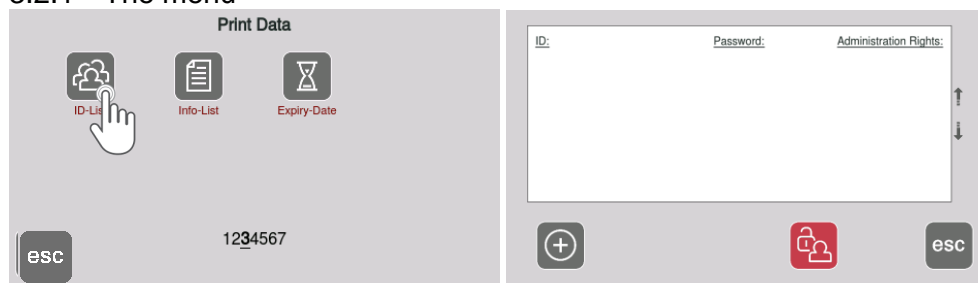
If the **User standby** function was activated in the **Settings menu**, the user is automatically logged out after a set time after which no sealing process has taken place.



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.

3.2.2 Name entry / administrator rights / language assignment


1. Activate **■Name list■** menu

2. **■Enter new name**

3. Enter **Name**, e.g. "User"
It is not possible to enter a name without a password

4. Enter **password**, e.g. "12345" and administrator rights can be assigned if desired by pressing the key

Administrator rights active



Display language




If this setting is made, the display language changes to the language set here, regardless of the default setting, as soon as the user has logged in.

5. End input(s) by pressing the **"Enter"** key

Exit this menu level

esc

Print Data



esc

1234567



ID:

Password:

Administration Rights:

esc

Q	W	E	R	T	Y	U	I	O	P	
A	S	D	F	G	H	J	K	L		
Z	X	C	V	B	N	M	.			
123							American English			

ar

yue

cn

nl

en

fi

fr

de

he

it

ja

ko

no

pl

pt

ru

es

sv

th

tr

hu

esc

ID:





Password:

Administration Rights:

User

12345

1








esc


3.2.3 Removing administrator rights

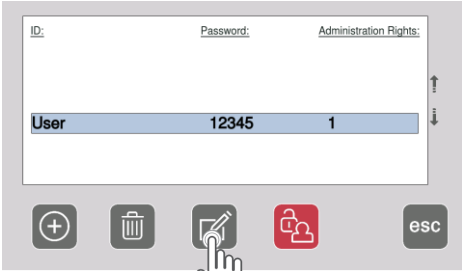
1. Select a name, e.g. "User"

2. Press the symbol to edit selected name.

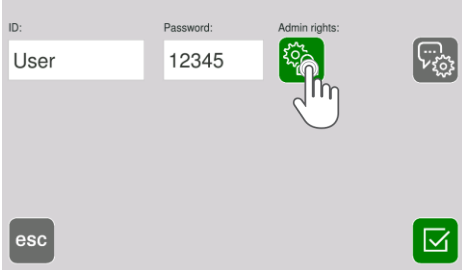
3. Remove the administrator data and confirm by pressing the  key.

Administrator rights inactive 

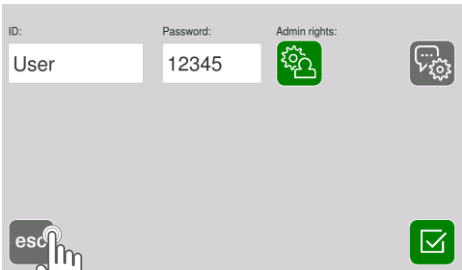
 Exit this menu level



Selection menu showing ID, Password, and Administration Rights. The row "User" is selected. Below the table are icons for add (+), delete (trash), edit (pencil), lock (red padlock), and an esc key.



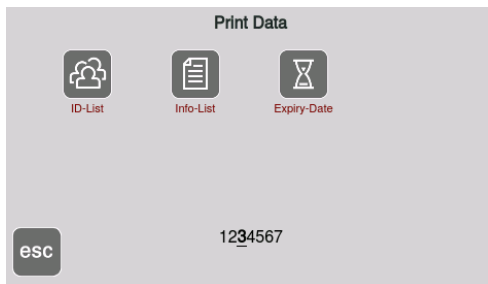
Edit rights screen. Fields for ID (User), Password (12345), and Admin rights (green gear icon). A green checkmark icon is in the bottom right. An esc key is in the bottom left.



Confirm screen. Fields for ID (User), Password (12345), and Admin rights (green gear icon). A green checkmark icon is in the bottom right. An esc key is in the bottom left.

3.3 Data lists

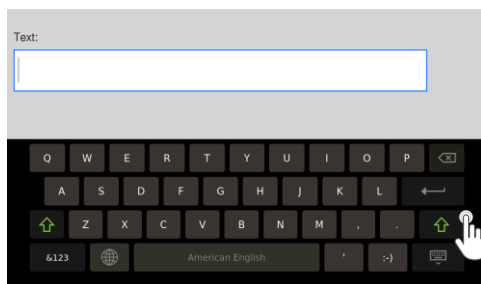
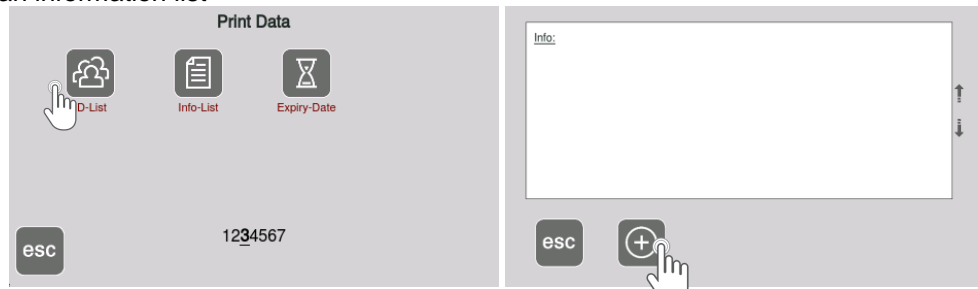
3.3.1 The selection menu



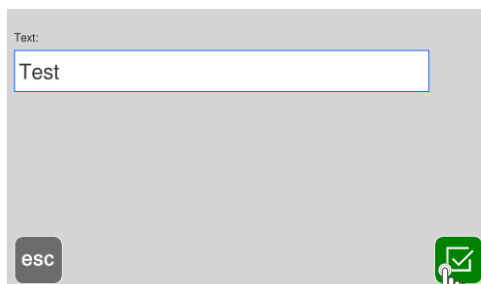
Key	Function	Example	Note
	List with names		Length of user data: Name: 20 alphanumeric characters Password: 5 numbers Number of user entries: 50, individual entry or one after another
	List with information	Device designations, department names	Length of list texts: 20 alphanumeric characters Number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







Enter the necessary informations



confirm the information by pressing the green hook.



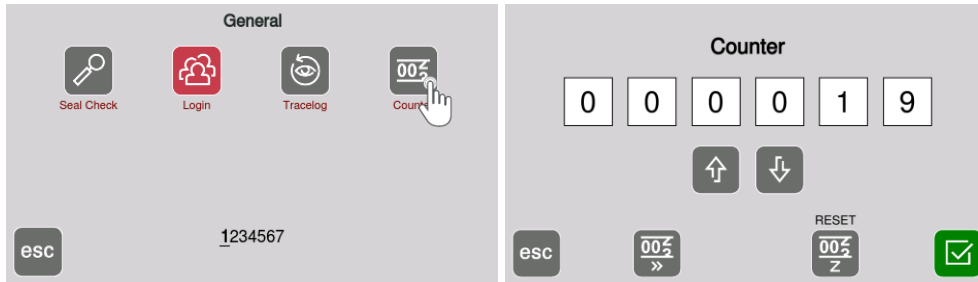
Key	Function
	Add new information
	Delete information
	Confirm/activate
	Exit menu level

4 Device configuration

4.1.1 Batch counter

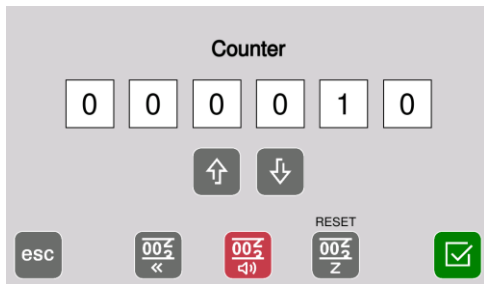
4.1.1.1 Batch counter functions

Counting forwards



Key	Function	Note
	000019	Displays the current value
	Switches the counter to forwards counting	
	Sets the counter to 000000	
	Confirms the settings	

Counting backwards





Key	Function	Note
	000019	Displays the current value
	000010	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.

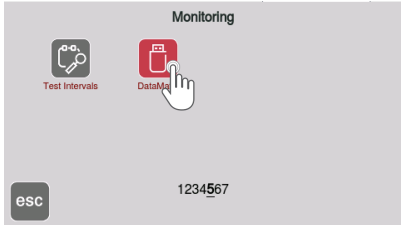
-  If the DataMatic function is activated, a sealing process can only be started if a USB stick is also plugged in!
-  The DataMatic data are output automatically via the RS 232 and Ethernet interfaces with each seal, even if the USB stick is not plugged in!


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 .




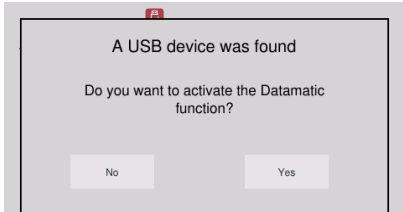
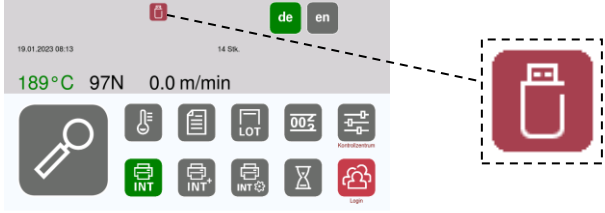


Inactive



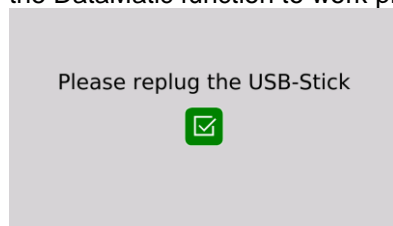
Active after long pressing

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

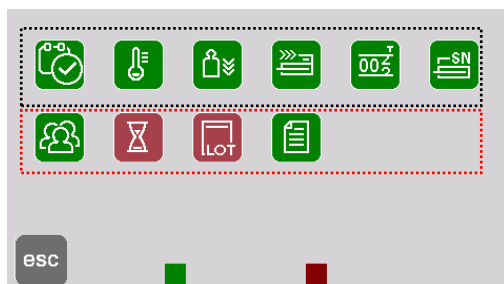
5.1.2 Rebooting with „DataMatic“

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.



→ Remove the USB and confirm with green hook before replug the USB

5.1.3 Configuring DataMatic data



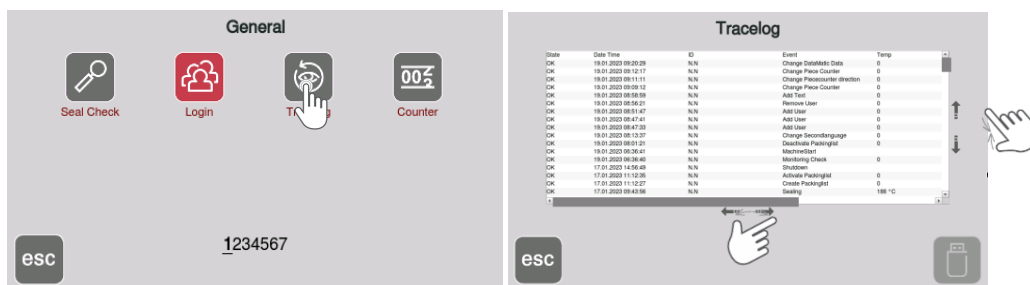
Keys	Data	Note
	Date and time Sealing temperature Contact pressure Throughput speed Unit counter TOTAL Device serial number	Fixed recording data
	Name Expiry date Batch number Info	Optional recording data

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

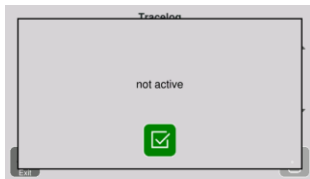


Key	Function	Display	Function
	Recorded TraceLog (logbook) data	10/01/2019	Date of the recording
	Scroll up and down	0 – 9	Data counter
	Scroll left and right		
	Exit menu level		
	Read the DataMatic data		

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

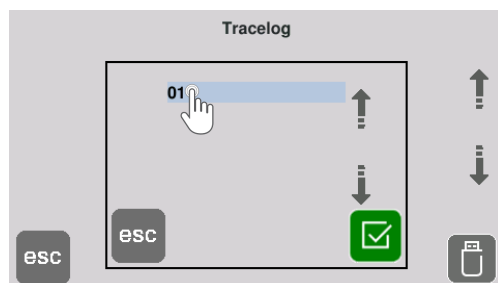
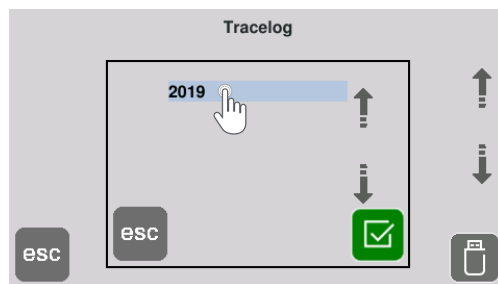
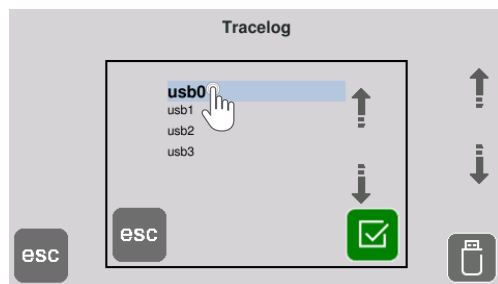
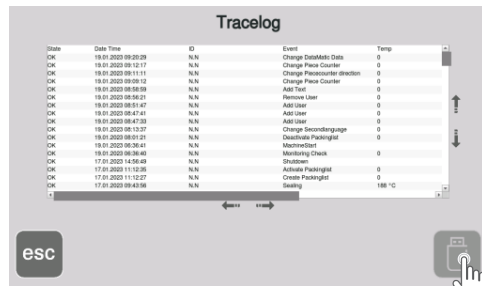
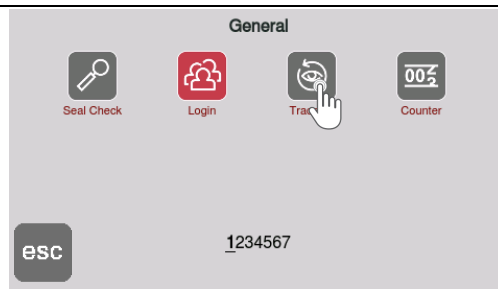


Confirm

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



Confirm



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



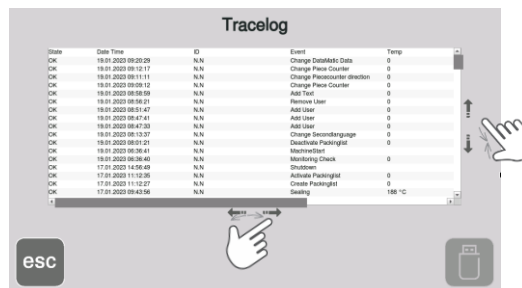
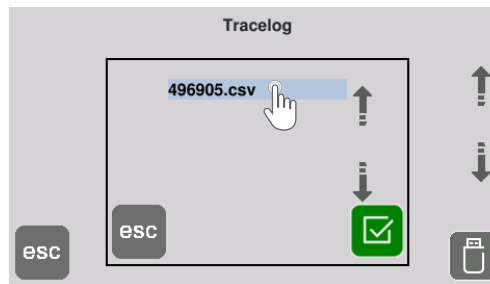
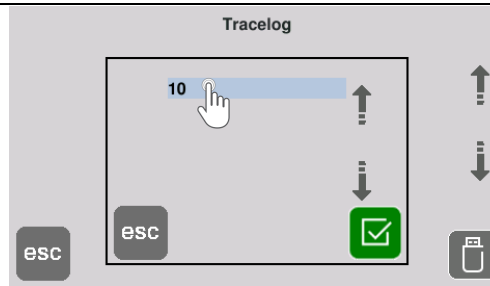
Confirm

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



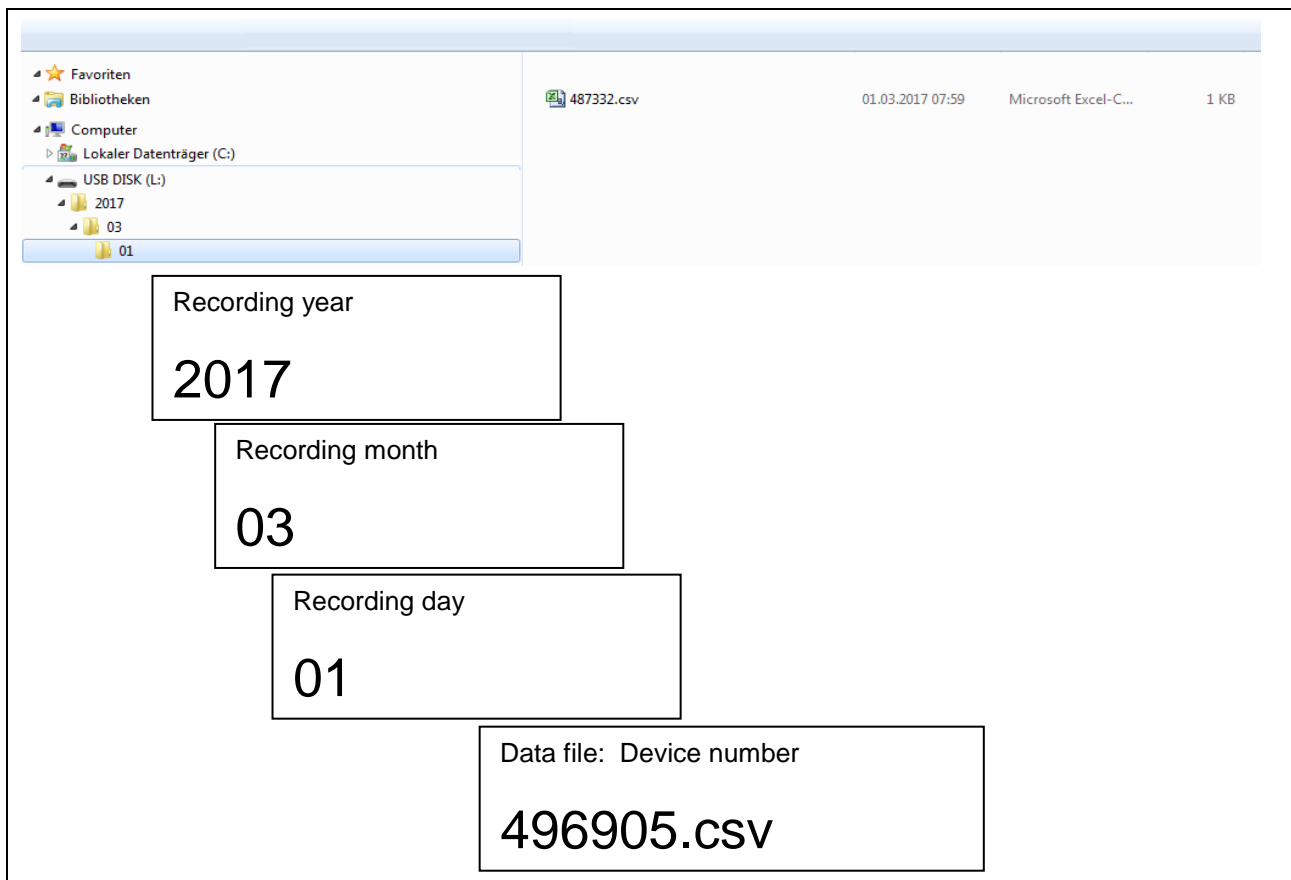
Confirm

→ 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

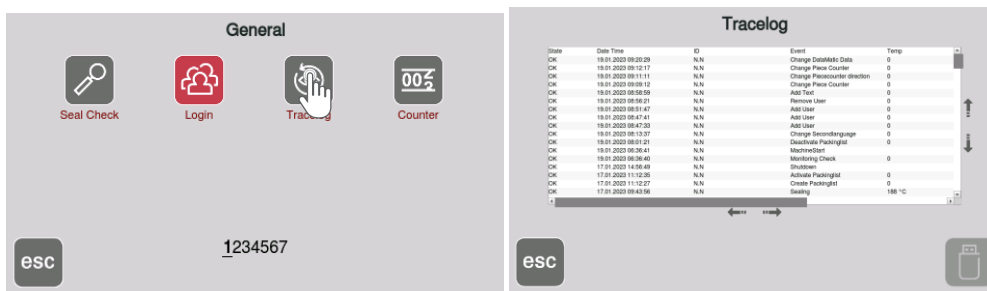
5.2 TraceLog (logbook)

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.
(See interface description 9.694.039)

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

Insert the keyboard into a free USB slot

Optional:

6.561.028 wireless keyboard

or

6.561.029 medical keyboard



5.5 Display

5.5.1 Standby

Standby is active, the sealing temperature returns to the ambient temperature

Reactivate device function

The display is darker and the device cools down to the default set temperature of 80°C.

5.5.2 Counter status 0

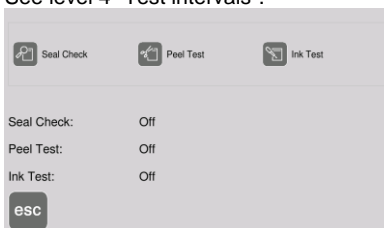
If the batch counter was configured to count backwards and the quantity reaches 000000, a message appears, a signal tone sounds and the drive is inactive.

For further use, the counter must be reset or the counting direction must be changed to count forward by pressing the "Stop counter" key.

5.5.3 Display of the set test interval

This symbol only appears if a test interval was selected

An individual date can be set for each test interval. See level 4 "Test intervals".



5.5.4 Maintenance indicator

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.

Default setting: 12 months.

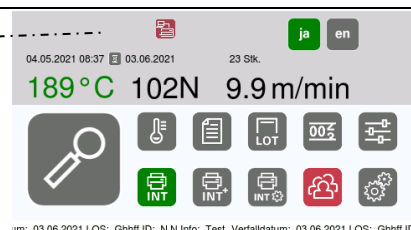
Customer setting via the Service menu (see device technical manual)



5.5.5 RS 232 data interface active display

This symbol appears if an external PC has made contact with the sealing device via the RS 232 data interface

(More details in the interface description 6.594.039)

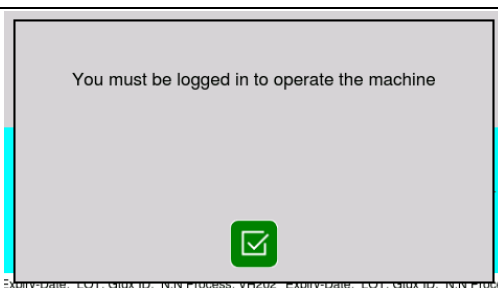


5.5.6 Display of password startup interlock

This symbol appears when the password startup interlock is active
This means that the motor will only start if a previously listed password has been entered


This function can only be activated or deactivated in service mode!

(see device's Technical manual)









5.5.7 The display of special settings

Tap the **control center** symbol









esc Exit the special display

Symbol	Display
	Switching from the machine display to the external HDMI port and backwards. (Password for switching see in the technical date)
	Start the monitoring
	Checking of the temperature sensor positive
	Checking of the contact force sensor positive
	Checking of the throughput speed sensor positive
	Device operating data

5.5.8 Display of operating data

1. Press control center button
2. Press operating data button


Symbol	Display
	Operating hours
	Software version
	Device serial number
	Batch counter total
	Firmware version
	Maintenance date

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

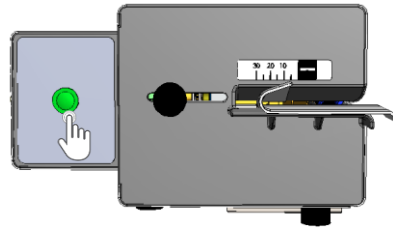


Cancel

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



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>

➤ 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.

8.2 Service

	<p>Your hawa customer service is available from Mon-Fri 8:00 to 16:00 at the following number: +49 (0)6261-9770-31.</p>
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8.3 Spart part service

	<p>Conveniently order parts via E-mail service@hawa.com Fax +49(0)6261 9770 45</p> <p>Simply copy the order form on the following page and enter the following information:</p>		
<p>① ②</p>	<ul style="list-style-type: none"> • Address, e-mail address or fax number • Enter order number • Enter device type • Enter serial number [SN] • Mark articles required • Enter quantity required • Sign order • Send order 		

To:		Sender:	
E-mail:			
Fax no.:			
Your order No.:		Date:	
Device type:		Serial number:	
<input checked="" type="checkbox"/>	Designation	Art. No	Qty.
<input type="checkbox"/>	Device printer ink ribbon	6.813.104	
<input type="checkbox"/>	Device printer ink ribbon, red	6.813.224	

8.4 Replacing the sealing device ink ribbon cassette

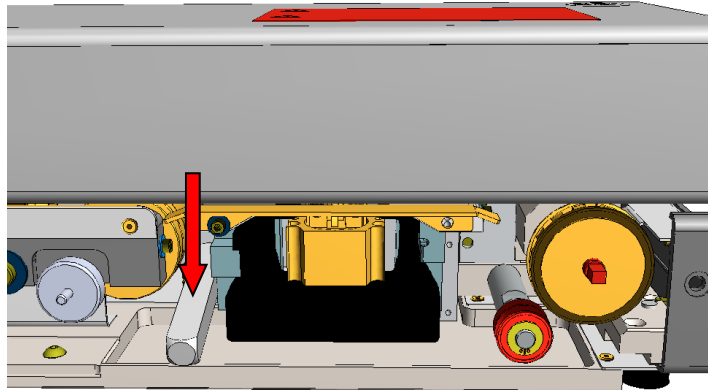


Switch off the device and DISCONNECT THE POWER SUPPLY

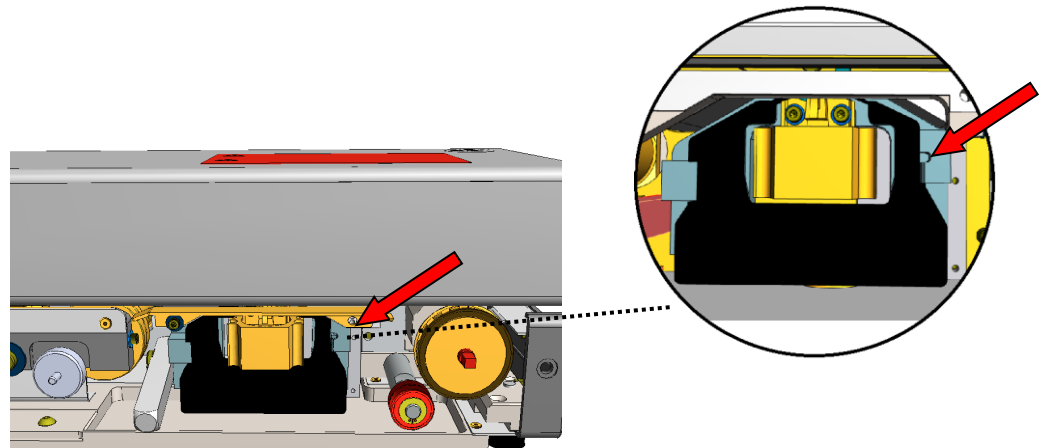
Step 1 Switch off the machine and remove the mains plug from the socket

Step 2 Open the front flap from the machine

Step 3 Press and hold the lever down

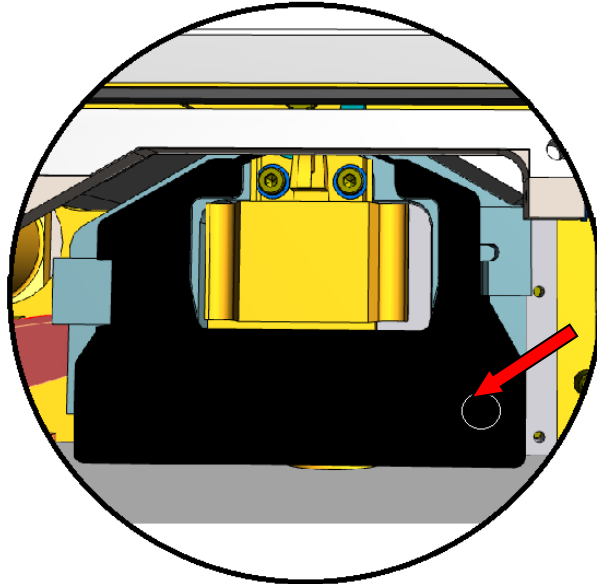


Step 4 Remove the ink ribbon by pressing the lock on the ink ribbon



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]	280

Mechanical system

Dimensions	Length [mm]	560
Including	Width	250
Infeed section	Height	145
Housing cover		Stainless steel AISI 304, powder-coated
Housing bottom		Metal powder-coated
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

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaración de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade	9.694.038C
Gültig ab: 12.01.2023 Valid from:	Seite 1/1 Version 1.04	
<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 align="center">NanoPak hm 950 DC-V / NanoPak hm 950 DC-VI</p>		
<p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: correspondre aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p>		
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 Directive da CEM Directiva CEM	2014/30/EU
WEEE-Richtlinie Directive WEEE Directiva 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 IEC 61000-6-3:2021
<p>Verantwortliche Person für die Technischen Unterlagen siehe unten Responsible person for technical documentation see below La personne responsable pour la documentation technique est mentionnée au-dessous</p>		
<div style="text-align: center;">  hawo GmbH 74847 Obrigheim/Germany T +49 (0) 6261 9770-0 info@hawo.com </div> <p>Torsten Ehrhardt Prokurist / authorized officer</p> <p>hawo GmbH, Obere Au 2, D-74847 Obrigheim, Germany</p>		
hawo GmbH Obere Au 2-4 74847 Obrigheim / Germany	T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 9770-69 info@hawo.com www.hawo.com	Amtsgericht Mannheim: HRB 441011 Geschäftsführer: Christian Wolf Firmensitz: Obrigheim
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9.610.007, Version 2.01

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	9.694.038D
Gültig ab: 10.11.2020 Valid from:		Seite 1/1 Version 1.03
<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;">NanoPak hm 950 DC-V / hm 950 DC-VI</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: correspondre aux dispositions suivantes et standards harmonisés: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <p>Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. KRINKO / BfArM Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention(KRINKO) beim Robert Koch-Institut(RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte(BfArM) Bundesgesundheitsblatt 2012 55:1244-1310</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 Torsten Ehrhardt (0) 6261 / 9770-0 info@hawa.com 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 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.

9.694.038D Version 2.01

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



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