



hm 4000 DC-VI

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 following EU directives:
2006/42/EC, 2014/30/EU and 2011/65/EU.

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 V4.02.xx 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, remove the mains plug from the socket and disconnect the machine with the plug from the power supply.

disconnect the machine from the power supply with the plug.

Cleaning the machine "outside"

Clean the "outside" of the machine with a damp cloth made of a cleaning cleaning agent suitable for stainless steel. Then allow the machine to dry well and/or dry it well.

Disinfection

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

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

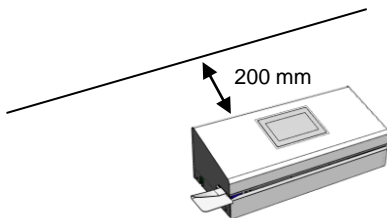
2 Commissioning

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



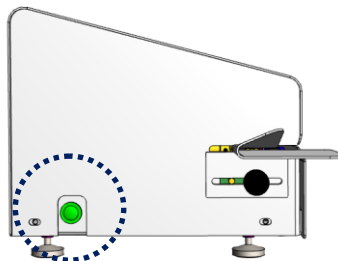
2.1.4 Step 4 Switch on the device

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.

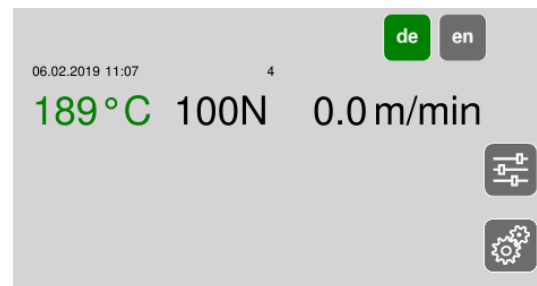
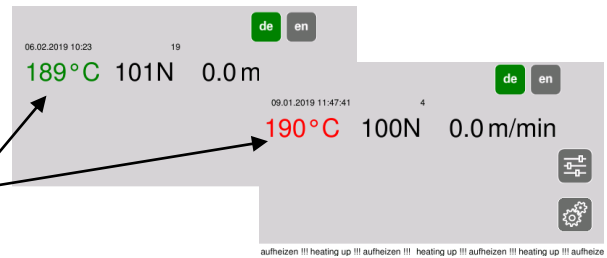


2.1.5 Step 5 Checking of the sealing parameter sensors

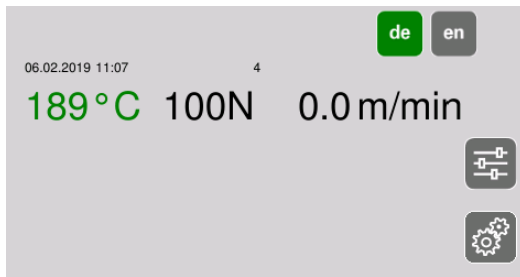
After switch-on, the device heats up to the default sealing temperature of 190°C. The process variables temperature, contact pressure and throughput speed are checked.

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



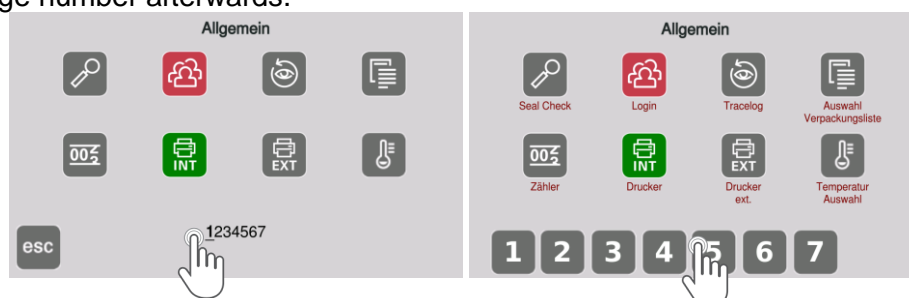
Symbol	Function	Note
190°C	Displays the current sealing temperature	
100 N	Displays the current pressing force	
0.0 m/min	Displays the current throughput speed	Value > 0 only when motor is running
	Settings	
	Control centre	Check of the functions heating, DMS module and motor as well as the device operating 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)
4	Display of the absolute batch counter / the set quantity	

2.1.7 Step 7 Switch of the individual menu levels

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

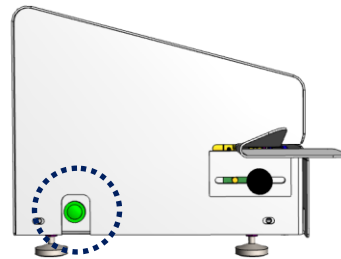
The default sealing temperature is 190°C and the throughput speed is 10 m/min. This ensures pouches and reels are sealed in accordance with EN 868-5 and EN ISO 11607-1.

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
	Select packaging list	Selecting packaging lists that have already been created
	Batch counter	Setting the batch counter for counting up/down
	Printer	Switching the internal printer on/off
	External printer	Switching the external printer on/off



2.1.9.2 Layer 2 Printer

Symbol	Function	Note
	Packaging lists	Creation of packaging lists
	Prefixes	Changing data names for print data
	Configuration of the external printer (ext. printer data)	Creating, editing and deleting formulas for external printer data
	Standard printer settings	Simplified printer configuration in standard mode




2.1.9.3 Level 3 Print data

Symbol	Function	Note
	Name list	Creating, editing and deleting users
	Batch data	Creating, editing and deleting batch data
	Steriliser list	Creating, editing and deleting steriliser data
	CE list	Creating, editing and deleting CE lists
	Reference list	Creating, editing and deleting reference numbers
	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.
	ProTrak	Recording of all data collected during the sealing process (temperature; contact pressure and sealing speed) (can only be used in conjunction with UDI/ProTrak USB 1.490.036)

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).
	ValiUp	Determining the ideal sealing temperature for the material used by means of an aid
	Key lock	Locks the settings on the home screen so that data can only be selected but not deleted or edited.
	UDI	Creating, editing and deleting UDI data (can only be used in conjunction with UDI/ProTrak USB 1.490.036)

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[°F] ● 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


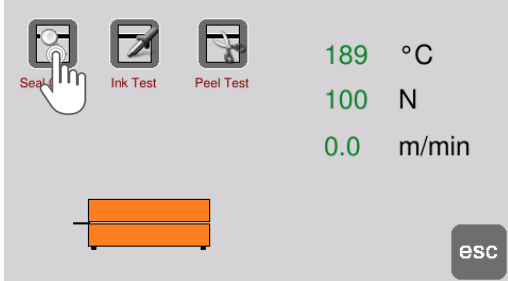
3.3 Peel test




Cut out the test strips after sealing



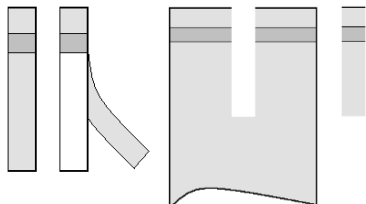
4. Insert med. packaging, width min. 200 m.

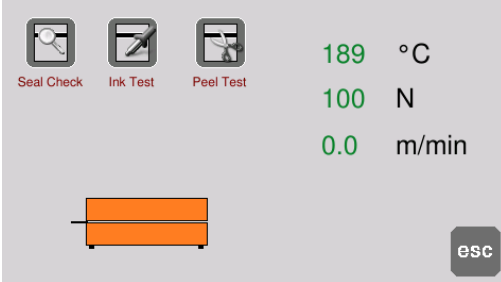
This key is used to cancel the function

esc



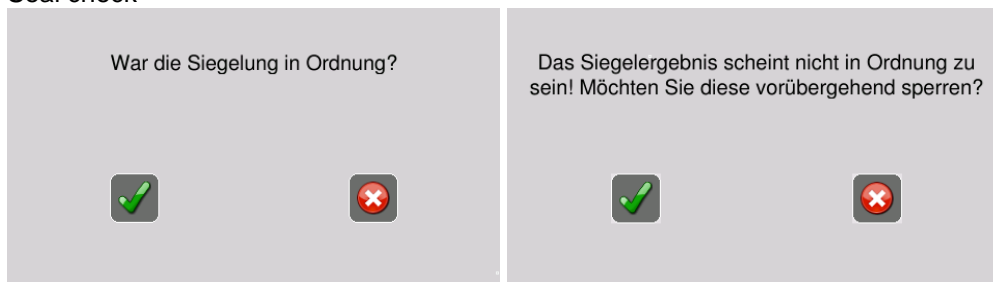
2.2.1 Blocked device due to failed seal check tests

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

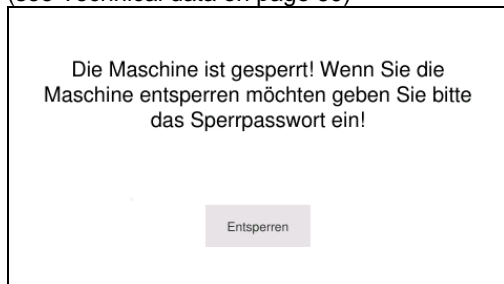
Notification after two messages rated as not OK

Seal check

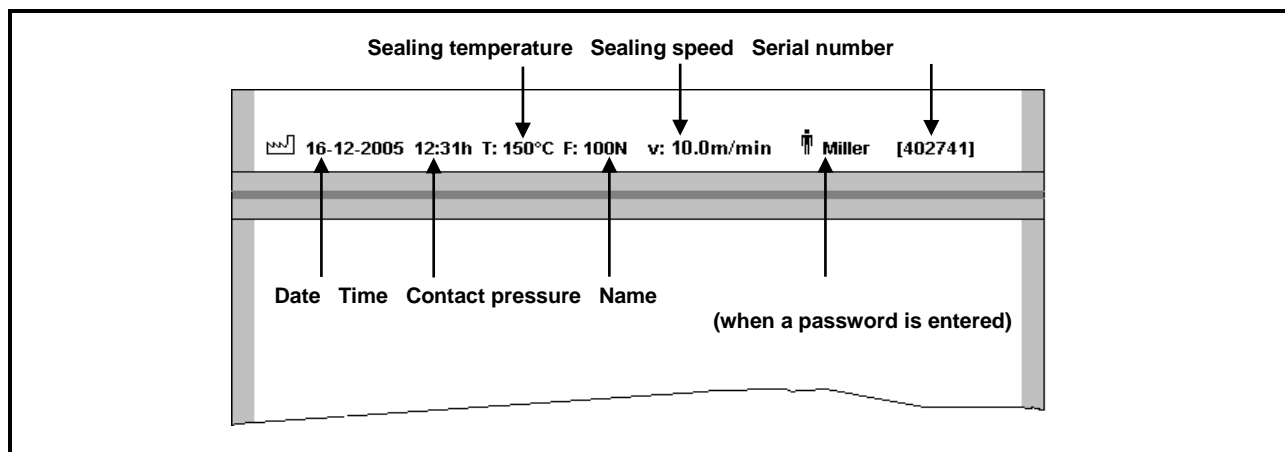


If the screen has been locked due to a faulty seal check, it can be unlocked again by entering the lock password.

(see Technical data on page 60)



2.2.2 Printing of the test parameters on a package



2.2.3 Printing of the test parameters on a label

ONLY with the label printer connected!

If the ValiPrint label printer is connected and switched on, a label is also printed with each test selected

	Date and time
T[°C]	Sealing temperature
F[N]	Contact pressure
v[m]	Sealing speed
	User name (when entering password)
SN	Serial number

23.08.2017 12:00
T[°C] 190
F[N] 100
v[m] 10.1
U1
SN 123456

Approval:

3 Data entry

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 a packaging list has been selected if they have been created in the selected language.

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

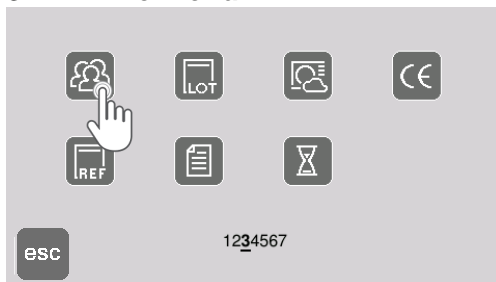
The names and passwords of users who will be operating the device are entered into the user list. The users on the list can/must log in to the device before starting their task via the password entered into the list, i.e. they can also log out when their task is complete.

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. You can activate the printout of a logged in user name on the packaging in a packaging list.

3.2.1 The menu



Benutzername:	Passwort:	Administrationsrechte:

+

esc

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

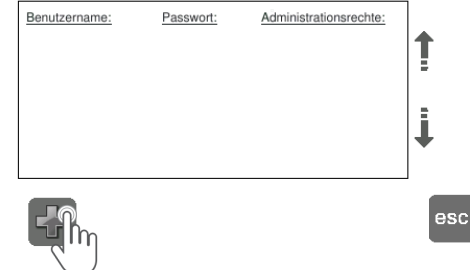
If this setting is made, the display language changes to the language set here, regardless of the default setting, as soon as the user has logged in.

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

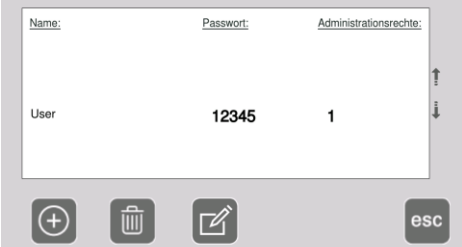



Exit this menu level



esc 1234567




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 

 it this menu level






Benutzername:	Passwort:	Administrationsrechte:
User	12345	1



Name: Passwort: Administrationsrechte: 

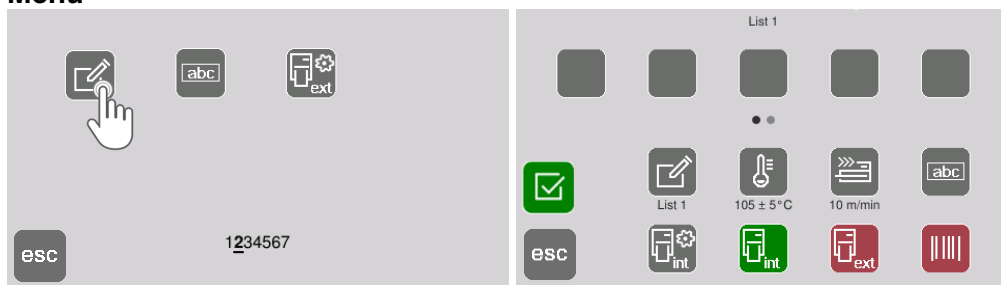




Benutzername:	Passwort:	Administrationsrechte:
User	12345	0



3.3 Packaging lists

Menu



Key	Function	Note
	Select the packaging list menu	
	Exit menu level	Back to the home screen

3.3.1 The settings of a packaging list

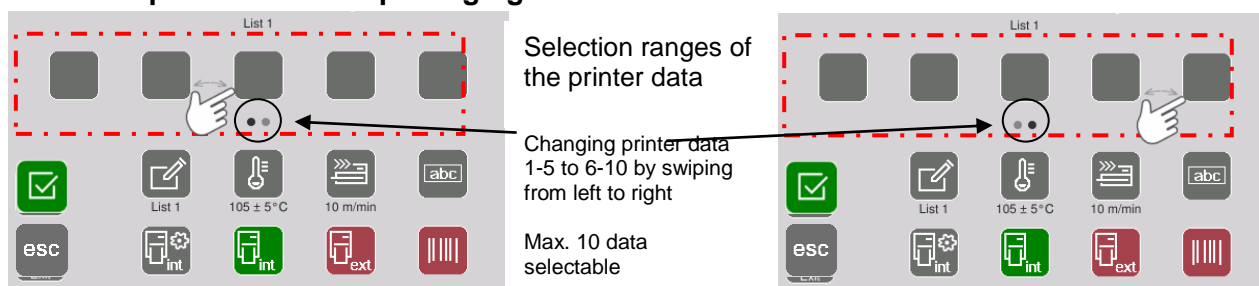
A max. of twenty lists can be created for different types of packaging.

These correspond to various "formulas" with different settings from the following table.



Key	Function	Note
	Entering the packaging designation Selection of additional colour identification	Alphanumeric text, max. 20 characters Colours: grey, violet, red, blue, green, white, yellow
	Selection of the sealing temperature and deactivation tolerance	[°C] 80 - 220 or [°F] 176- 428 [°C] ± 2 - ±5 or [°F] ±36 - ±41
	Selection of the throughput speed	5.0 m/min – 13.0 m/min
	Configuration of the internal printer	<ul style="list-style-type: none"> ●Automatic character width (FontMatic) or manually set character width ●Manually set character spacing Spacing of the start print to the side edge 1 mm – 100 mm ●Image of print data can be rotated 180° relative to the upper packaging edge
	Activate printer activity by pressing and holding the key	Switch the label printer for the selected packaging list on or off → Press symbol: Setting the printer data → Press + hold symbol: Switching the printer on, off
	Configuration of the internal printer	<ul style="list-style-type: none"> ●Automatic character width (FontMatic) or manually set character width ●Manually set character spacing Spacing of the start print to the side edge 1 mm – 100 mm ●Image of print data can be rotated 180° relative to the upper packaging edge
	Printer activity	Switch the internal printer for the selected packaging list on or off
	Selection of text or barcode	The selected data are printed as a barcode
	Selection of data designation	Data description (prefix) Symbol: or Text: Date
	Exit menu level	

3.3.2 The printer data of a packaging list



Key	Data	Note
	Date	Formatting depends on the selected configuration
	Expiry date	Months 1 ● 3 ● 6 ● 9 ● 12 ● 24 ● 60 ● fixed date ● 1 - 365 days
	Name list	Only with previously setup list (how to create described in 3.1)
	Batch data	Only with previously setup list (how to create described in 3.3)
	Info	Only with previously setup list (how to create described in 3.3)
	CE information	Only with previously setup list (how to create described in 3.3)
	Batch counter	
	Unit counter TOTAL	Batch counter total since the first sealing
	Time	
	Sterilisation type	STEAM ● EO ● FORM ● VH2O2 ● IRRAD ● DRY
	Steriliser data	Only with previously setup list (how to create described in 3.3)
	Package content quantity	1 - 10
	Serial number	Printout of the current device serial number
	Sealing temperature	Printout of the actual values used during the sealing process
	Contact pressure	Printout of the actual values used during the sealing process
	Throughput speed	Printout of the actual values used during the sealing process
	"One-time use" symbol	
	"Observe note" symbol	
	Reference data	Only with previously setup list (how to create described in 3.3)
	No print data	No printout in the print sequence

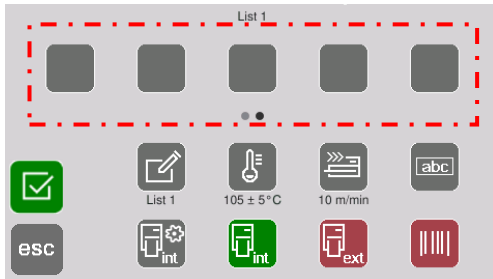


A red symbol means variable data such as the expiry date

3.3.3 Printer data selection

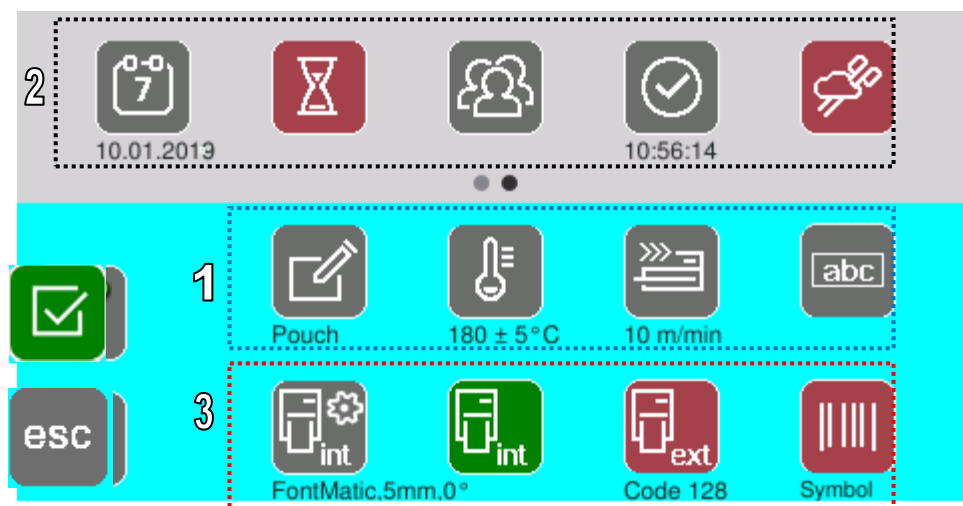
The individual printer data can be printed by pressing the desired free fields several times
1-5 or 6-10 can be set in the selection ranges.

➔ Selectable data is shown and explained in Chapter 3.3.3.



3.3.4 Example of creating a packaging list

Packaging parameters	Parameter data	
Packaging designation	"Pouch"	
Colour identification	Blue	
Sealing temperature	180°C	
Switch-off tolerance	± 5°C	
Sealing time	10.0 m/min	
Print data of the internal printer	Display of the print data:	As text
5 print data on one line	Date	Current date
	Expiry date / deadline	3 months
	Name	Miller
	Time	Current time
	Sterilisation type	STEAM
Configuration of the internal printer	Character width	automatic, FontMatic
	Spacing of the start print to the side edge	10 mm
	Relative to the upper packaging edge	0°
	Active printer:	Int. printer "ON" Ext. printer "OFF"
	Selection of text or barcode:	Text



3.3.4.1 Enter the package designation and determine an identification colour

1. Activate the **■ Designation ■** entry

2. Enter packaging designation by pressing the input field

3. Press the button several times until the background colour of the packaging designation appears in the desired colour.

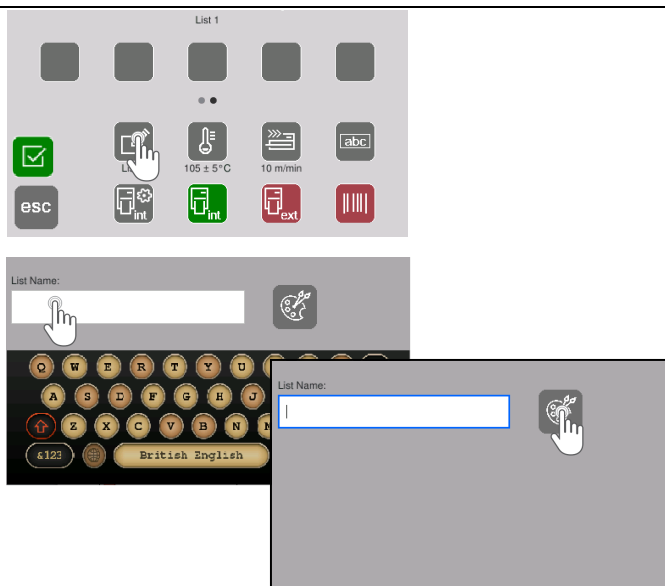
4. Confirm the packaging designation by pressing the Enter button.



Activate



Cancel



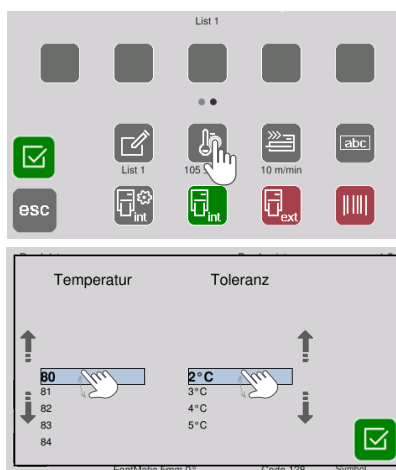
3.3.4.2 Select the sealing temperature

1. Activate the **■ Temperature ■** selection

2. Change the temperature and tolerance by swiping upwards or downwards



Activate

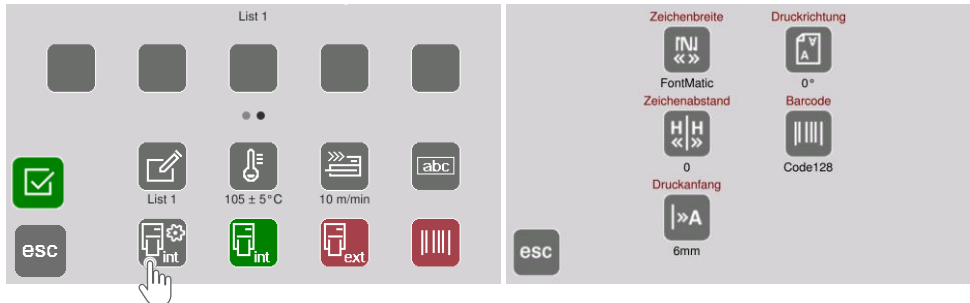


3.3.4.3 The settings of the internal printer




The internal printer can be set individually for each packaging list!

3.3.4.3.1.1 The menu

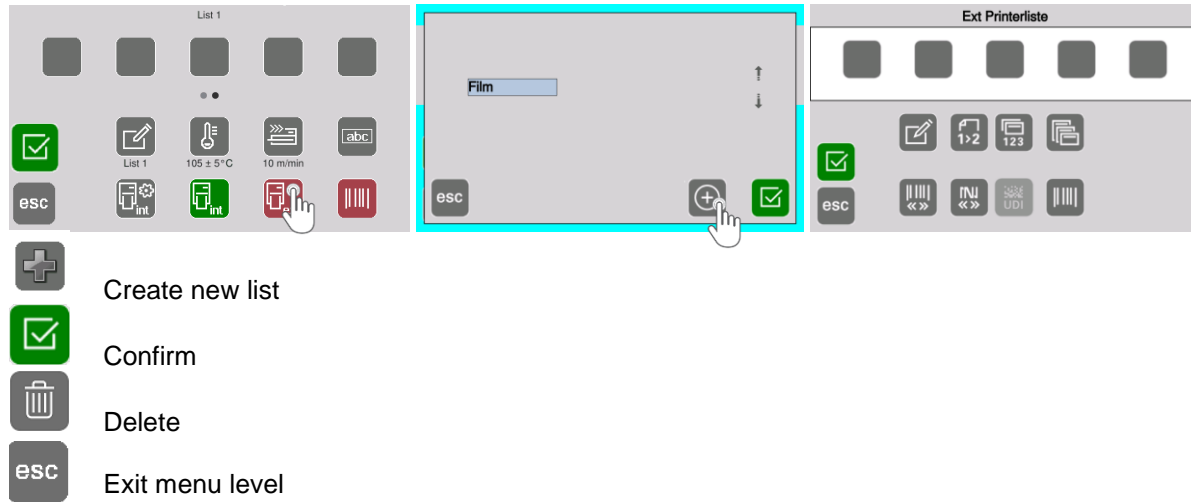


Key	Function	Note
	Character width	<ul style="list-style-type: none"> ● FontMatic, ● character width 1, ● character width 2, ● character width 3
	Character pitch	Only active when FontMatic is not active <ul style="list-style-type: none"> ● character spacing 1, ● character spacing 2, ● character spacing e 3
	Print start	Spacing of the print line from the side edge of the packaging adjustable 1 mm – 100 mm (default setting 5 mm)
	Print direction	Representation of the print image to the upper edge of the packaging 0° or flipped 180° (default setting 0°)
	Barcode type	Data that will have the barcode character in the print sequence can be printed using either <ul style="list-style-type: none"> ● Code 128, ● Code 39, ● Code 93, ● Code 2/5 (default setting code 128)
	Exit menu level	

3.3.4.3.2 The settings of the external label printer

 The external label printer can be set individually for each packaging list!

3.3.4.3.2.1 The menu













➔ The external printer is activated by pressing the symbol.







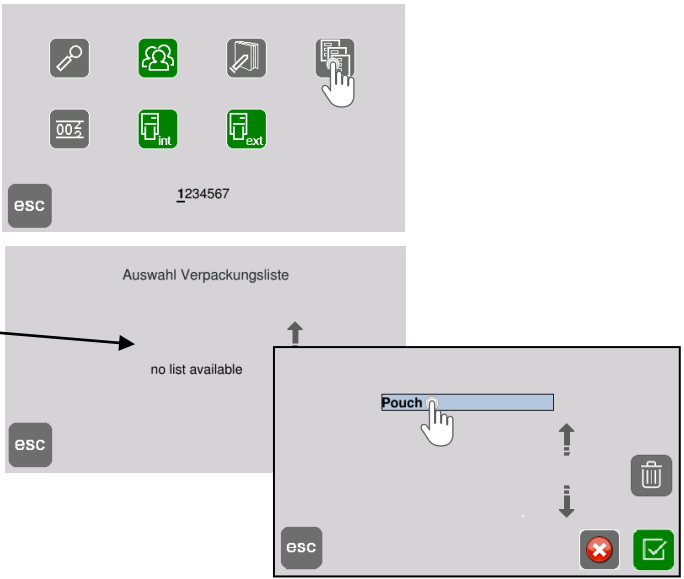
Not active



Active

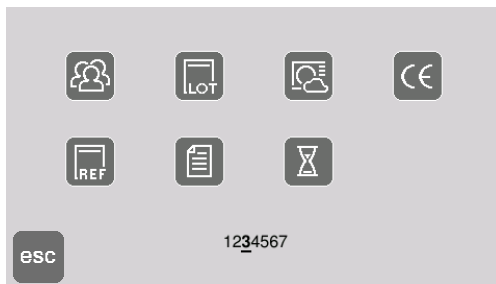
Key	Function	Note
	Print mode	<ul style="list-style-type: none"> ● Manual label printing ● Label printing after each sealing (default setting) ● Label printing after every second sealing
	Label size	<ul style="list-style-type: none"> ● 55 x 33 mm Number of lines of print without HIBC data: 5 With HIBC data: 4 ● 60 x 44 mm Number of lines of print without HIBC data: 7 With HIBC data: 5
	Character width	<ul style="list-style-type: none"> ● 1 Text ● 2 Text (default setting)
	Label quantity	Selection 1 - 10, number of printed labels
	Width of the barcode	<ul style="list-style-type: none"> ● 1  (default setting) ● 2 
	Print UDI	Print HIBC data Primary code (UDI-DI) and secondary code (UDI-PI) in one DataMatrix code (can only be used in conjunction with UDI/ProTrak USB 1.490.036)
	Barcode	All data on the label are printed with code 39.
	Exit menu level	

3.3.4.4 Display the packaging list

<p>1. Activate the ■ Packaging lists ■ menu</p> <p>2. Select the packaging list → If no list has been created, this is displayed accordingly</p> <p>3. Select and activate the packaging list</p> <div> Activate</div> <div> Delete a list</div> <div> Cancel/deactivate the packaging list</div> <div> Exit menu level</div>	 <p>The screenshot shows the device's menu interface. At the top, there is a row of icons: a magnifying glass, a group of people, a document with a pencil, and a document with a hand. Below these are icons for '00%', 'int', and 'ext'. An 'ESC' button is at the bottom left. The main display area shows 'Auswahl Verpackungsliste' and 'no list available'. A callout box highlights the 'Pouch' list, which is selected. The callout box also shows an 'ESC' button, a red X icon, and a green checkmark icon.</p>
--	---

3.4 Data lists

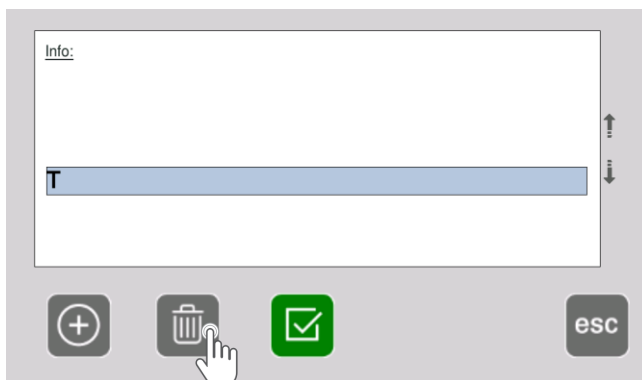
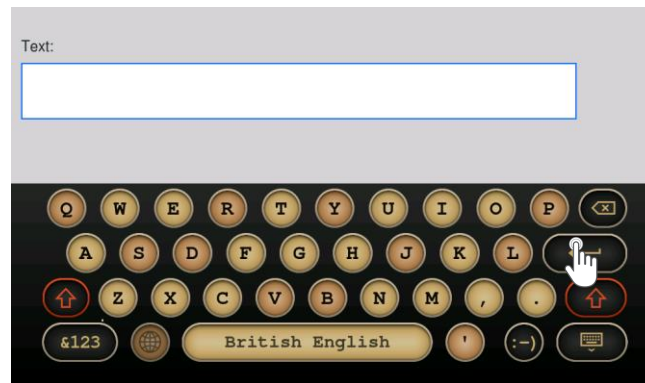
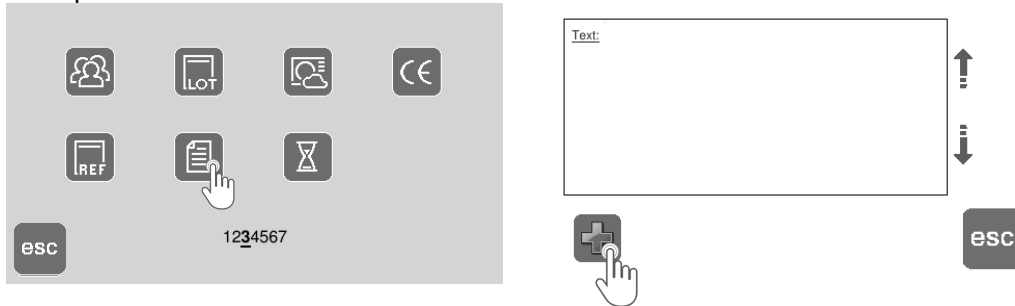
3.4.1 The selection menu



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 batch data	Batch name, batch numbers	The number is overwritten after each new entry
	List with steriliser data	Steriliser designation or serial number	Length of list texts: 20 alphanumeric characters Number of list texts: 500, individual entry or one after another
	List with CE data	EN 980	
	List with reference data	Article number, serial number	
	List with information	Device designations, department names	
	Selection of the expiry date		
	Exit menu level		

3.4.2 The Processing menu

Example of an information list



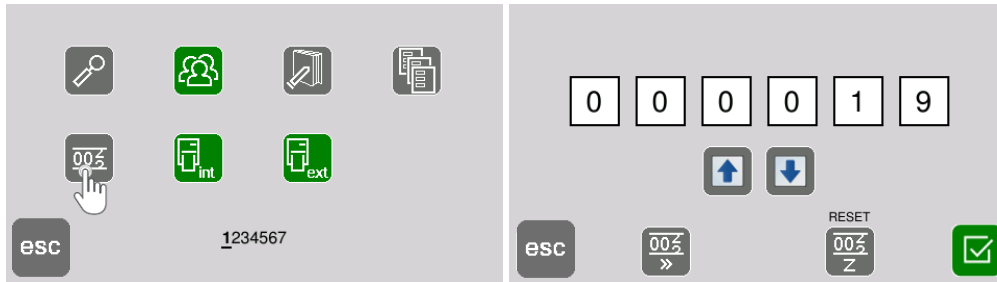
Key	Function
	Re-enter information
	Delete information
	Confirm/activate
esc	Exit menu level




4 Device configuration

4.1.1 Batch counter

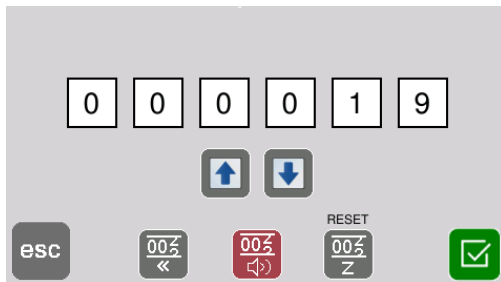
4.1.1.1 Batch counter functions





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

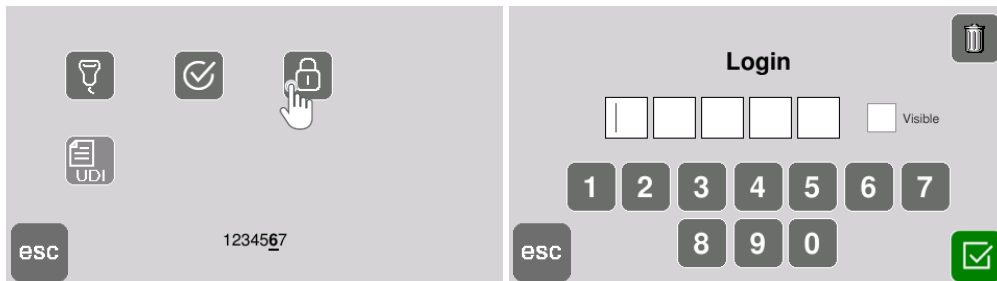




Key	Function	Note
	0 0 0 0 1 9	Displays the current value
	0 0 0 0 1 0	Select the individual digits of the batch counter; the respective number is highlighted in blue and the desired quantity can be set using the ↑ and ↓ arrow keys (e.g.: 10 items)
	Switches the counter to forwards counting	With a counter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

4.1.2 Key lock



You can only lock the keys if a list with names was created in which at least one person in the list has the administrator right! Selecting or scanning data is not affected.



Key	Function	Note
 	Lock deleting and editing settings.	<p>All symbols stored on the home screen can be selected by users, but not deleted or edited. An administrator is required for this.</p> <p>The lock can be deactivated by entering the password of someone in the name list who has the administrator right</p>



Not active



Active




The screen is locked for users without special rights once an administrator has been configured in the list of names.


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.

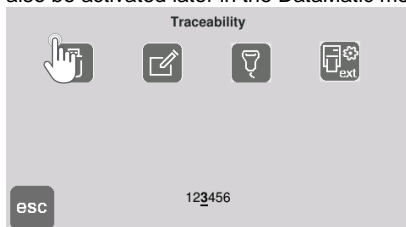
 If the DataMatic function is activated, a sealing process can only be started if a USB stick is also plugged in!

 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 .

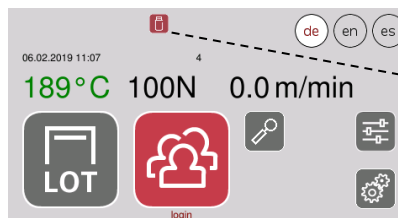
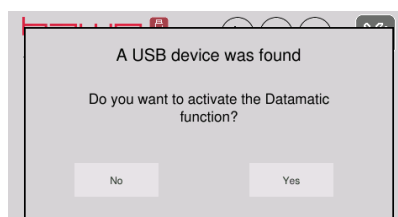


Inactive

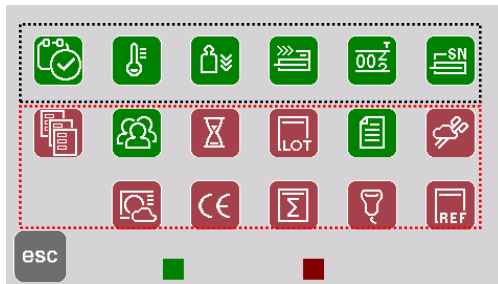


Active after long pressing

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



5.1.2 Configuring DataMatic data



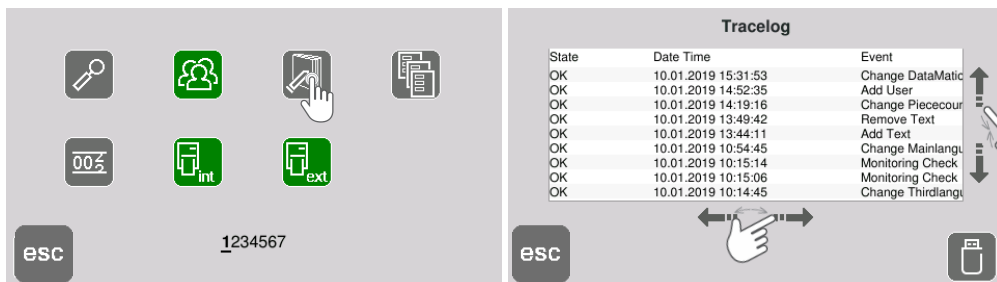
Keys	Data	Note
	Date and time Sealing temperature Contact pressure Throughput speed Unit counter TOTAL Device serial number	Fixed recording data
	Selected packaging Name Expiry date Batch number Info Sterilisation type Steriliser data CE data Package content quantity Data of the barcode scanner Reference data	Optional recording data

5.1.3 Show the DataMatic data on the device display



Only possible with a contacted USB stick containing recorded data!

5.1.3.1 The display menu

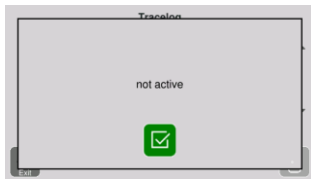


Key	Function	Display	Function
	Recorded TraceLog (logbook) data	10/01/2019	Date of the recording
	Scroll up and down	0 – 9	Data counter
	Scroll left and right		
	Exit menu level		
	Read the DataMatic data		

5.1.3.2 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

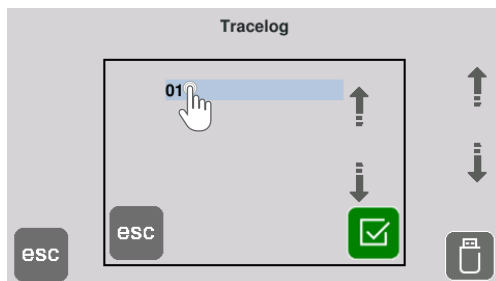
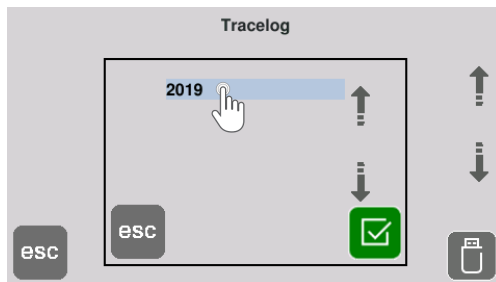
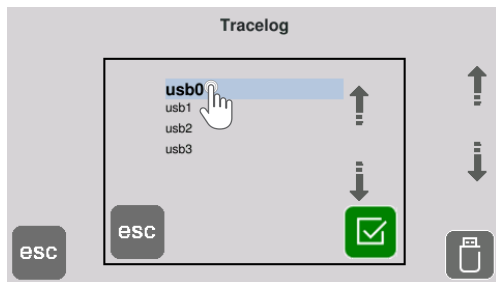
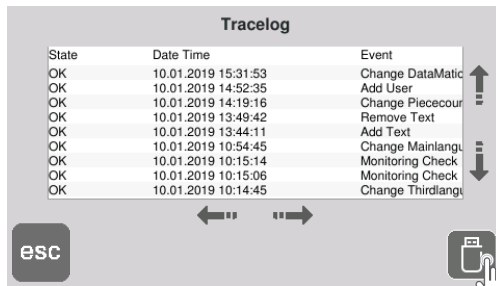
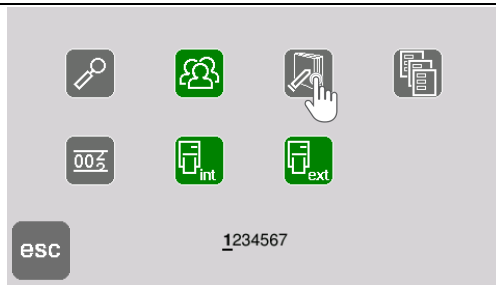


Confirm

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

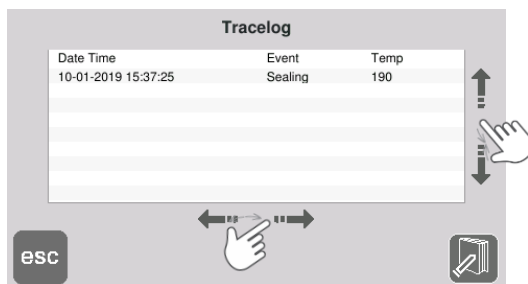
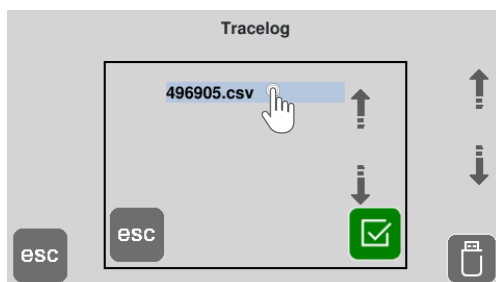
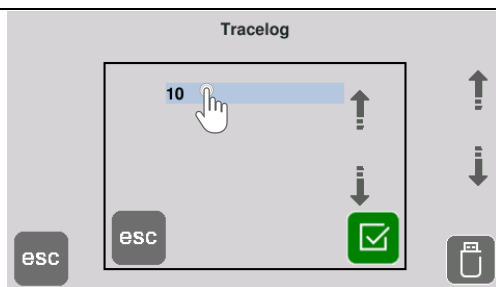
Sterilisation type

CE data

Package content quantity

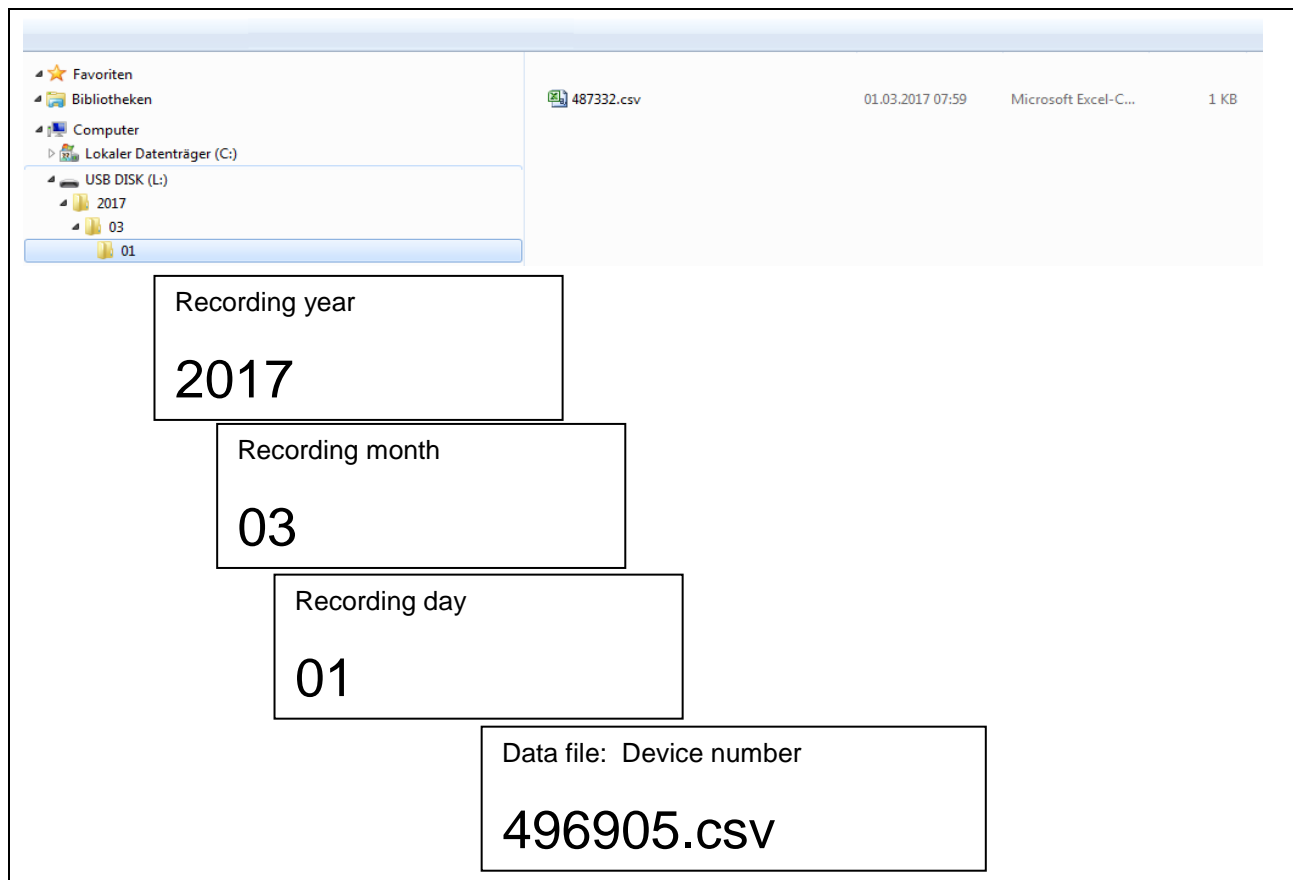
Data of the barcode scanner

Reference data



5.1.4 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)

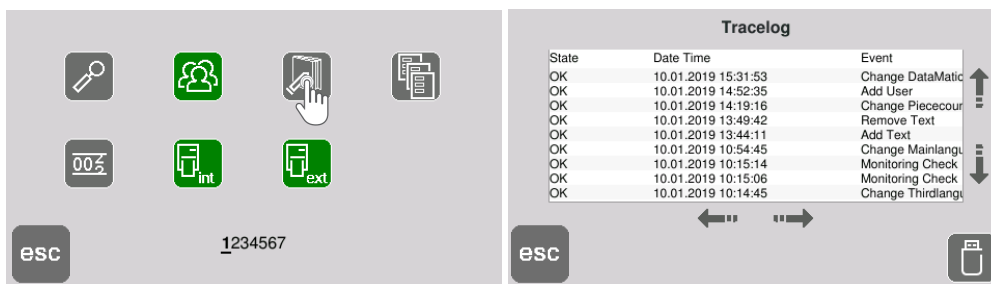
This logbook contains the temporary recording of various completed actions, events and faults that have occurred on the device.

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 Data designator (prefix) - Symbol or text



A text as a data designator is only possible for the internal printer!

The data designator for different print data can be a symbol or text.

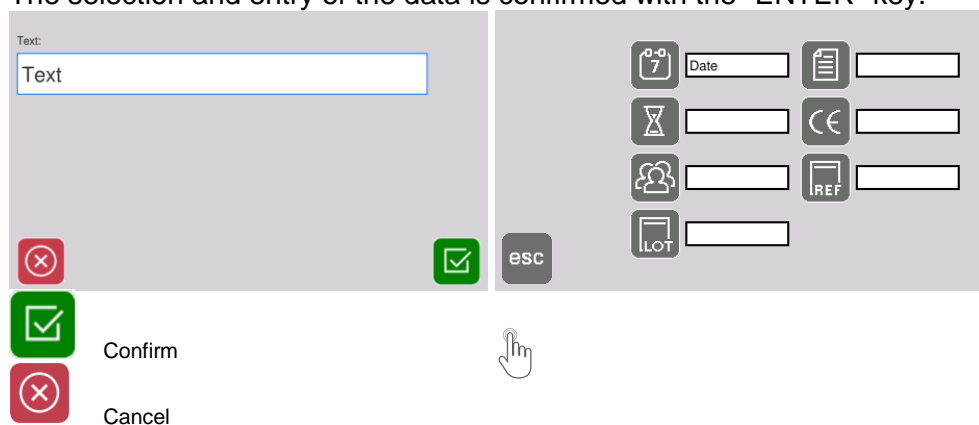
If the text is selected as the data designator, this must be created beforehand

**The prefix is defined in the individual packaging lists
See Chapter 3.3.2**

Using the packaging date as an example:



The selection and entry of the data is confirmed with the "ENTER" key.



Key	Function	Example	Replaces the symbol
	Text date	Packaged:	
	Text for sterile product storage period	Use by:	
	Text for names	Mr./Mrs./Miss/Ms.:	
	Text for batch data	Lot:	
	Text for information	Instrument:	
	Text for CE data	CE EN:	
	Text for reference data	Art. no.:	
	Exit menu level		

5.5 Print data as a barcode



The printing of data as a barcode is only possible if the language German or English has been set!
This applies for the internal printer and the label printer!

The following data are NOT printed as a barcode:

	Data		Data
	Time		"One-time use" symbol
	Sealing temperature		"Observe note" symbol
	Contact pressure		
	Throughput speed		

1. Activate packaging list

2. Press the Barcode button
→ Symbol changes colour from grey to red

Not active

Active

3. Tap data
e.g. the user name
The barcode symbol appears next to the serial number symbol

If you wish to undo this function, it can be done in the same order!

Exit this menu level

The screenshots show the following steps:



- Initial menu with 'Barcode' button in grey.
- 'Barcode' button is pressed and turns red.
- The red 'Barcode' button is used to activate the barcode for the 'User' data field.
- The 'User' data field now shows a red barcode icon next to the serial number.
- The 'ESC' button is used to exit the menu.

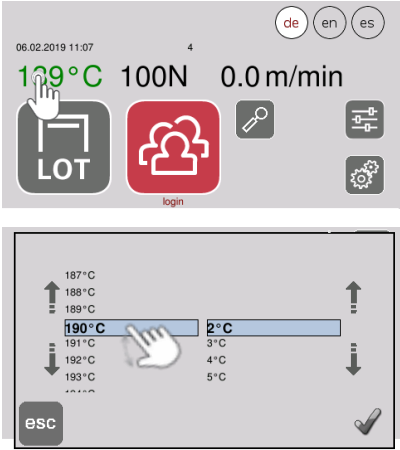
5.6 Direct change of the process variables of a selected packaging

The sealing temperature or throughput speed of the packaging currently selected can be changed directly without calling up any menus.

5.6.1 Changing the sealing temperature



1. Activate the temperature by pressing and holding down the display.
2. Select the desired temperature
3. Confirm the selection

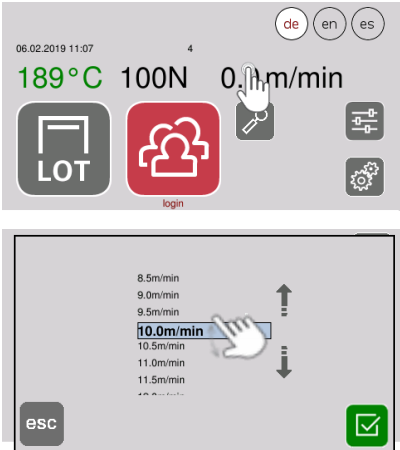
 Confirm
 Cancel



5.6.2 Changing the throughput speed

1. Activate the selection of the throughput speed by pressing and holding down the display.
2. Select the desired throughput speed
3. Confirm the selection

 Confirm
 Cancel





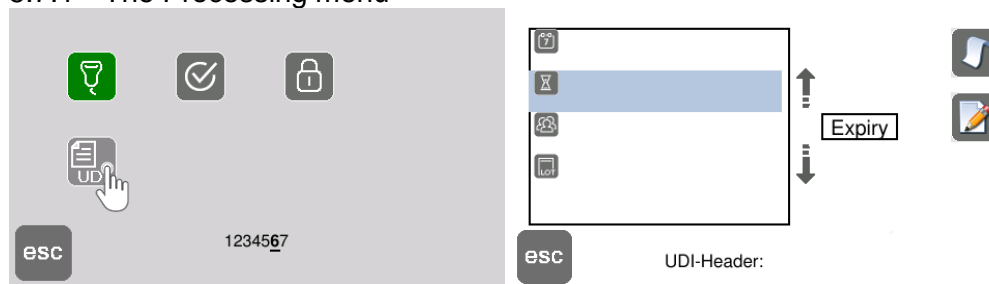
5.7 UDI marking

The marking is made using the HIBC coding system in accordance with the ANSI standard "ANS HIBC 2.5" embedded in the ISO standards for product and packaging marking ISO 22742, ISO 28219.

If the UDI marking is created and active, the primary code (UDI-DI) and secondary code (UDI-PI) are printed as separate, rectangular DataMatrices (DMRE) on the packaging and if the label printer is connected as a standard, square DataMatrix on one label.

To create or activate a UDI marking, the coding key (Art. No.: 1.561.007) must be inserted in one of the USB sockets!

5.7.1 The Processing menu



Function is not active without special USB stick

Key	Function	Note
	Enter the product code	Entry according to the listing in the GUDID (USA) or EUDAMED (Europe) databases The system identifier "+" is added automatically
	Enter data identifiers	Only use data identifiers compliant with the definitions in ASC MH 10 ISO/IEC 15418! The "/" separator is added automatically
	Exit menu level	

Example for entering the UDI header

Select the header symbol and enter the corresponding names using the keypad. Confirm with the ENTER key and finally activate with the checkmark.



Confirm



Cancel

5.8 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



5.9 Display

5.9.1 Standby

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

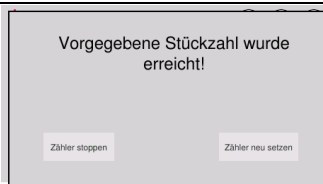
Reactivate device function

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

5.9.2 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.

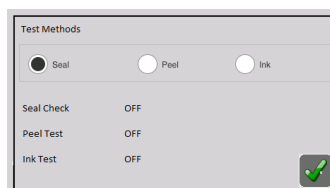
For further use, the counter must be reset or the counting direction must be changed to count forward by pressing the "Stop counter" key.



5.9.3 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".



5.9.4 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.

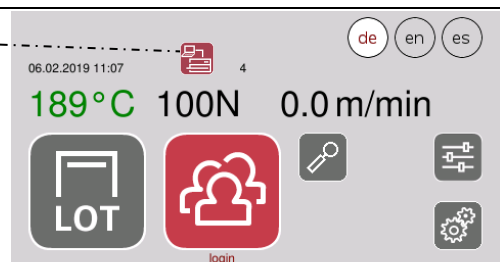
Customer setting via the Service menu (see device technical manual)



5.9.5 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)



5.9.6 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)

Sie müssen eingeloggt sein, um die Maschine zu bedienen










5.9.7 The display of special settings

Tap the **Information** symbol

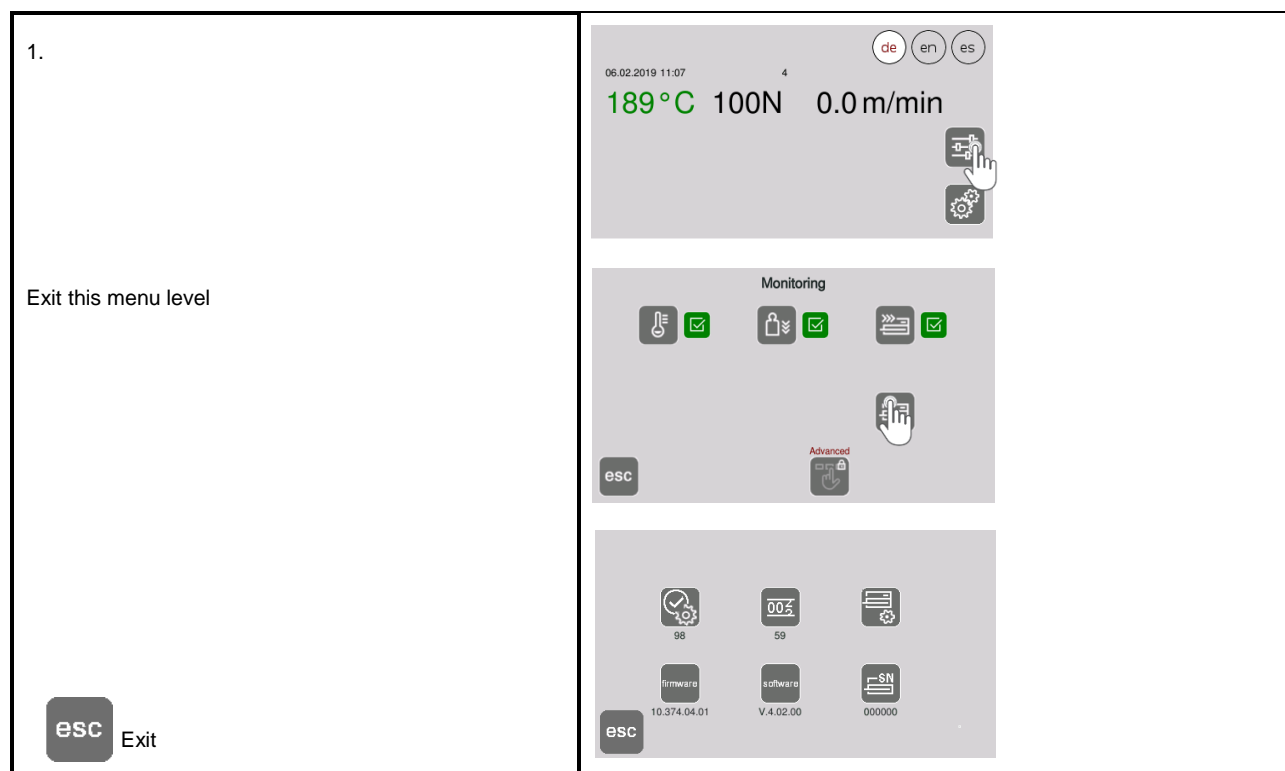
Exit the special display

The screenshot shows a device display with the following elements:

- Top status bar: 06.02.2019 11:07, 4
- Main display area: 189°C, 100N, 0.0 m/min
- Information symbol (hand icon) and settings symbol (gear icon) on the right.
- Bottom section with four status icons: temperature sensor (thermometer), contact force sensor (hook), throughput speed sensor (conveyor belt), and device operating data (document).
- 'esc' button at the bottom left.

Symbol	Display
 	Checking of the temperature sensor positive
 	Checking of the contact force sensor positive
 	Checking of the throughput speed sensor positive
	Device operating data

5.9.8 Display of operating data

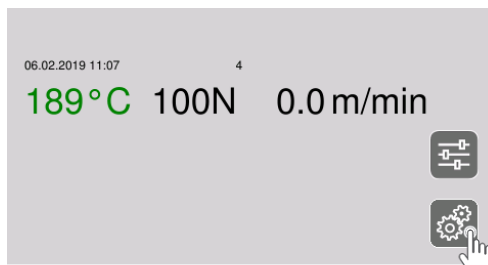


Symbol	Display
	Operating hours
	Software version
	Device serial number
	Batch counter total
	Firmware version
	Maintenance date

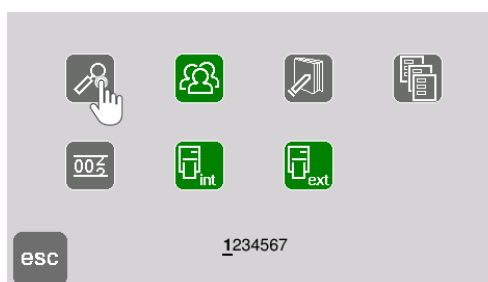
6 Special functions

6.1 Individual setting of the home screen

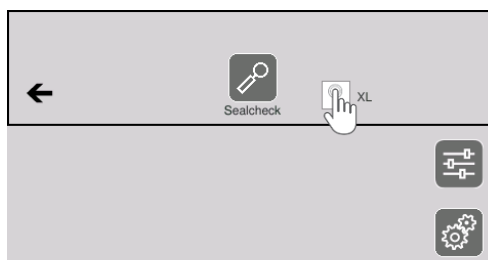
1. Activate the operating data menu



2. Press and hold to select any symbol

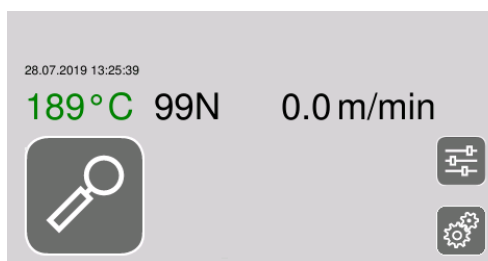
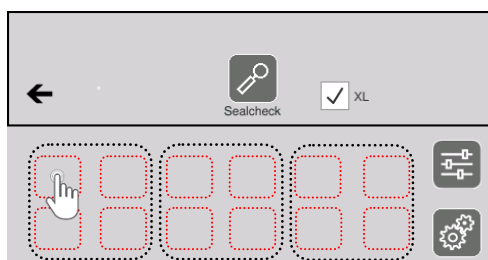


3. The size of the symbol can be changed by activating the "size XL" key.



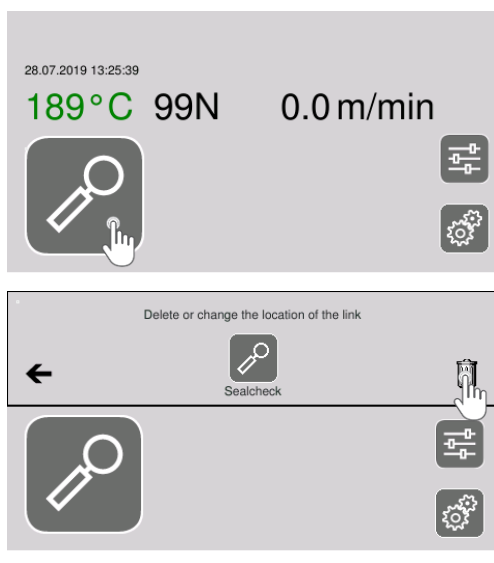
4. The symbols can only be freely positioned on the home screen. Only the big symbols can only be selected in two positions.

→ For large symbols, always select the upper left corner of the respective placeholder by tapping.



If the symbol in the home screen is to be deleted again or the position is to be changed, the respective symbol can be edited by holding it down for a long time.

→ The position of the symbols can only be changed for small symbols.



6.2 Advanced mode / standard mode switch

1. Activate the operating data menu

2. Change the individual modes by pressing the button.
(see picture)
(The name displayed above the symbol corresponds to the current selection of the mode)

3. After selecting the button, a password must be entered.
(for more details, see Chapter 11/Passwords)

4. Confirmation to change modes.
After entering the password, a final confirmation of the change is required.

CAUTION:

The previously individually set home screen is reset after switching to standard mode and must be reset when switching to advanced mode again.



If the query made under point 4 has been confirmed, the corresponding mode is displayed in the start screen after pressing the ESC button.

→ In this case, the standard mode

Switching back to advanced mode is done in the same order.




7 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!

7.1 Commissioning the barcode scanner

7.1.1 Step 1 Unpack the barcode scanner

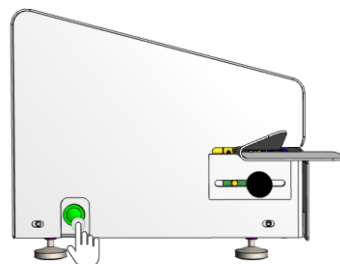
<p>Open the packaging</p> <p>Check to ensure that all parts are there and undamaged.</p>	<p>Barcode scanner with USB connection cable Art. No.: 1.490.029</p> 
--	--

7.1.2 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



7.2 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!


7.2.1 Data of a created barcode list

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

The data are read in via a scan list that has been created with the hs 980 BR software (Art. No.: 1.490.028). 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
 Names	Scan list with user names	
 Info	Scan list with information	Assignment of general barcode data possible
 Batch data	Scan list with batch data	Assignment of general barcode data possible
 Steriliser data	Scan list with steriliser data	Assignment of general barcode data possible
 CE data	Scan list with CE data	Assignment of general barcode data possible
 REF Reference data	Scan list with reference data	Assignment of general barcode data possible

7.2.2 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.

7.2.2.1 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.

8 The external printer

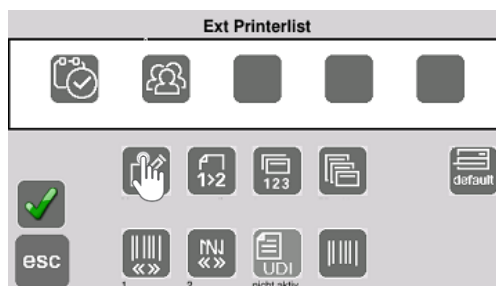
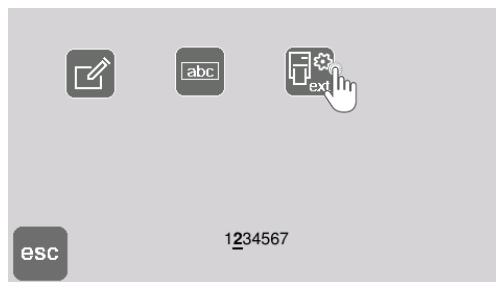
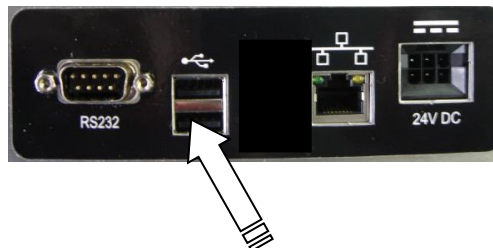
1. Connect the external printer according to the instructions supplied with the printer and connect it to one of the USB slots on the back of the device.

2. Only then switch on the device

3. Open menu level 3 "Traceability" and select the symbol for the external printer

4. Configure the external printer and save it under the desired formula name using the save function.

For the creation of formulas and their function see also Chapters 3.3.2 and 3.3.3



Key	Function	Note
	Name of the external printer formulas	
	Print mode	● Manual ● Each seal ● Every 2nd seal
	Label quantity	Freely selectable from 1-10
	Label size	<ul style="list-style-type: none"> 55 x 33mm 60 x 44mm
	Width of the barcode	<ul style="list-style-type: none"> 1 (default setting) 2
	Character width	<ul style="list-style-type: none"> 1. Text 2 Text (default setting)
	Print UDI	Print HIBC data Primary code (UDI-DI) and secondary code (UDI-PI) separately as rectangular data matrix (DMRE according to DIN 16578) format 12x26 & 12x36
	Barcode type	Data marked in the print sequence with the barcode character is optionally printed with ● code 128, ● code 39, ● code 93, ● code 2/5 (default setting code 128)
	Default settings	Print UDI Not active
	Exit menu level	

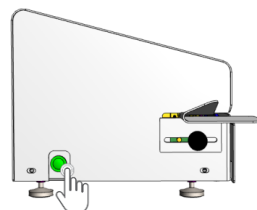
9 Switch off the device

Briefly press the Power button

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

10 Troubleshooting and maintenance

10.1 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>

10.2 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.

10.3 Service

	Your hawa customer service is available from Mon-Fri 8:00 to 16:00 at the following number: +49 (0)6261-9770-31.
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10.4 Spare parts 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>Address, e-mail address or fax number Enter order number Enter device type Enter serial number Mark articles required Enter quantity required Sign order Send order</p> <p>➡ ① ➡ ②</p>

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	
<input type="checkbox"/>	PTFE tape sealing die	6.105.285	
<input type="checkbox"/>	PTFE tape Guide rail 500 mm	6.105.139	
<input type="checkbox"/>	Plastic pressure roller	2.230.008	
<input type="checkbox"/>	Toothed belt, drive 375 mm	6.271.011	
<input type="checkbox"/>	Toothed belt transport hm 4000 480 mm	6.271.022	
<input type="checkbox"/>			
<input type="checkbox"/>			

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"/>	Top die assembly	1.616.066	
<input type="checkbox"/>	Bottom die assembly	1.616.067	
<input type="checkbox"/>	Controller	1.410.117	
<input type="checkbox"/>	Touch display	1.410.118	
<input type="checkbox"/>	Heating cartridge	6.536.050	
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			

10.5 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

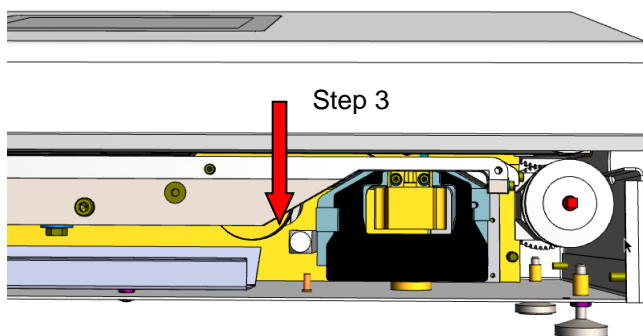
Step 2

Loosen the two screws on the underside of the device and then carefully remove the front panel.



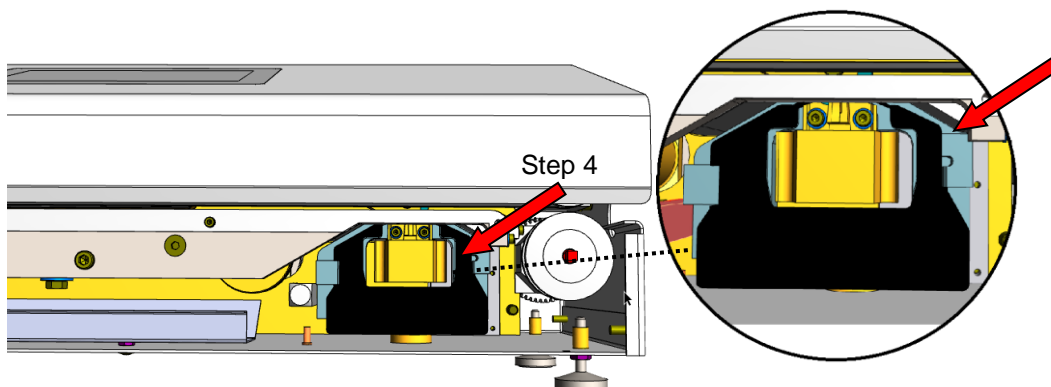
Step 3

Press and hold the lever down



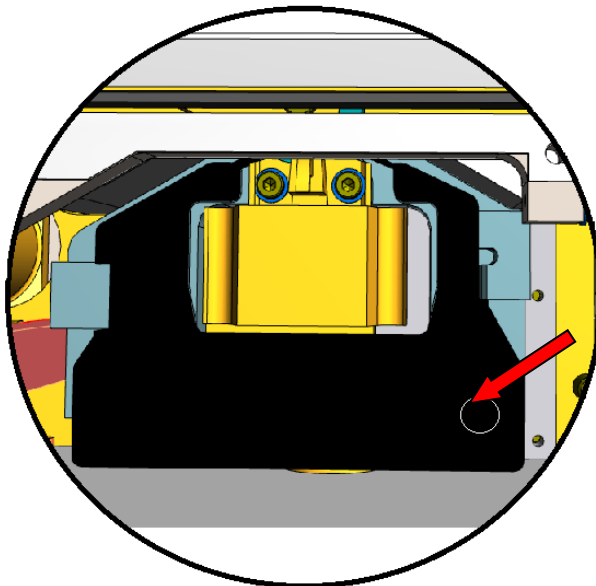
Step 4

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 **Fit the front panel using the two screws and perform a test printout.**

11 Technical data

11.1 Specifications

Connection data

Mains connection	[V]	100 - 240
Mains frequency	[Hz]	50 / 60
Power consumption	max. [W]	280

Mechanical system

Dimensions	Length [mm]	710
Including	Width	260
Infeed section	Height	220
Housing cover		Stainless steel AISI 304
Housing bottom		Stainless steel AISI 304
Weight	[kg]	19
Seal distance from edge	[mm]	0 – 35
Sealing seam width	[mm]	12
Sealing system		SealPeak (hawaFlex)
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



12 Declarations of conformity

12.1 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	9.694.045C																																																									
Gültig ab: 16.08.2021 Valid from:		Seite 1/1 Version 1.02																																																									
<p>Hiermit erklären wir, daß die Folienschweissmaschinen: Herewith we declare that the Foll 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;">hm 4000 DC-VI</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> </tr> <tr> <td>Machinery directive</td> <td></td> </tr> <tr> <td>Directive "CE" rel. aux machines</td> <td></td> </tr> <tr> <td>Directiva de Maquinaria de la CE</td> <td></td> </tr> <tr> <td colspan="2">Direttiva CE sulle macchine nella versione</td> </tr> <tr> <td colspan="2">Directiva da UE relativa a maquinaria</td> </tr> <tr> <td>EMV-Richtlinie</td> <td>EMC-directive</td> <td>2014/30/EU</td> </tr> <tr> <td>Directive CEM</td> <td>Directiva da 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</td> </tr> <tr> <td>Standard harmonise</td> <td>Las normas armonizadas</td> <td>EN ISO 13857:2019</td> </tr> <tr> <td>Norme armonizzate</td> <td>Normas harmonizadas</td> <td>EN IEC 63000:2018</td> </tr> <tr> <td></td> <td></td> <td>EN 60204-1:2018</td> </tr> <tr> <td></td> <td></td> <td>EN IEC 61000-6-1:2019</td> </tr> <tr> <td></td> <td></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 www.hawa.com </p> <p>Torsten Enhardt 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 da 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	Standard harmonise	Las normas armonizadas	EN ISO 13857:2019	Norme armonizzate	Normas harmonizadas	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																																																									
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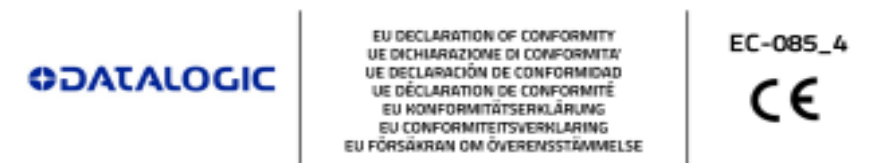
9.694.045 / Version 2.01

12.2 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	9.694.045D
Gültig ab: 01.11.2020 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;">hm 4000 DC-VI</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 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> </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="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 45%;">  hawa GmbH 74847 Obrigheim / Germany T +49 (0) 6261 / 9770-0 info@hawa.com www.hawa.com </div> <div style="width: 45%;"> <p>Torsten Enhardt Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany</p> </div> </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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12.3 CE declaration of conformity for barcode scanner



Apparatus / Apparato / Aparato / Appareil / Gerätetyp / Apparaatmodel / Apparatmodell

QuickScan QD2430 ; Barcode Reader

and all its models / e tutti i suoi modelli / y todos sus modelos / et tous ses modèles / und seine modelle / en al haar modellen / och alla sina modeller

Manufacturer / Produttore / Fabricante / Fabricant / Hersteller / Fabrikant / Tillverkaren

Datalogic S.r.l.
Via S. Vitalino 13, 40012 Lippo di Calderara (BO) - Italy

This declaration of conformity is issued under the sole responsibility of the manufacturer / La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante / La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante / La présente déclaration de conformité est établie sous la seule responsabilité du fabricant / Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller / Deze conformiteitsverklaring wordt verstrekt onder volledige verantwoordelijkheid van de fabrikant / Denna försäkran om överensstämmelse utfärdas på tillverkarens eget ansvar.

The object of the declaration described above is in conformity with the relevant Union harmonization legislation: / L'oggetto della dichiarazione di cui sopra è conforme alla pertinente normativa di armonizzazione dell'Unione: / El objeto de la declaración descrita anteriormente es conforme con la legislación de armonización pertinente de la Unión: / L'objet de la déclaration décrit ci-dessus est conforme à la législation d'harmonisation de l'Union applicable: / Der oben beschriebene Gegenstand der Erklärung erfüllt die einschlägigen Harmonisierungsrechtsvorschriften der Union: / Het hierboven beschreven voorwerp is in overeenstemming de desbetreffende harmonisatiewetgeving van de Unie: / Föremålet för försäkran ovan överensstämmer med den relevanta harmoniserade unionslagstiftningen:

2014/30/EU - EMC Directive
2011/65/EU RoHS Directive

References to the relevant harmonised standards: / Riferimento alle pertinenti norme armonizzate: / Referencias a las normas armonizadas: / Références des normes harmonisées: / Angabe der einschlägigen harmonisierten Normen: / Vermelding van de toegepaste relevante geharmoniseerde normen: / Hänvisningar till de relevanta harmoniserade standarder:

EN 55032, MAY 2015

ELECTROMAGNETIC COMPATIBILITY OF MULTIMEDIA EQUIPMENT - EMISSION REQUIREMENTS

EN 55024, NOVEMBER 2010

INFORMATION TECHNOLOGY EQUIPMENT - IMMUNITY CHARACTERISTICS - LIMITS AND METHODS OF MEASUREMENT

EN 50581, SEPT 2012

TECHNICAL DOCUMENTATION FOR THE ASSESSMENT OF ELECTRICAL AND ELECTRONIC PRODUCTS WITH RESPECT TO THE RESTRICTION OF HAZARDOUS SUBSTANCES

Lippo di Calderara,
 February 24th 2017



Ruggero Cacioppo
Product Quality Leader

12.4 CE declaration of conformity for label printer

EU DECLARACION DE CONFORMIDAD DEL FABRICANTE**Identificación de producto**

Producto: Impresora de código de barras
Marca: SATO
Tipo: CG2
Modelo: CG2
Opciones: Todas

Conformidad:

Este producto está conforme con las indicaciones de las Radio Equipment Directive: 2014 / 53 / EU basado en los resultados de prueba utilizando criterios armonizados.

Criterios Radio Equipment Directive utilizados:

EN 300 330 V2.1.1
EN 301 489-1 V2.1.1, EN 301 489-3 V2.1.1,
EN 62311: 2008

(EMC : EMC Directive : 2014/30/EU)

EN 55024:2010,
EN 61000-4-2 : 2009, EN 61000-4-3 : 2006 + A1 : 2008 + A2 : 2010,
EN 61000-4-4 : 2004, EN 61000-4-5 : 2006,
EN 61000-4-6 : 2009, EN 61000-4-8 : 2010,
EN 61000-4-11 : 2004,
EN 55032:2012,
EN 61000-3-2 : 2014,
EN 61000-3-3 : 2013

(Safety : LV Directive : 2014/35/EU)

EN 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013

Este producto cumple con la Directiva de RoHS 2011/65/EU en las restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos.

El marcado de CE tuvo lugar en el año 2014

Fabricante: SATO VIETNAM CO., LTD.
Plot B-2 Thang Long Industrial Park,
Kim Chung Commune, Dong Anh Dist,
Hanoi, Vietnam

Nombre y dirección del representante autorizado

Representante de la CE: SATO EUROPE GmbH;
Waldhofer Str. 98-104
69123 Heidelberg
Germany

Cargo: Director General
Nombre: Sr Tetsushi Kondo

Fecha: 13/06/2018





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