



HD 650 DCT-V EcoPak 07 and 07S

ORIGINAL OPERATING INSTRUCTIONS

Valid for machine software versions 10-0505-02-02 / 10-0496-02-08

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1 Introduction

1.1 Foreword

Thank you for choosing to purchase this sealing machine.

In these instructions you will find information on the use and care of this machine.

This sealing machine is a microprocessor-controlled continuous (inline) sealing machine for the packaging of sealable transparent pouches and tubes (medical packaging).



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

1.2 Explanation of symbols

	The exclamation mark in the triangle draws your attention to important notes in the operating instructions that must be observed.
	This warning symbol refers to measures that could pose a risk to human health if not observed. It must be observed without fail.
	Tips with an adjacent hand symbol refer to everyday practice.

1.3 Important note



In accordance with the intended use, the CE marking is declared on the basis of the following EU directives.

The Medical Device Directive 93/42/EEC and the Medical Device Regulation 2017/745 (MDR) do not apply to sealing machines.

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

The manufacturer accepts no liability for damage caused by tests according to standards that are not listed in the declaration of conformity.

In the event of modifications or interventions to the machine that are carried out without the express permission of the manufacturer, the warranty becomes void and any liability for physical or material damage is transferred to the operator.

Note

As we continuously improve our products, we reserve the right to change these operating instructions and the functions described therein.

These operating instructions apply to products of the EcoPak 07 series.

1.4 Cleaning

Before cleaning, pull the mains plug out of the socket and disconnect the machine from the power supply. Clean the machine only with a dry or slightly dampened soft cloth and a mild cleaning agent. (e.g. isopropanol, spirit, etc.) Prevent water from entering the machine.

Caution! Never clean the machine wet!

1.5 Safety instructions



1. When they leave our factory, our products are in perfect condition with regard to their safety technology.
2. To maintain this condition, the content of these safety instructions as well as the rating plates, labelling and safety information attached to the machine must be observed during handling of the machine (transport, storage, setup, commissioning, operation and maintenance).
3. This machine is suitable for processing sealable pouches and tubes. See „Intended use“ in this regard.
4. Please check the packaging and report any defects to the freight forwarder or parcel service immediately before setting up the machine.
5. Before commissioning, make sure that the machine shows no signs of damage. In case of doubt, contact the manufacturer or a service partner authorized by the manufacturer.
6. Do not use the machine if the mains cable, the mains plug or the power supply unit is damaged. Do not use the machine if it does not function correctly or is damaged in any way. If the mains cable or the machine has been damaged, it must be repaired by the manufacturer or by one of the manufacturer's authorized service partners.
7. The machine must be connected to an earthed socket with a stable voltage using the mains cable included in the scope of delivery. Use in IT power systems is not permitted.
8. Place the machine on a stable surface.
9. The machine may only be set up and operated in dry rooms that are not at risk of explosion.
10. If the sealing machine is brought directly from a cold environment into a warm environment, condensation may form. Wait until temperature equalization has taken place.
11. Repairs and the replacement of wearing parts/spare parts may only be carried out by the manufacturer or by one of the manufacturer's authorized service partners.
12. After maintenance, servicing or repair work, it must be ensured that the sealing device complies with the applicable safety requirements.
The responsibility for this lies with the operator.
13. Switch off the machine when it is not in use and pull the mains plug out of the socket.
14. Do not use the machine if you have doubts about its safety.
15. Do not insert any pointed or flat objects into the infeed slot of the machine. This can lead to damage to the machine and the instruments as well as electric shock.
16. The machine may not be set up or operated by persons under 14 years of age.
17. The machine may not be operated unattended.
18. It is prohibited to operate the machine under the influence of drugs or alcohol.



19. Keep hair, clothing and gloves away from moving parts! Loose clothing, jewellery or long hair can become caught in moving parts.



20. The machine contains valuable materials that can be recycled and reused. The machine should therefore be disposed of and recycled at a public disposal facility near you.

The machine has been marked in accordance with Directive 2012/19/EU (WEEE) on waste electrical and electronic equipment.

This directive governs the return and recycling of waste equipment within the EU.

2 Before commissioning

2.1 Intended use

SEALABLE MATERIALS

Sealable paper pouches in accordance with EN ISO 11607-1/EN 868-4	X
Sealable pouches and tubes made of film in accordance with EN ISO 11607-1/EN 868-5 and paper in accordance with EN 868-3	X
Sealable pouches and tubes made of film in accordance with EN ISO 11607-1/EN 868-5 and uncoated polyolefin materials in accordance with EN 868-9 (e.g. Tyvek ^{®1} or ULTRA ²)	X
Sealable pouches and tubes in accordance with EN ISO 11607-1/EN 868-5 made of PP nonwoven or PP textile composite	X ³
Aluminium-laminated film	X ³

NON-SEALABLE MATERIALS

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

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

² ULTRA is a product of STERIMED infection control

³ Release and / or testing required

The machine is furthermore intended

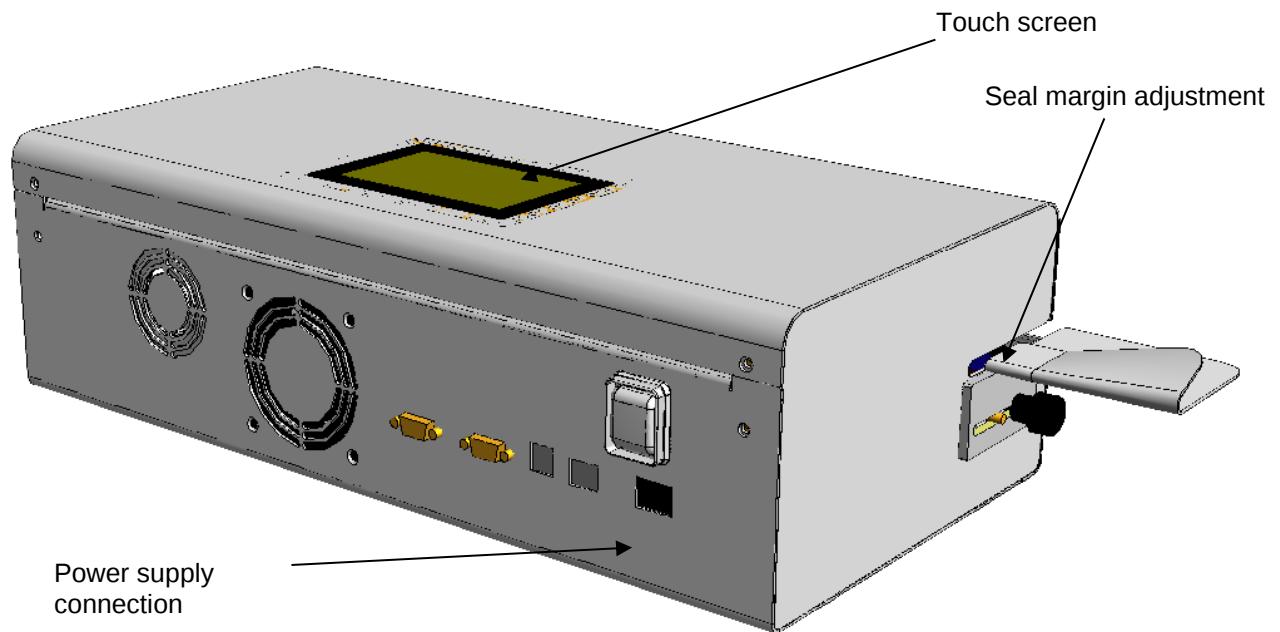
- a) for use at work
- b) for use by persons aged 14 and over
- c) for operation by instructed persons



The packaging of food and hazardous substances (substances harmful to health, in particular toxic, corrosive, flammable, highly flammable and explosive substances) is not in accordance with the intended use.

Operation in a potentially explosive environment is not in accordance with the intended use.

2.2 Design and functions



2.2.1 Sequence of the sealing process

- Step 1:** After the medical packaging has been inserted, the feed is switched on automatically.
- Step 2:** The medical packaging is now fed in and the area of the seal seam is heated to the set sealing temperature by the heating elements mounted above and below.
- Step 3:** The now heated seal seam is pressed together by the sealing rollers and sealed.
- Step 4:** The finished medical packaging is transported to the removal side.
- Step 5:** Without further feeding of medical packaging, the feed switches off automatically after 10 seconds.

2.3 Setup



Setting up or operating the machine in potentially explosive areas is not permitted.

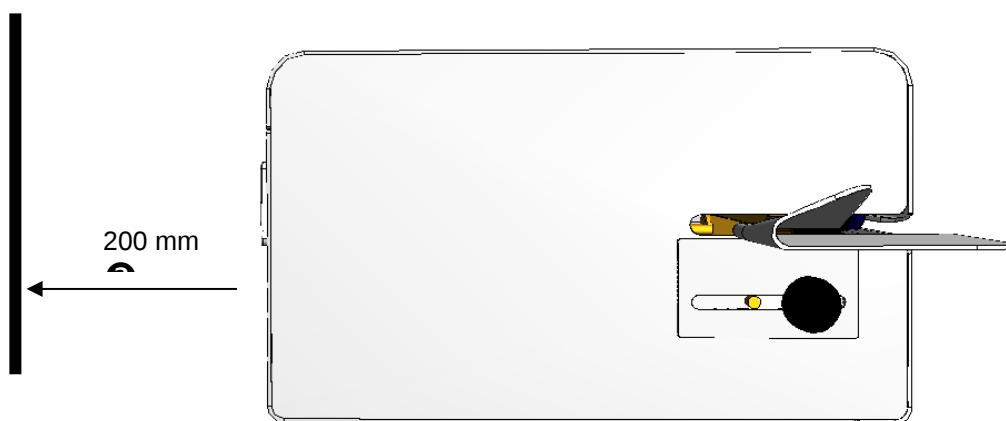


Use only sockets that are equipped with a protective earth conductor and connected to a stable mains voltage.

The machine may only be set up in a dry environment. Its function is impaired by high levels of dust and steam as well as by dripping or splashing water.

Make sure that the operating voltage corresponds to the information on the machine's rating plate.

- ❶ Do **not** transport the machine by the infeed plate.
- ❷ The distance to the wall must be at least 200 mm!



2.4 Inspecting the machine

After opening the packaging, check the machine and accessories for damage and completeness.

Sealing machine

Power supply unit



Infeed plate

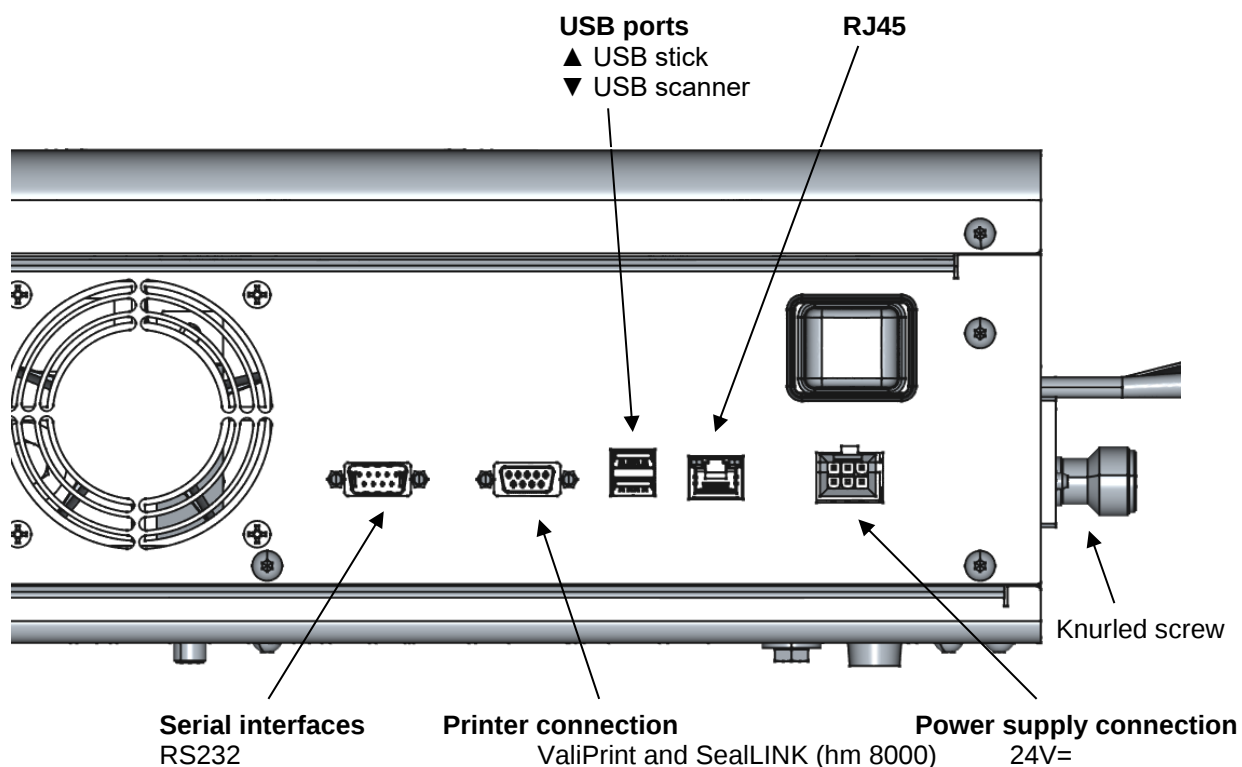
Mains cable



Operating instructions – (as a link on the machine)

Test report

2.5 Operation



- Step 1** Set the desired width of the seal margin. After loosening the knurled screw, the infeed plate can be adjusted continuously to seal edge widths between 0 and 35 mm.
- Step 2** Insert the packaging into the machine from the left over the infeed plate.
- Step 3** Remove the sealed packaging at the outfeed side and let it cool down briefly.



Checking the seal seam (see chapter Seal seam test)

If leakage occurs, the sealing temperature must be increased. If the film melts, the setpoint temperature is too high.

In accordance with DIN 58953-7, the appropriate sealing temperature must be determined with a test seal.

2.6 Explanation of symbols

Symbol	Function	Note
	Cancel	Changes and / or settings are not applied
	Add	Example when adding an operator
	Reduce	
	Confirm	Confirm selection and / or changes
	Delete	In the seal test area as a selection if the result was not OK.
	Count „Up“	
	Count „Down“	
	Export data	
	Import data	
	Search function	

3 Basic functions

3.1 System check

The system check is carried out after every restart of the machine. During this, the sensors installed in the machine are checked for their functionality.

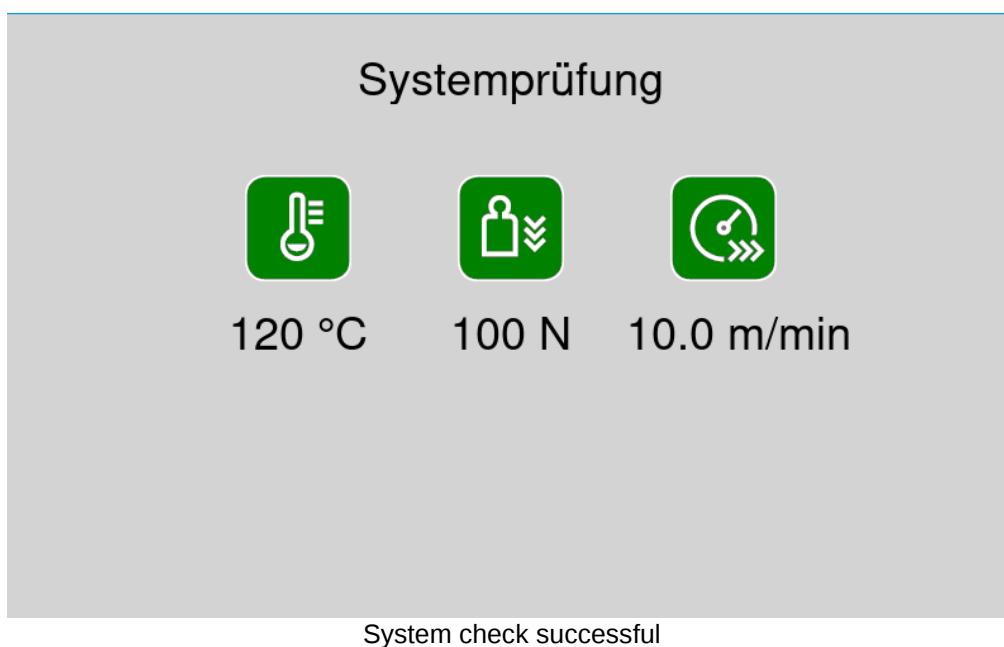
System check „green“

If all three sensors are functional during the check, they are displayed in green. The heating process continues to run and the sealing process can, after the setpoint is reached, be started.

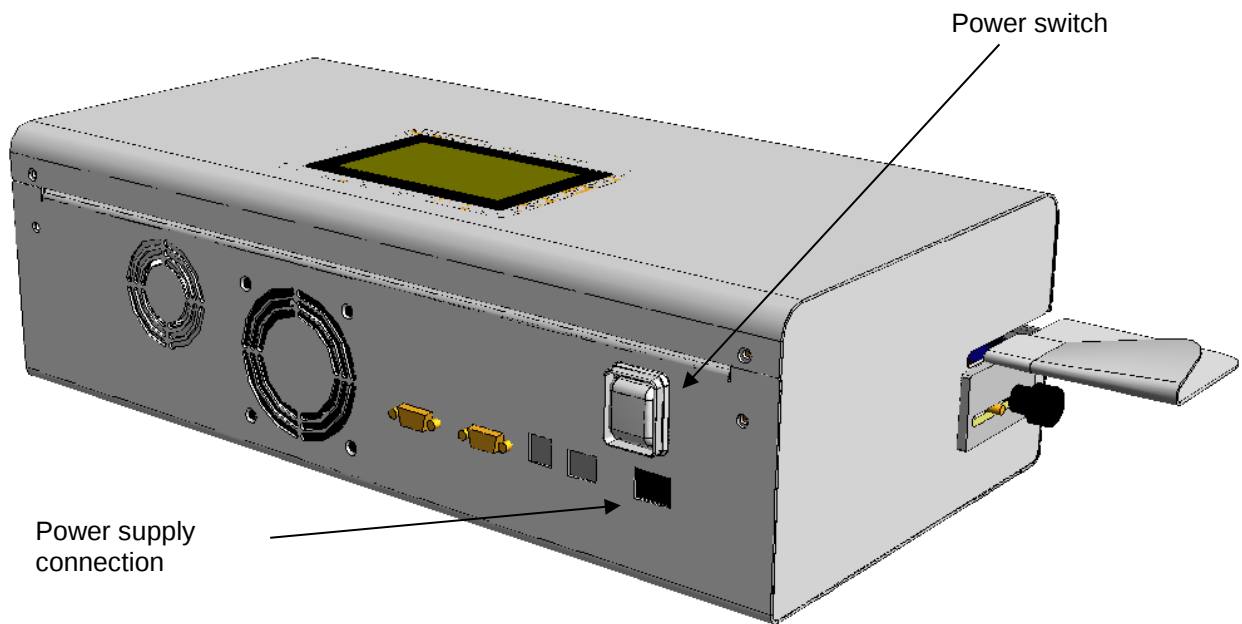
System check „red“

If a sensor has a fault or defect, the corresponding symbol is marked red. In this case, normal sealing operation is not possible.

→ If necessary, contact a service technician.



3.2 Switching on the machine



Plug the power supply unit into the power supply connection of the machine.

Now plug the power supply unit into the socket using the supplied mains cable.

Switch on the machine by setting the power switch to position „1“.

Set the desired sealing temperature.

The machine heats up and is ready for operation as soon as the set sealing temperature has been reached.

3.3 Process variables

Sealing temperature

The temperature is monitored electronically via a temperature sensor. In the event of a deviation from the setpoint by the set tolerance value, or by a maximum of 5°C (requirements according to DIN 58953-7), the drive is blocked.

Contact pressure

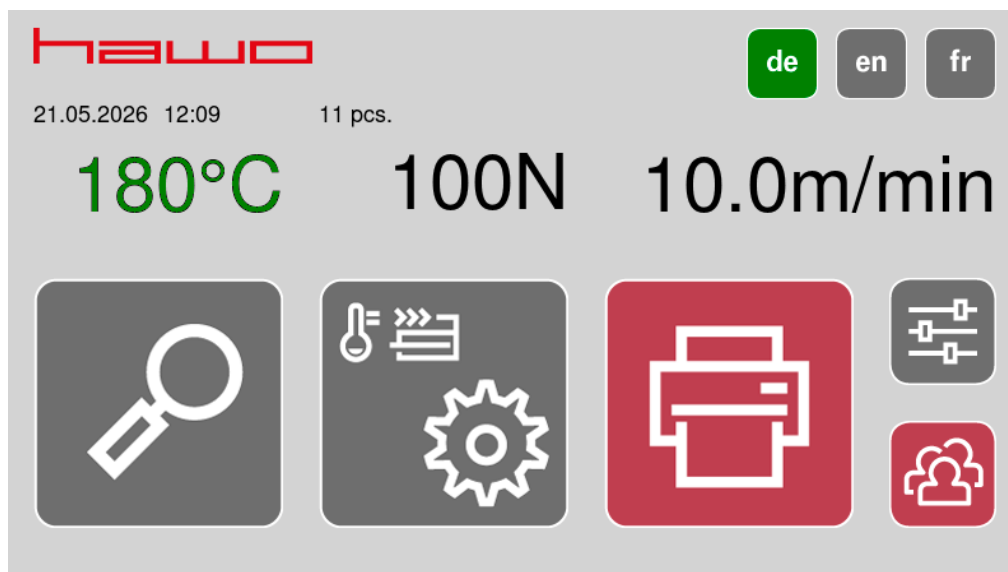
The contact pressure is monitored electronically via a strain gauge.

If the value deviates from the setpoint by more than the tolerance range of +/-20%, an alarm message is output (requirement of DIN 58953-7) and the sealing process is blocked.

Sealing speed (dwell time)

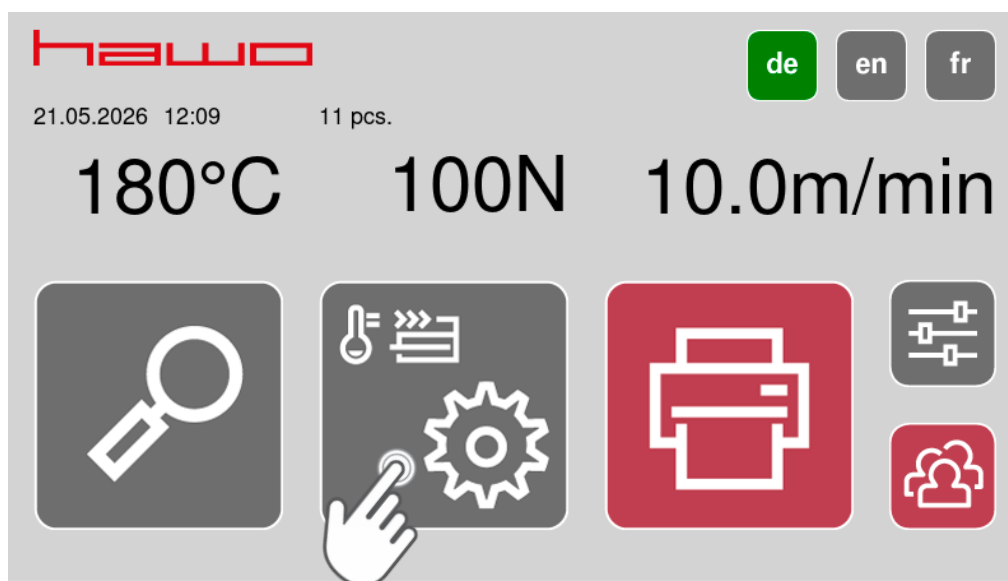
The sealing speed (dwell time) is monitored electronically via a speed sensor. If the value deviates by +/-10% from the set setpoint, an alarm message is output (requirement of DIN 58953-7) and the sealing process is blocked.

3.4 Explanations of the start screen



Symbol	Function	Note
180°C	Display of the current sealing temperature	Green: Setpoint reached Red: Temperature exceeded or not reached Blue: Cooling down to changed setpoint
100 N	Display of the current contact force	
0.0 m/min	Display of the current throughput speed	Value > 0 only when the motor is running
	Log in	Log user in/out (see chapter Operator)
	Control center	Checking the functions heating, strain gauge module and motor as well as the machine operating data
	Display of the total piece counter / the set quantity	
	Seal test	SealCheck
	Selection of the sealing parameters used	
	Print settings	Settings for internal printer.

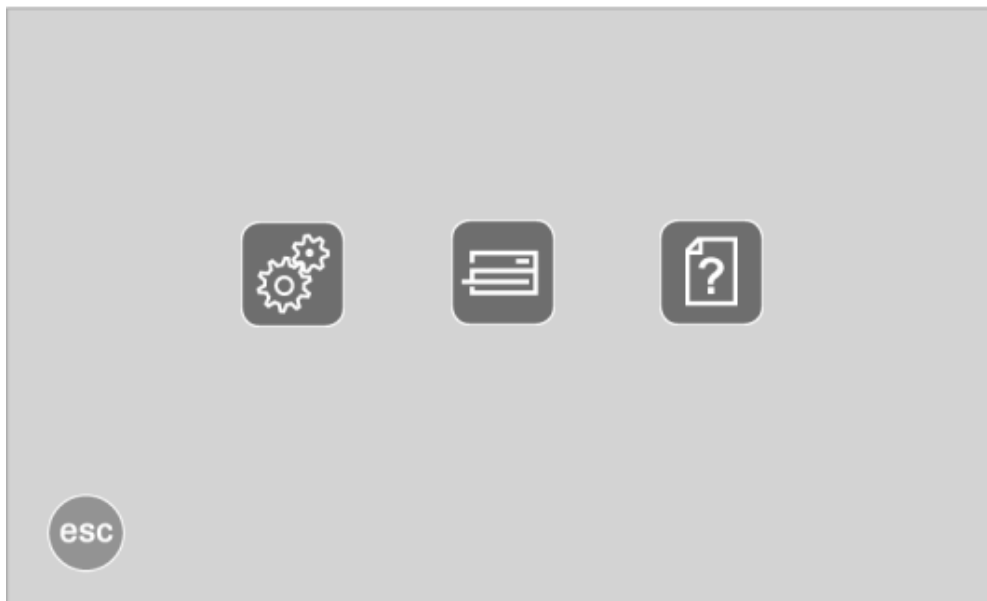
3.5 Temperature setting



Symbol	Function	Note
	Setting of the sealing parameters	Only temperature and sealing speed
	Temperature selected by tapping	Press and hold one of the buttons 1, 2 or 3 if the corresponding settings are to be changed.
	Temperature not selected	A temperature must be selected.
	Colour selection for the different temperatures	The colour changes with each press of the button.



3.6 Control center



3.6.1 Monitoring display (only after a system restart)

Symbol	Function	Note
	Monitoring of the temperature	Monitoring of the process variables The symbols indicate whether the respective sensors of the machine are working. By tapping one of the 3 symbols, the sensor status of all 3 values is queried and the respective symbol is then marked as „red“ or „green“.
	Monitoring of the contact force	
	Monitoring of the speed (dwell time)	

3.6.2 Machine operating data display.



3.7 Seal test – “Seal Check”

Checking of the process variables (temperature, contact pressure and sealing speed [dwell time]) with the help of the „SEAL CHECK“ function.



The Seal Check sealing indicators are not suitable for packaging with side gussets.

This check should be carried out and documented before and after the daily work process and/or before/after each batch.

In addition to the „SealCheck“ sealing indicator, it is recommended to use the seal test function of the sealing machine.

Before the check, the sealing machine must be ready for operation and the setpoint temperature must be reached.

Symbol	Function	Note
	Seal test	Carrying out a routine check SealCheck, InkTest and peel test

Activation and start of the seal seam test

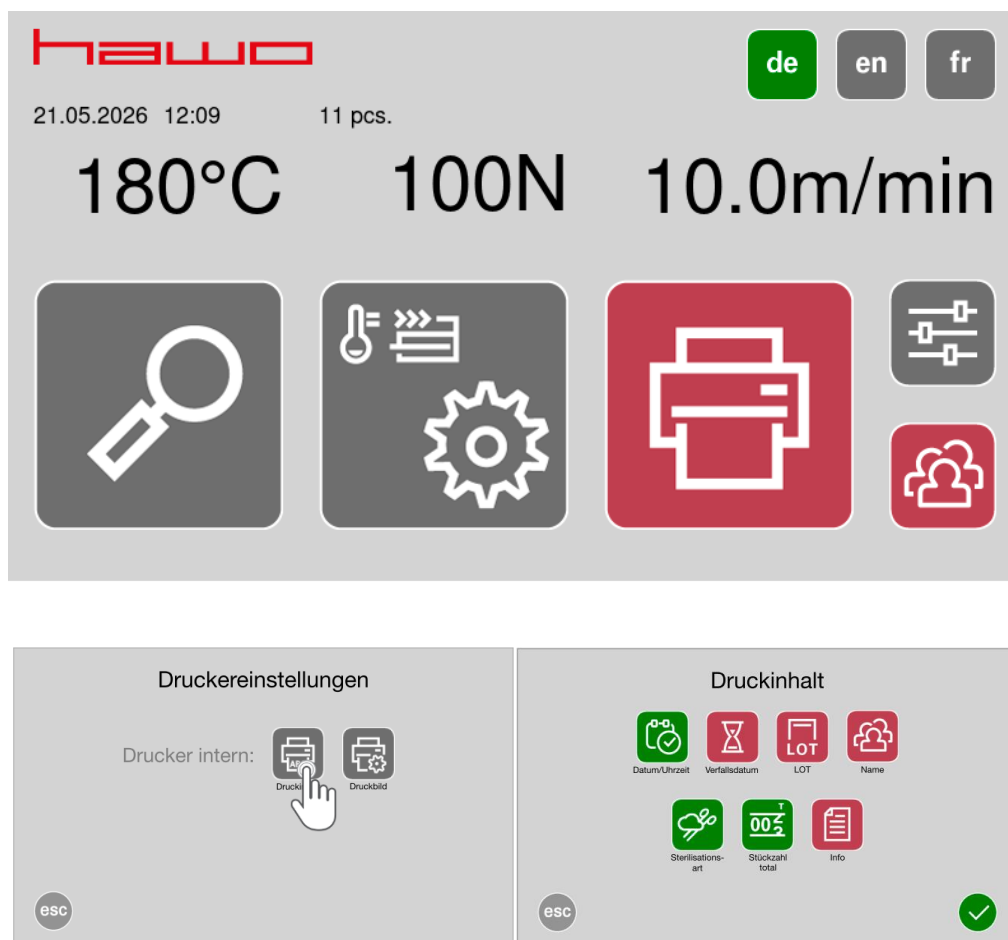
1. Activate seal test
2. Select the type of test
 - SealCheck
 - InkTest
 - Peel test
3. Insert a medical package with a minimum width of 200 mm and start the seal test.

This button cancels the function

4. Assess the result of the seal seam and confirm the question with the respective button.

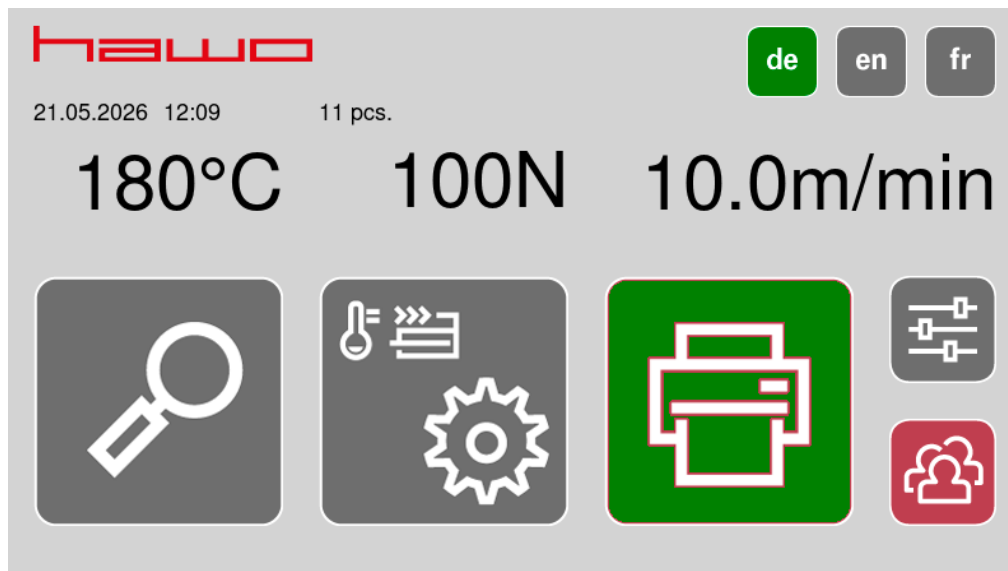
3.8 Printer settings

3.8.1 Printer functions

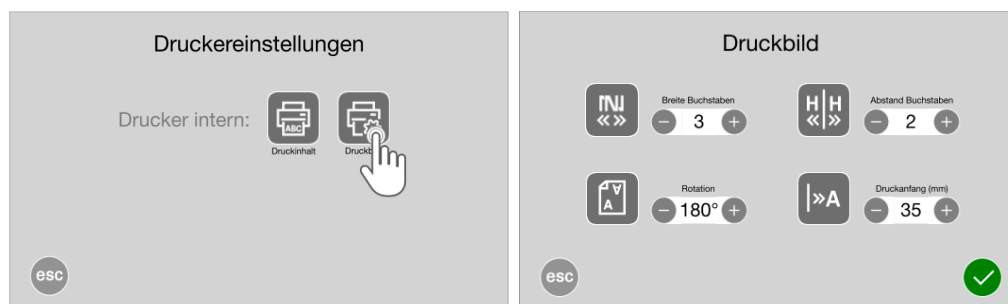


Symbol	Function	Note
	Date / time	Switches the individual print functions on or off Print function ON Print function OFF
	Expiry date	
	LOT number	
	User name	
	Sterilization information	
	Total piece counter	
	Info	

3.8.2 Printer settings „INTERNAL“

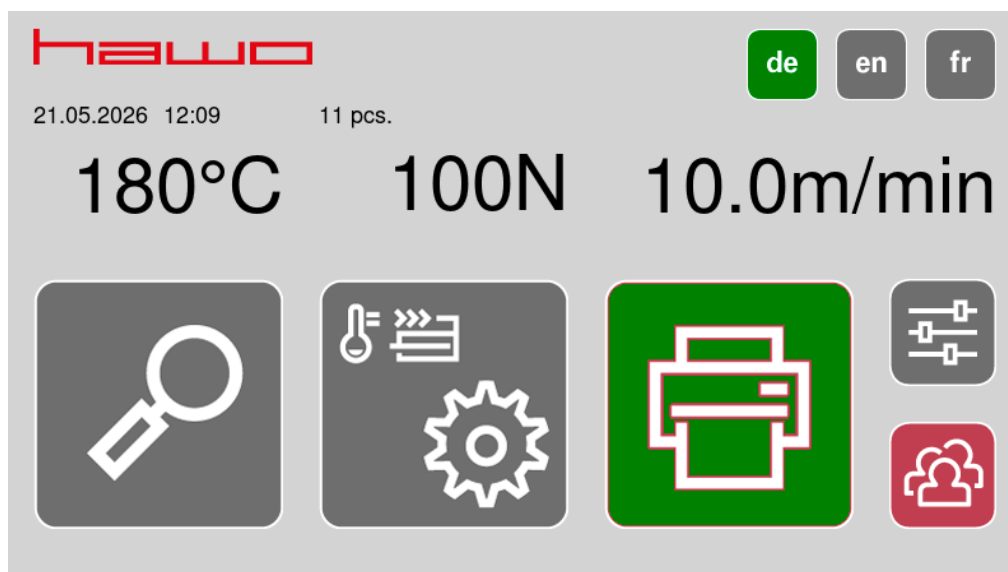


Symbol	Function	Note
	Printer OFF / ON	Press and hold the button to switch the printer on or off.

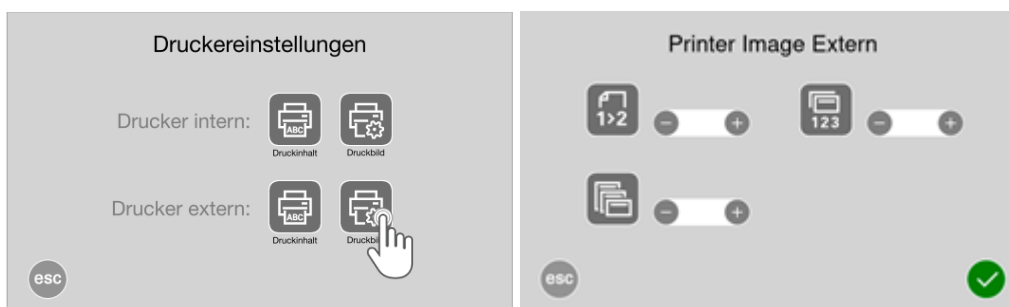


Symbol	Function	Note
	Character width	Adjustable from 1 - 3 or automatic "A" (FontMATIC®)
	Character spacing	Adjustable from 1 - 3
	Print direction	0° or 180°
	Print start	Adjustable from 0 - 100 mm

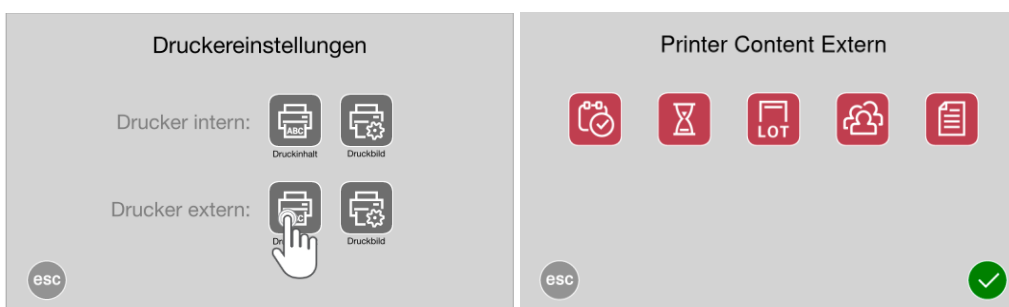
3.8.3 Printer settings „EXTERNAL“



The external printer settings are only visible when a ValiPrint printer (1.421.015) is connected!



Symbol	Function	Note
	Print mode	1 → after every seal 2 → after every second seal
	Number of labels	Freely selectable between 1 – 10
	Label size	S 55 x 33mm L 60 x 44mm



3.9 Settings 01



Symbol	Function	Note
	DataMatic	Selection of individual DataMatic data: date, time, temperature, contact pressure, sealing speed, total piece counter and serial number are fixed default values.
	Name list	Creation, editing and deletion of users
	Scanner	Assignment of scanned data to other functions
	Piece counter	Setting of the piece counter for counting up/down
	Test intervals	Setting of various intervals for seal test, ink test and peel test
	Standby	After the selected period, the machine reduces the heating power and cools down to 80°C
	User standby	After a selected period, a logged-in user is automatically logged out
	Data entry	Entry of the information for LOT, CE, Info, REF and Steri

3.9.1 DataMatic



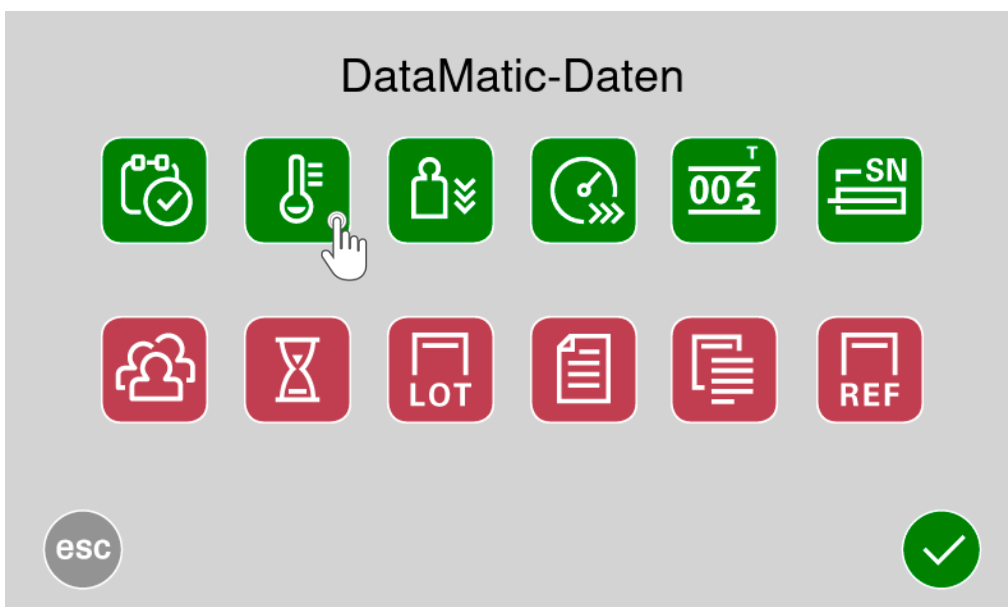
Activation of the individual DataMatic function

Press and hold the button

DataMatic **not** active

DataMatic active

Tapping the button opens the DataMatic data menu for activating / deactivating the individual functions.



Activate and deactivate by tapping.

Recording **not** active

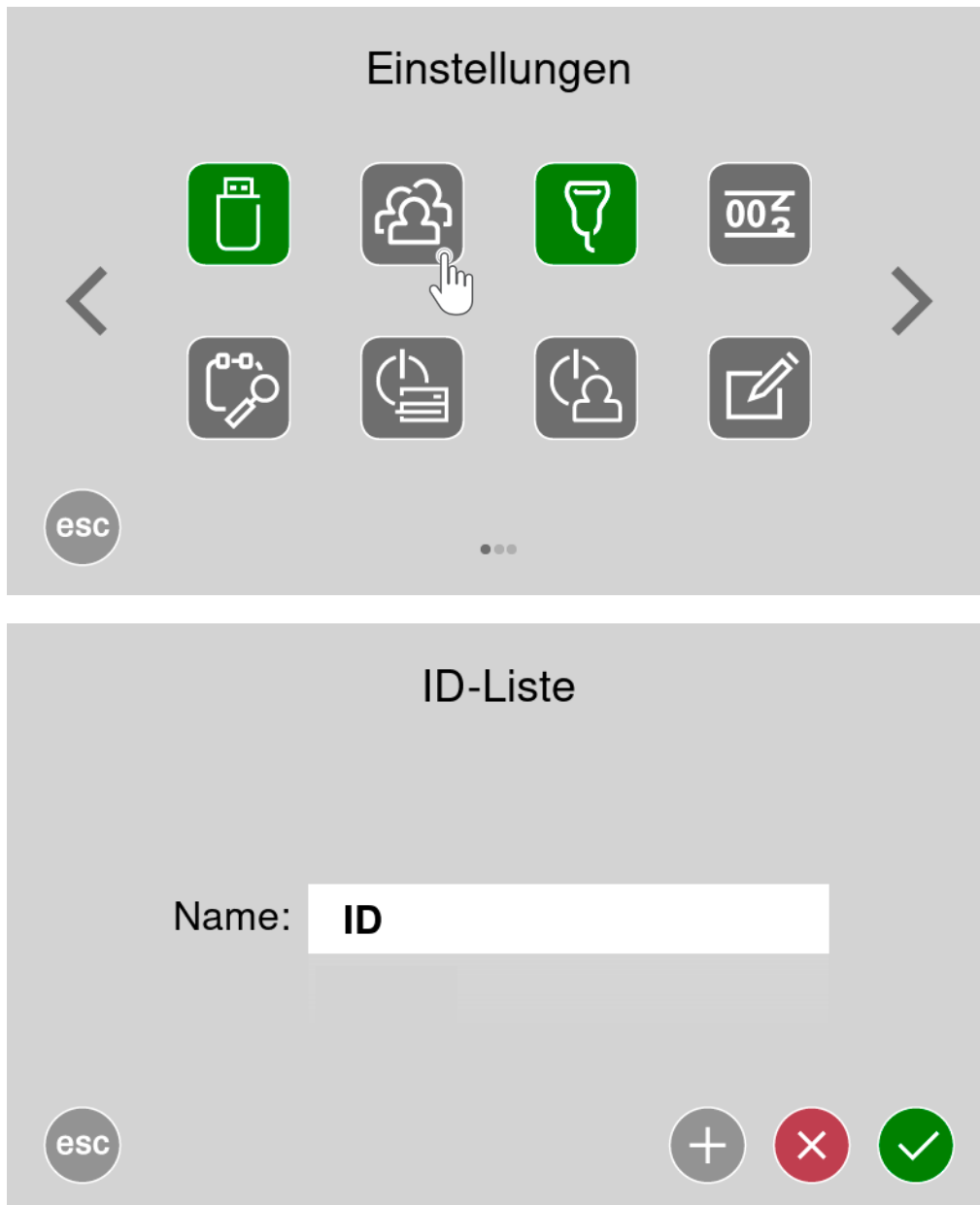
Recording active

Green symbols are recorded in the DataMatic, red symbols are not stored in the DataMatic data record.

ATTENTION:

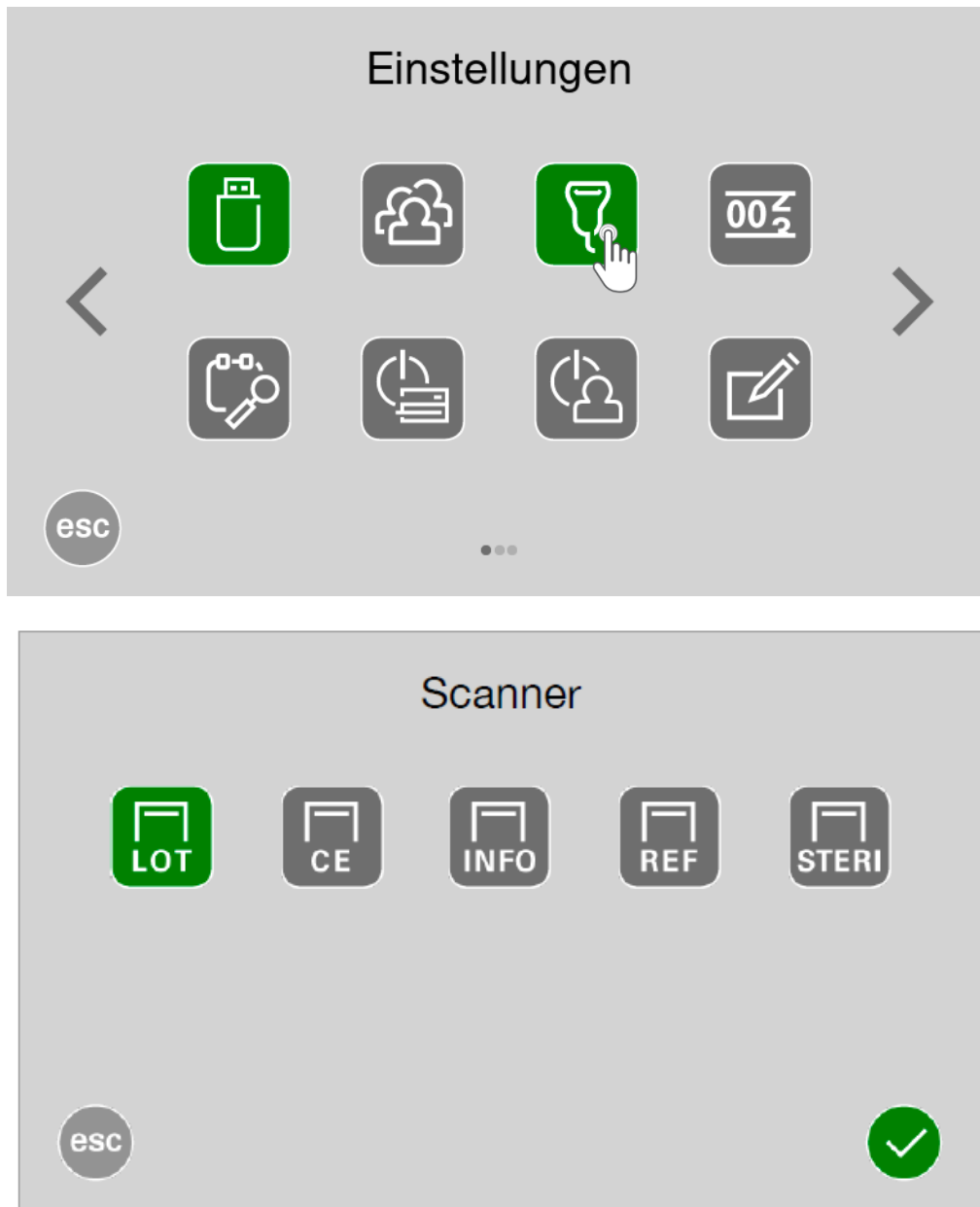
Without activation of the DataMatic data, no data output to RS232, RJ45 or Wi-Fi takes place.

3.9.2 Name list



 Create a new operator  Save changes  Delete operator (only admin or the operator themselves)  Discard changes and exit menu	A new operator is entered using the on-screen keyboard. Alternatively, a USB keyboard can be used.  After entering the name, the system requires a numeric password with at least 5 digits. 
---	--

3.9.3 Scanner function



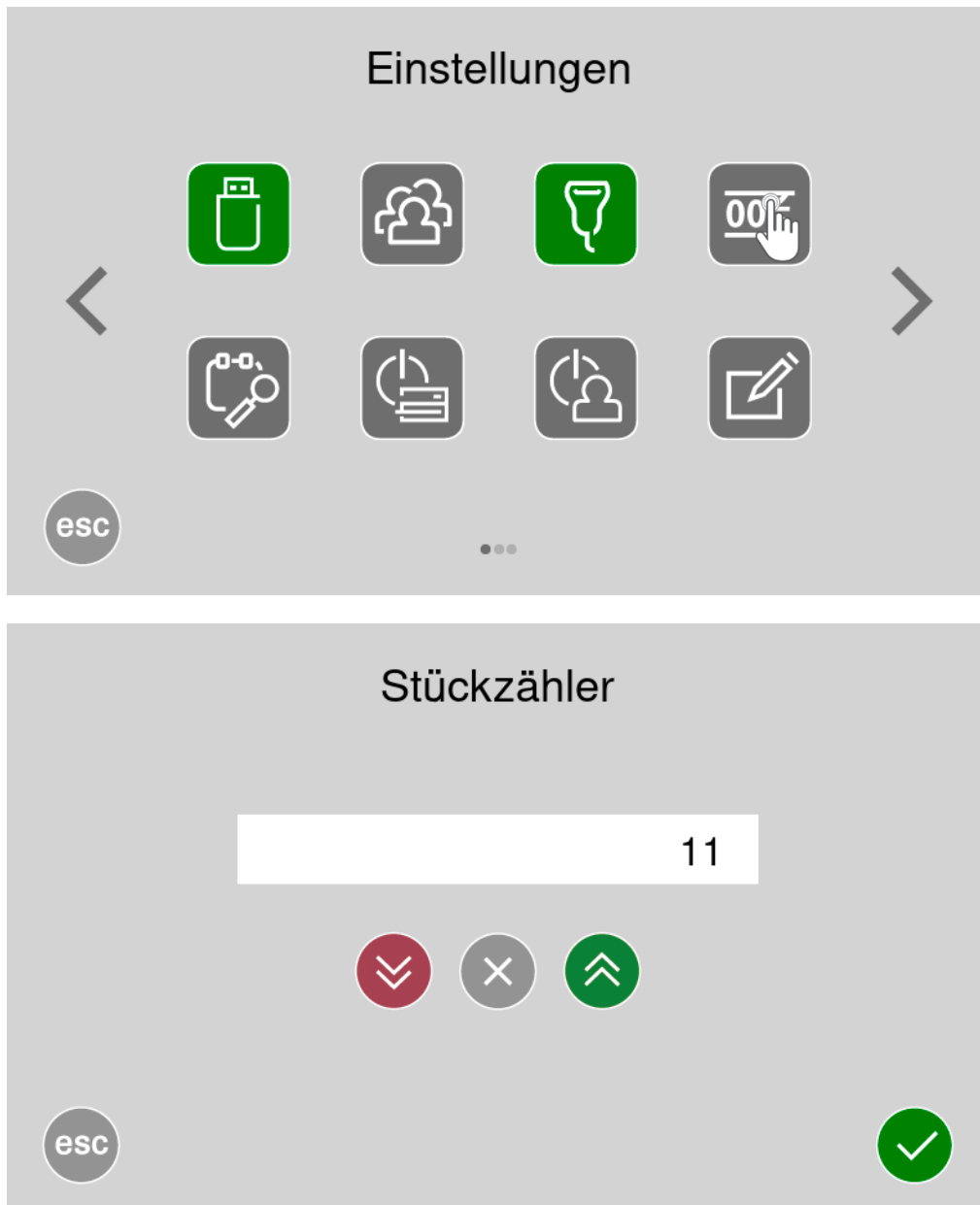
Activation of the scanner function

Tapping the button selects which data the scanned information is assigned to.



The scanned data are assigned to the information.

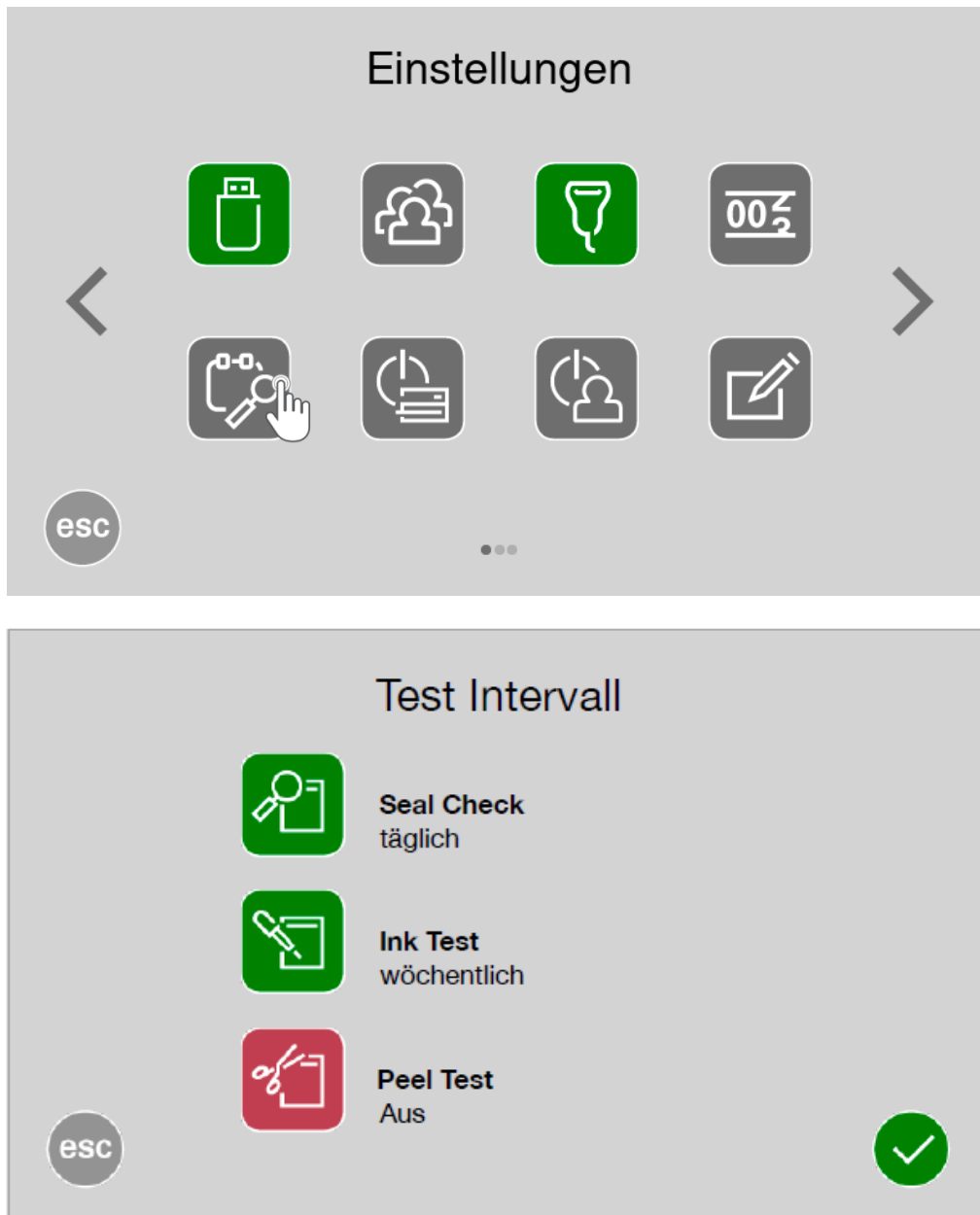
3.9.4 Piece counter



Activation of the counter function

 Save changes  Discard changes and exit menu	  Piece counter counts down or up  Set piece counter to zero The piece counter is entered using the on-screen keyboard. 
--	--

3.9.5 Test intervals



Activation of the test intervals

By tapping the button, the respective test interval can be set.

Once a test interval has been set, the button changes colour from **red** to **green**.



Save changes



Discard changes and exit menu

Adjustable test intervals:

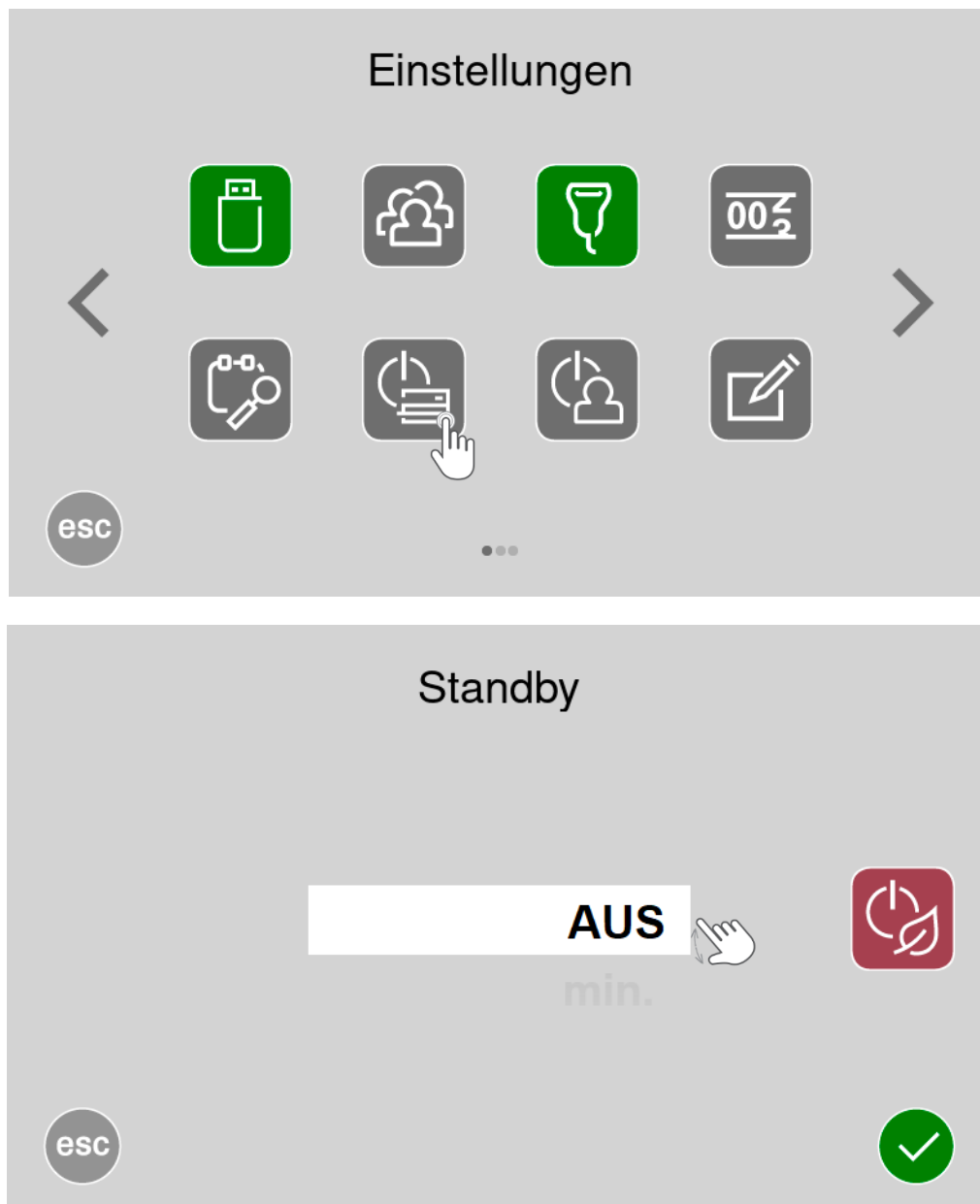
- OFF
- Daily
- Weekly
- Monthly

The interval starts as soon as a selection has been made.

Example when selecting „daily“:

- ➔ Selection on 18.02.2025 at 8:00
- ➔ Reminder on 19.02.2025 at 8:00

3.9.6 Standby



Activation of the standby function

After the set time, the standby reduces the heating power and regulates the machine to a temperature of 80°C.



Save changes



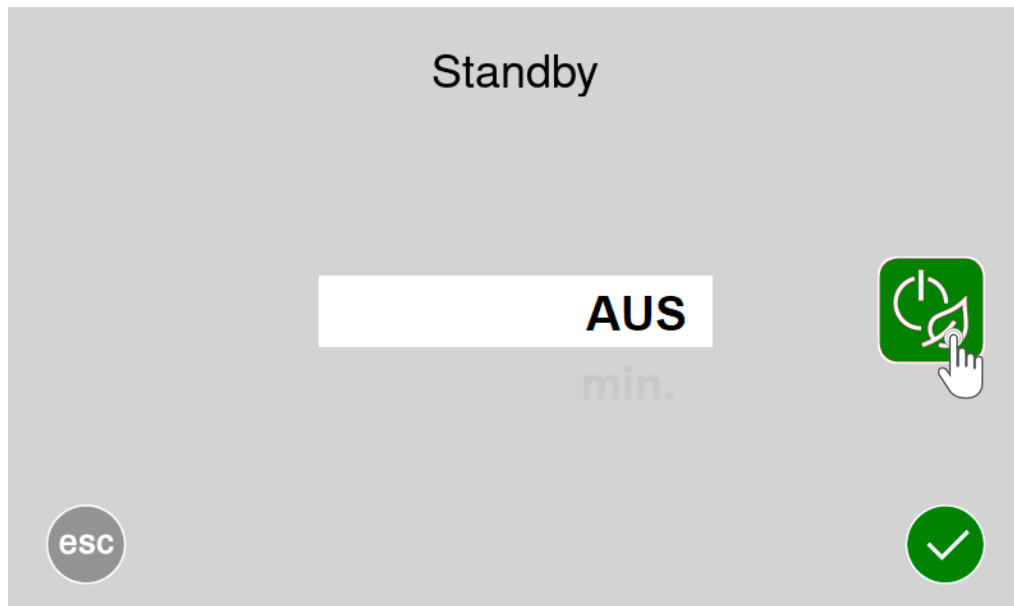
Discard changes and exit menu

Adjustable times:

- 0 = OFF
- 5 min.
- 10 min.
- 15 min.
- 20 min.
-
- 60 min.

After inserting a new package or by tapping the display, the machine heats up again to the preset value. During this time, sealing is not possible!

3.9.6.1 Standby + (PLUS)



Activation of the Standby+ (PLUS) function

After the set time, Standby+ switches the heating off completely and therefore consumes hardly any energy.



Active „Recommended“



Inactive



Save changes



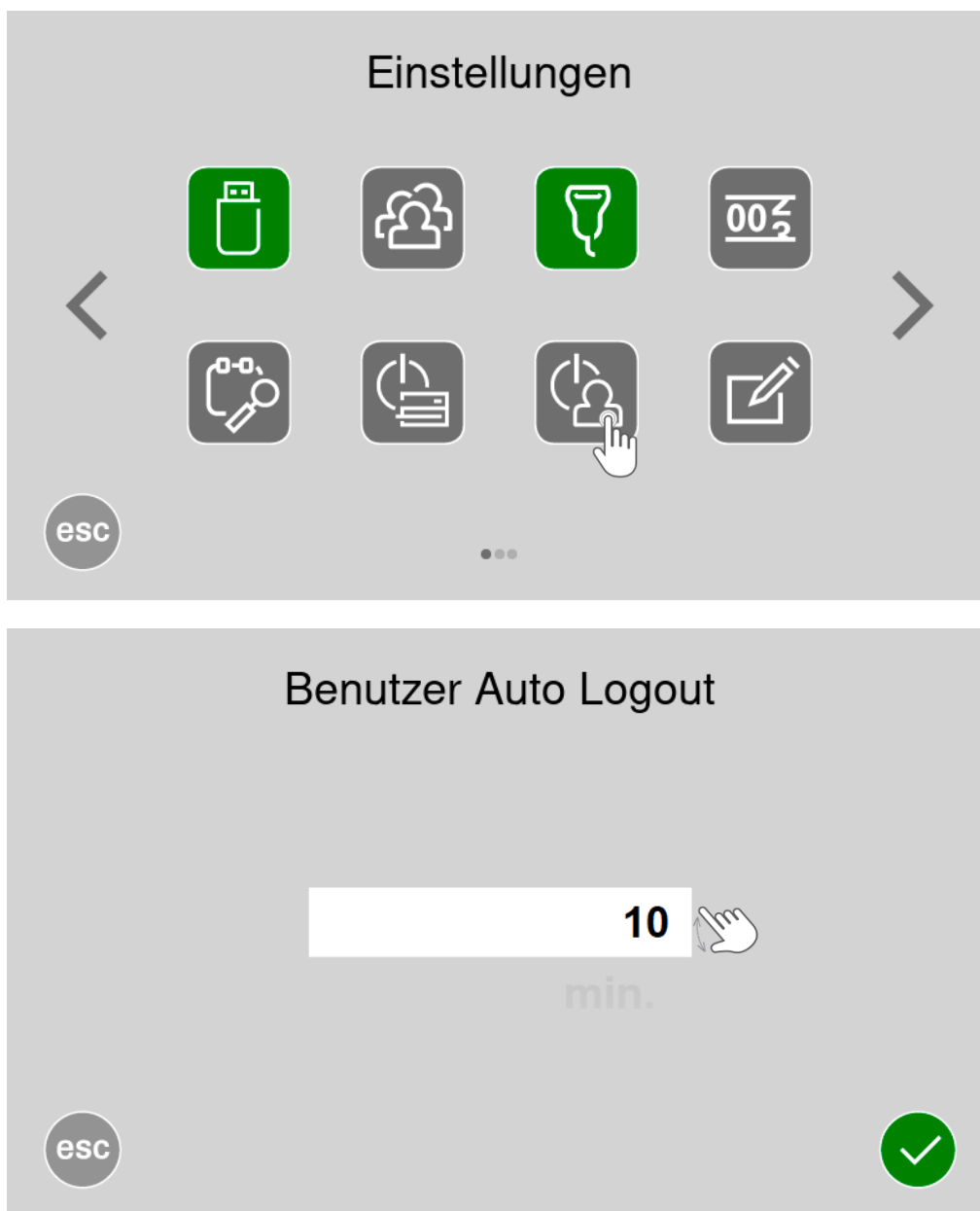
Discard changes and exit
menu

Adjustable times:

- 0 = OFF
- 5 min.
- 10 min.
- 15 min.
- 20 min.
-
- 60 min.

After inserting a new package or by tapping the display, the machine heats up again to the preset value. During this time, sealing is not possible!

3.9.6.2 Operator standby



Activation of the operator logout function

After the set time, the standby automatically logs out the currently logged-in operator.



Save changes

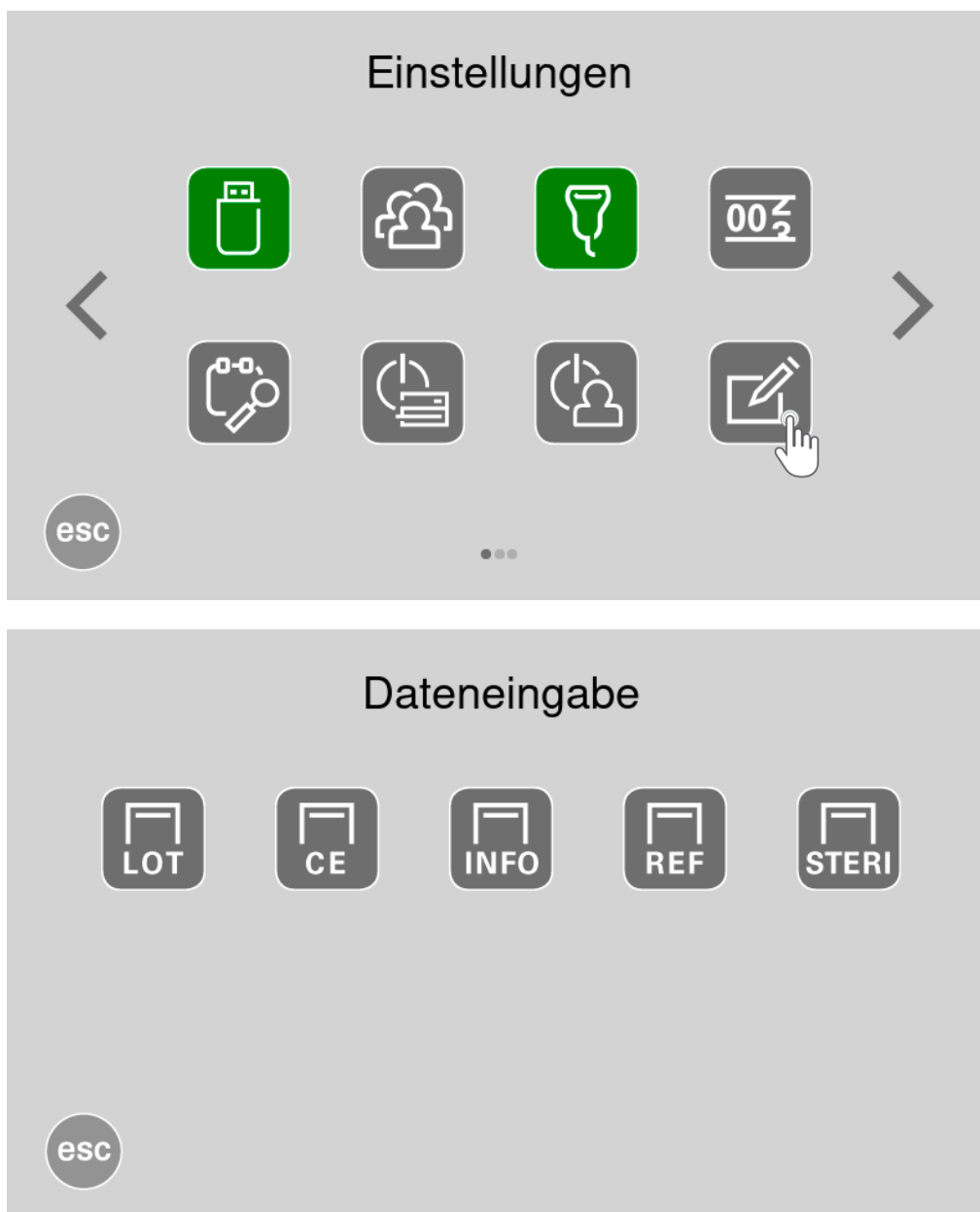


Discard changes and exit menu

Adjustable times:

- 0 = OFF
- 5 min.
- 10 min.
- 15 min.
- 20 min.
-
- 60 min.

3.9.7 Data entry



The data are entered by selecting the respective symbol and then entering them via the alphanumeric display keyboard.

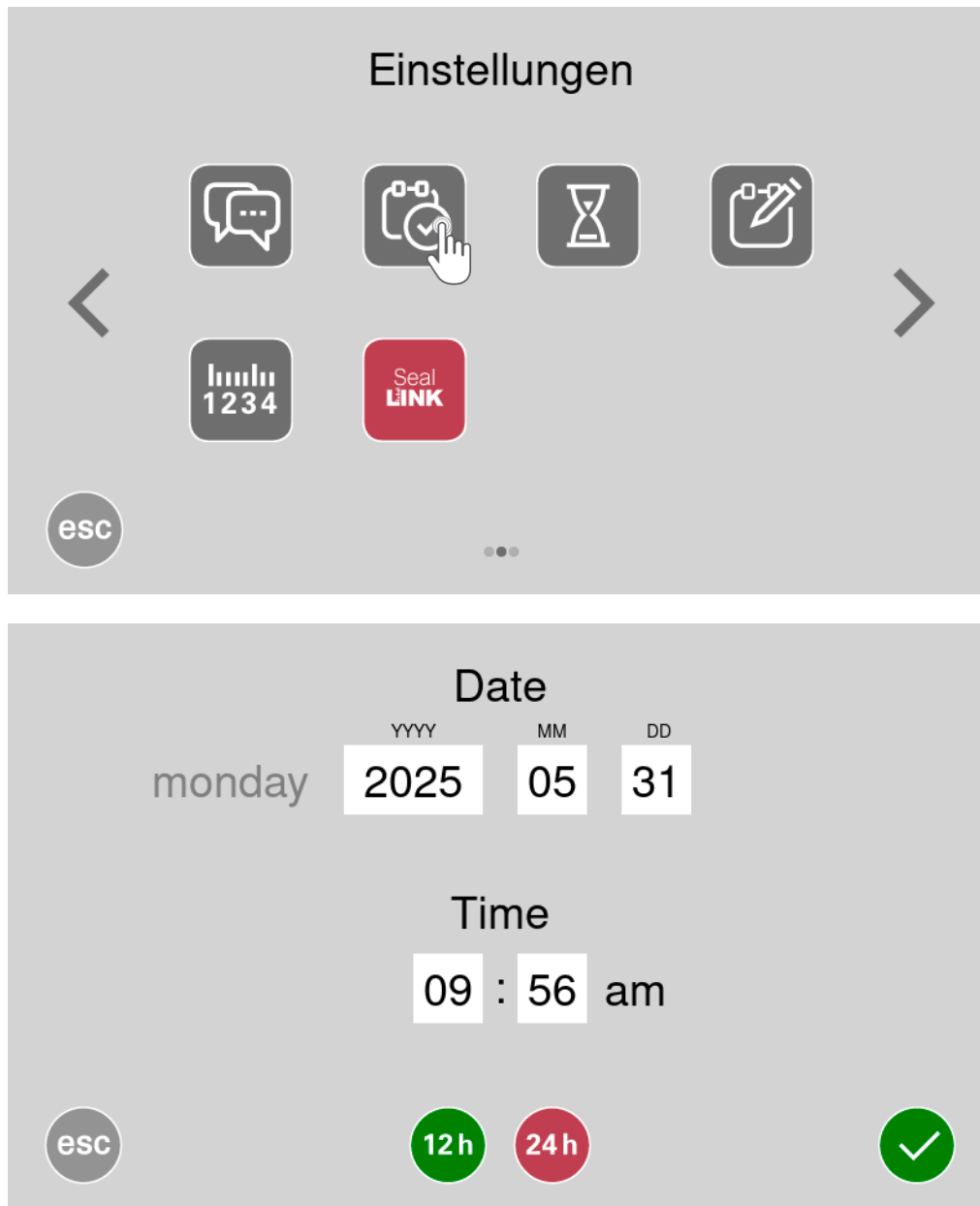


3.10 Settings 02



Symbol	Function	Note
	Language	Definition of the three languages that can be preselected via the start menu
	Date/time	Current setting of date and time
	Expiry date	Entry of the expiry date in days, months or as an individual entry with a fixed date
	Date format	DD.MM.YYYY MM.DD.YYYY YYYY.MM MM.YYYY YYYY YYYY.MM.DD Month.DD.YYYY
	Unit of measure	Conversion of the units of measure from si T[°C] ● F[N] ● v[m/min] fps T[°F] ● F[lbf] ● v[ft/min]
 	SealLINK	Through the direct interaction of a hawa sealing machine equipped with SealLINK software with our hm 8000 AS-V pouch production machine, automatic and customized pouch production is made possible with just a single scan.

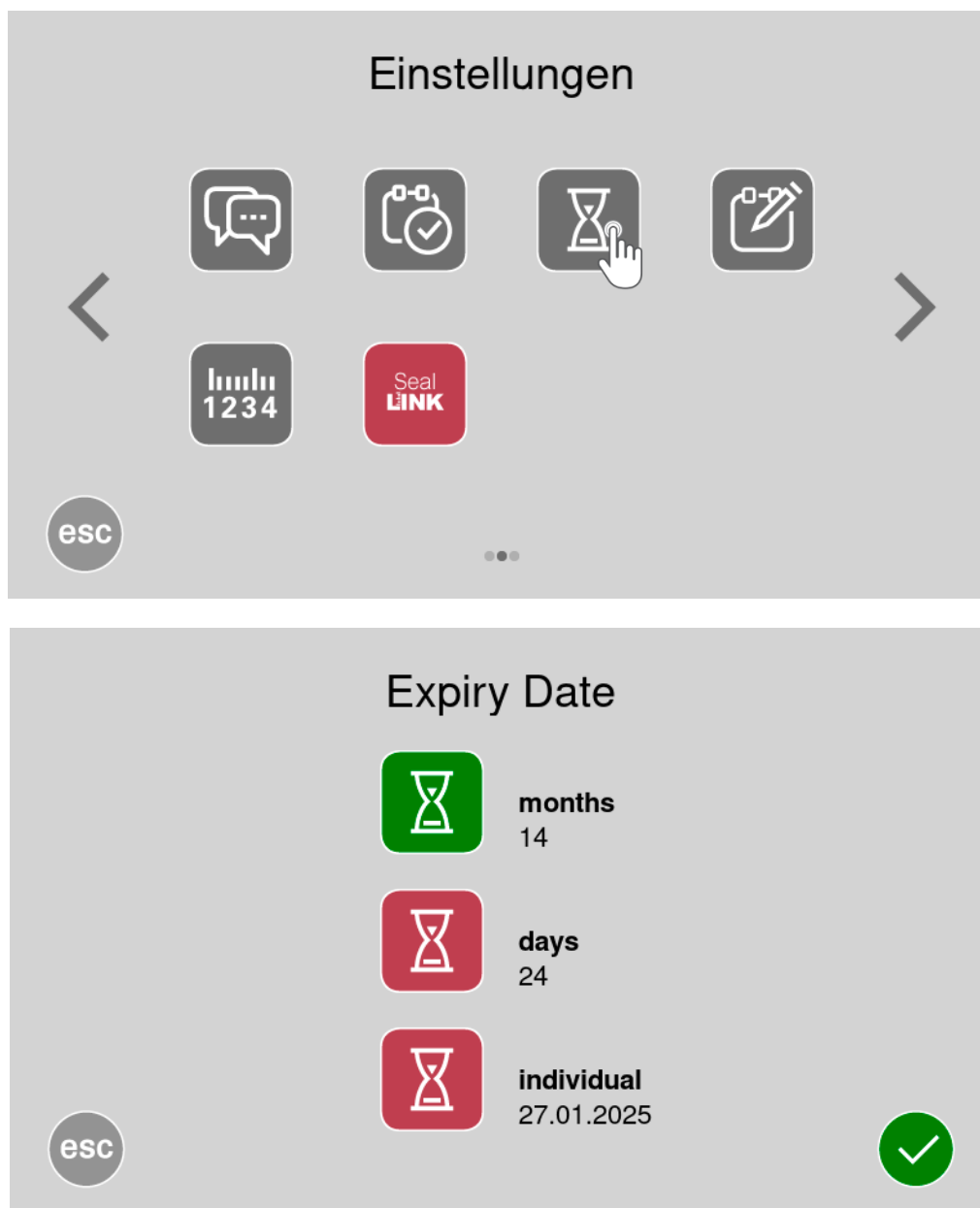
3.10.1 Date/time



Change date / time

✓ Save changes esc Discard changes and exit menu	12 h Selection 12 hours [am / pm] 24 h Selection 24 hours time The individual data are entered by selecting the digits to be changed and entering them using the keyboard. 
--	---

3.10.2 Expiry date



The expiry date can be selected from 3 different formats.



Save changes



Discard changes and exit menu

Selection of months, days or an individual date entry



Active



not active

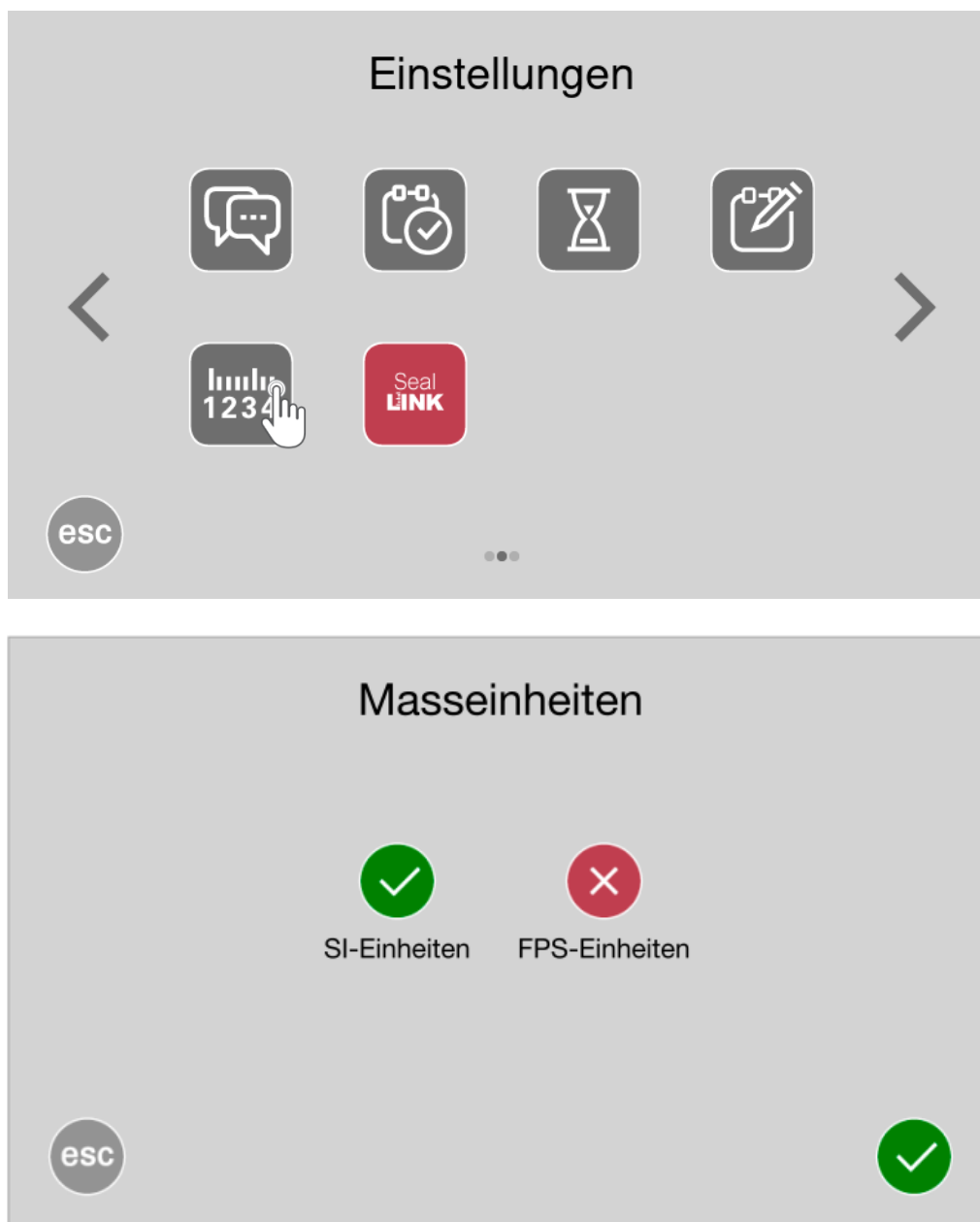
The selection for days and months is made using the scroll wheel.

The individual date is entered using the keyboard.

After selecting the respective field, the value can be entered using the keyboard.



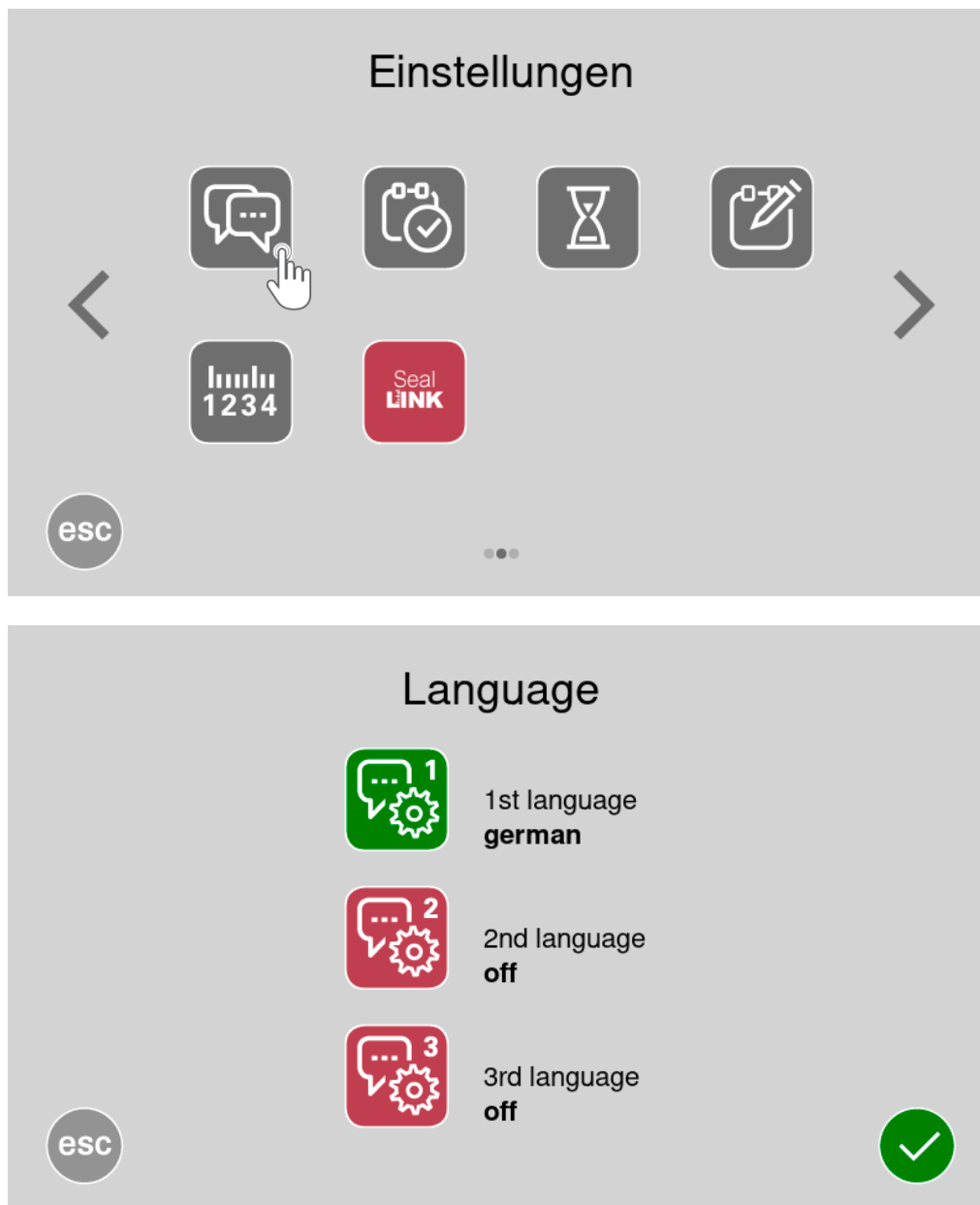
3.10.3 Unit of measure



Change of the units of measure

	Save changes		Active
	Discard changes and exit menu		not active
		Si	T[°C] F[N] v[m/min]
		Fps	T[°F] F[lbf] v[ft/min]

3.10.4 Language



 Save changes  Discard changes and exit menu Adjustable languages • German • English • Spanish • French • (subject to change)	Up to 3 languages can be preset on the machine. Once the languages are activated, they can be changed at any time in the main menu.  Active  not active 
--	---

3.10.5 SealLINK

The innovative SealLINK networking system takes the packaging process of medical devices to a new, even more efficient level.

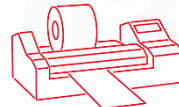
Through the direct interaction of a hawa sealing machine equipped with SealLINK software with our hm 8000 AS-V pouch production machine, automatic and customized pouch production is made possible with just a single scan. Thanks to the self-learning SealLINK technology, pouches that are too short or too long are a thing of the past. With every new instrument captured via the Datamatrix reader, the process is further optimized.



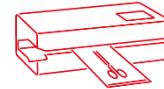
Capture the code of the instrument with the Datamatrix reader



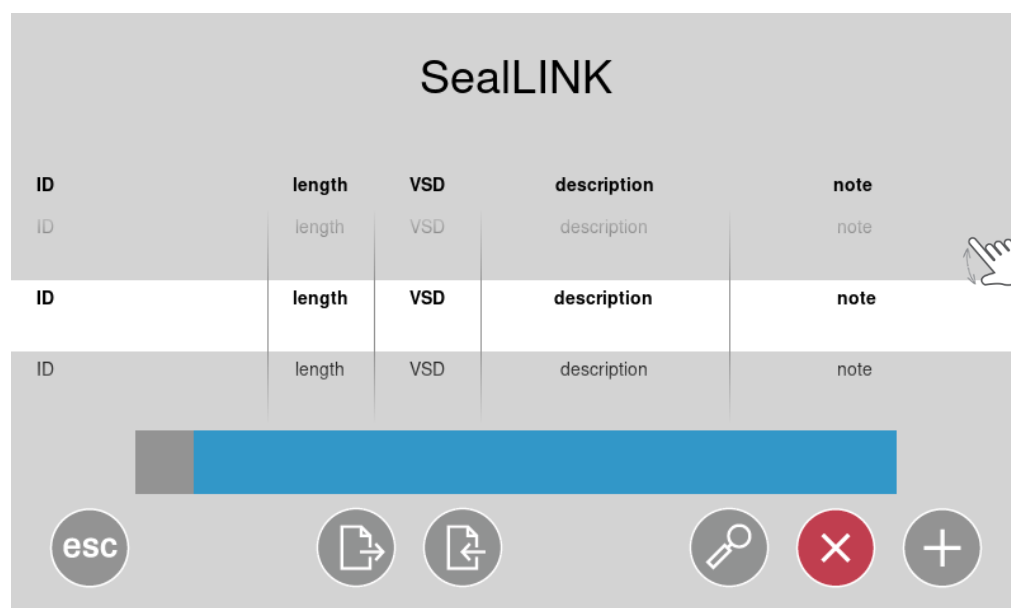
SealLINK automatically assigns the matching pouch length and saves it



At the next scan, the hm 8000 AS-V directly produces the matching pouch.



Insert instrument and seal. Done!



SealLINK

ID

VSD

length

VSD

description

note

esc

✓

✓ Save changes esc Discard changes and exit menu delete ✕ delete 📄 Export of SealLINK data 📄 Import of SealLINK data 🔑 Search function	• If the SealLINK function is active, all scanned data are assigned to this function. Seal LINK Active Seal LINK not active • This function is activated by pressing and holding the SealLINK button. • Changes to the description, notes or the actual product size are possible at any time via the library. Attention: The ID number cannot be edited
---	---

Procedure

1. Scan the medical instrument or product via the SealLINK function. Alternatively, the ID number can be entered manually.
2. During initial configuration, the SealLINK input mask opens automatically.
3. The ID number is displayed in the upper area of the mask. This corresponds to the content of the scanned barcode.
4. In the lower area, enter the actual length of the instrument.
5. Based on the entered instrument length, the SealLINK function automatically calculates the correct pouch length.
6. Optionally, a note or description of the product can be entered. This makes it easier to identify and search for the product later, even without a direct number assignment.
7. Save the entries to complete the SealLINK configuration for this instrument.
8. This procedure is repeated with every new instrument captured via the Datamatrix reader. An instrument that has been scanned once no longer needs to be created via this mask.

4.1 Settings 03



Important information on the network settings

→ Please read and observe this information beforehand

Should any questions arise in this regard, please contact an authorized service team.

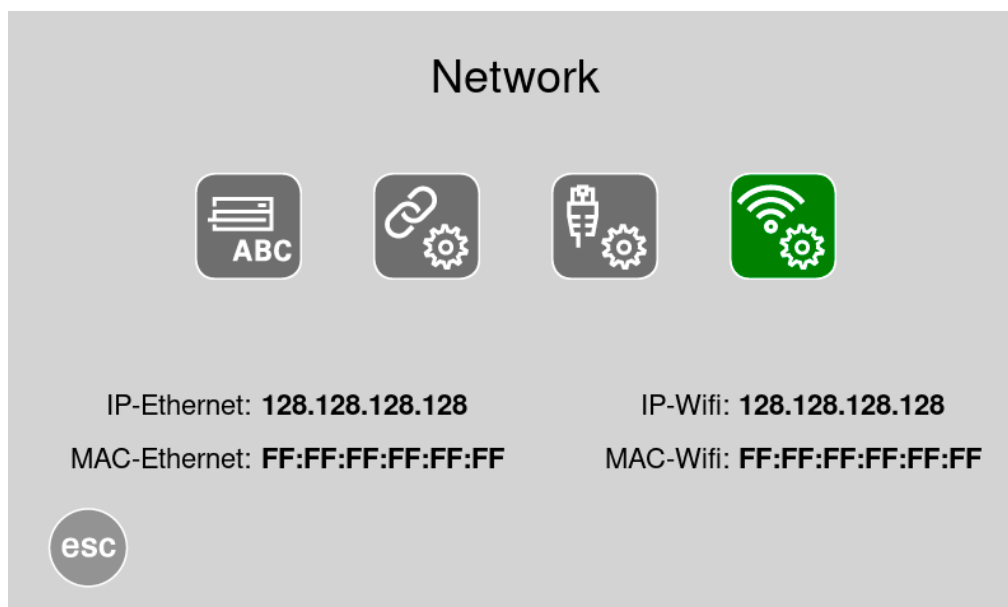
The setting of network data, IP addresses and ports should be carried out by trained personnel.

**When activating the Wi-Fi function, a check should be carried out beforehand that legitimizes the use of this interface.
By default, this function is switched off!**

Further information on the interface can be found in document 9.694.056

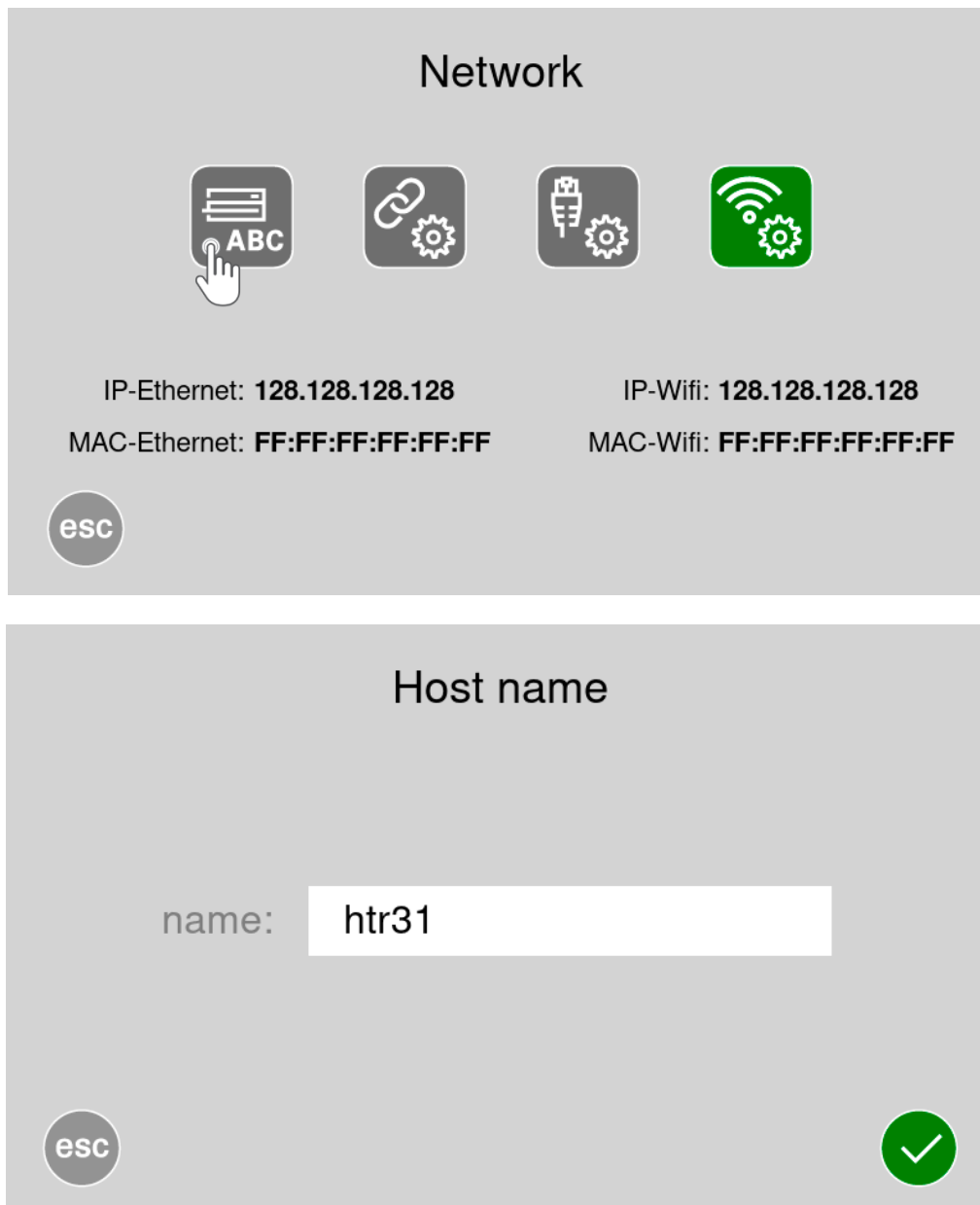
„Schnittstellenbeschreibung_ECOPAK_06_07“.

Our service team will be happy to send you this document by email on request.



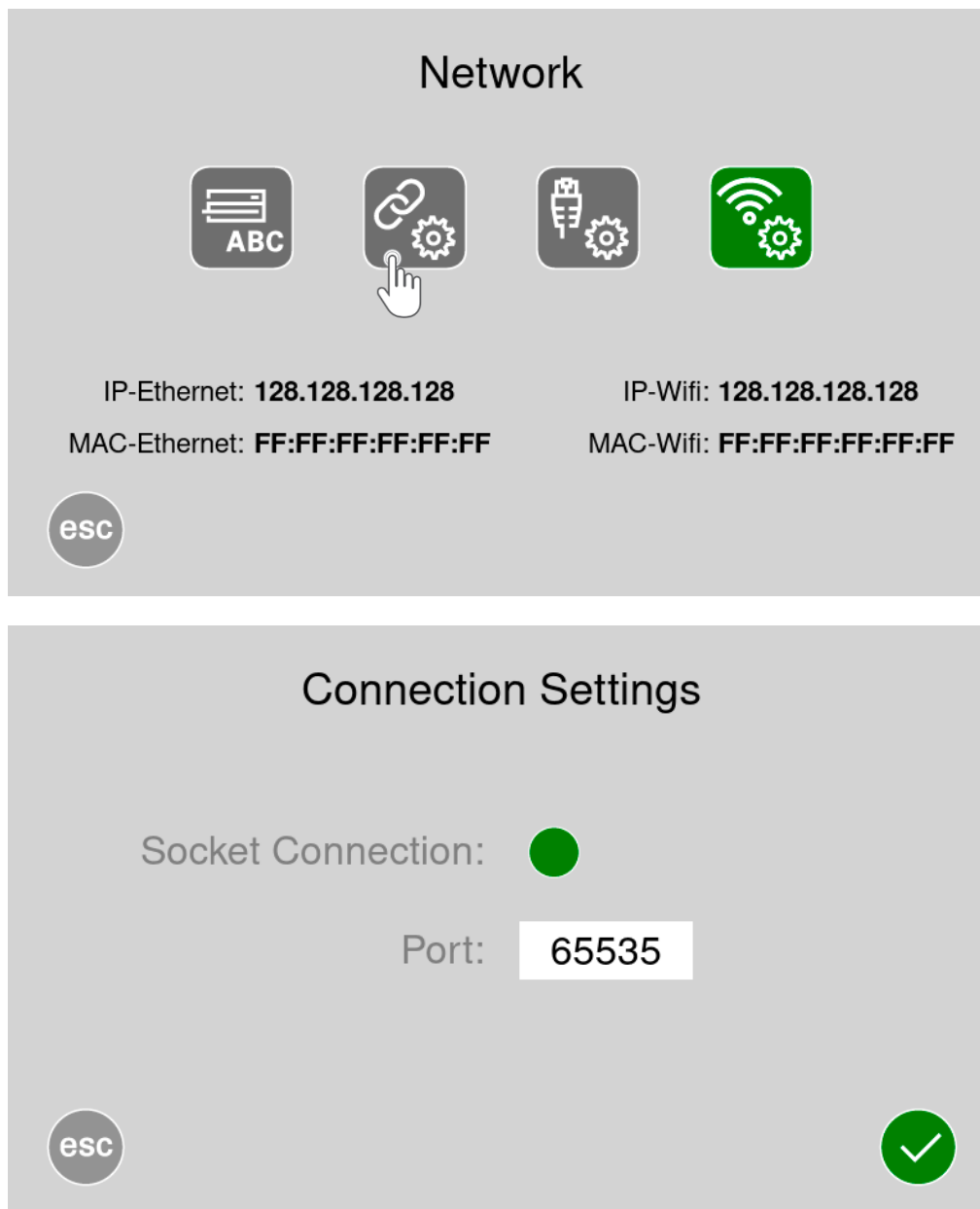
Symbol	Function	Note
	Entry of the machine name (host)	Facilitates the later assignment of machines in the network
	Settings of the network ports	Entry and activation / deactivation of the socket connection
	Ethernet settings	Entry of the IP address, gateway and subnet address as well as selection of DHCP and static IP
	Wi-Fi settings	Entry of the IP address, gateway and subnet address as well as selection of DHCP and static IP

4.1.1 Machine name



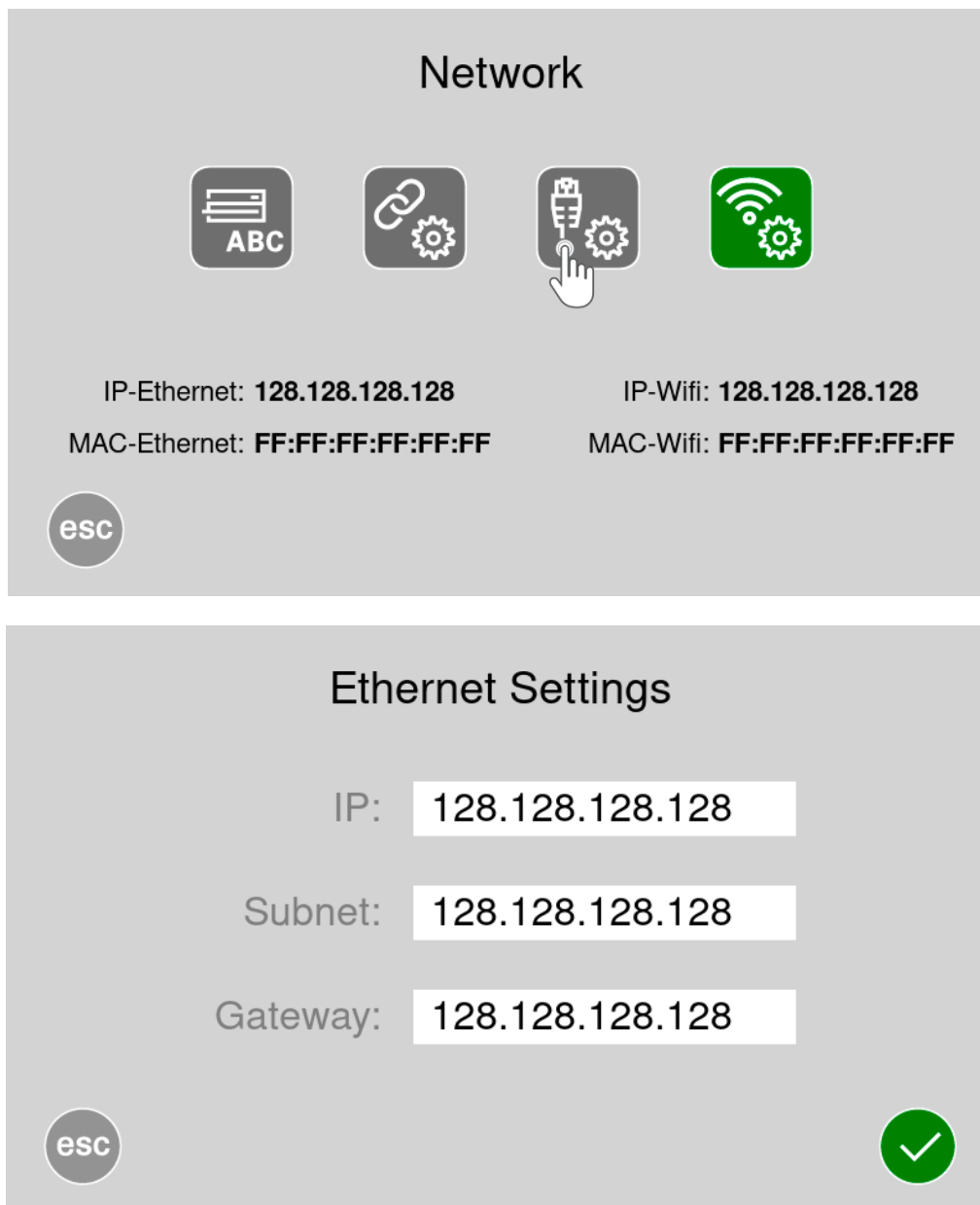
 Save changes  Discard changes and exit menu	The name is entered using the keyboard in alphanumeric form. 
--	--

4.1.2 Connection settings



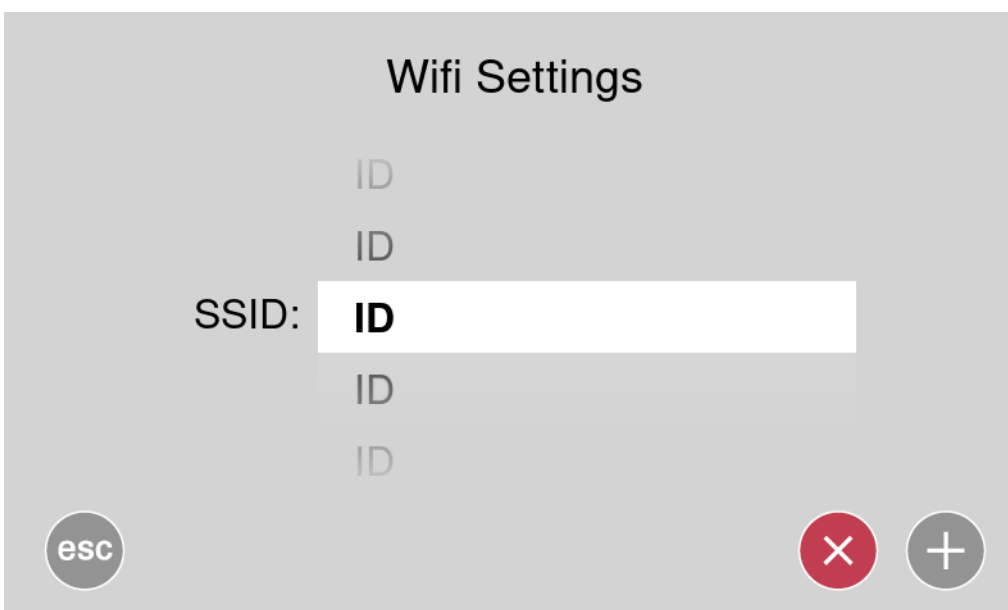
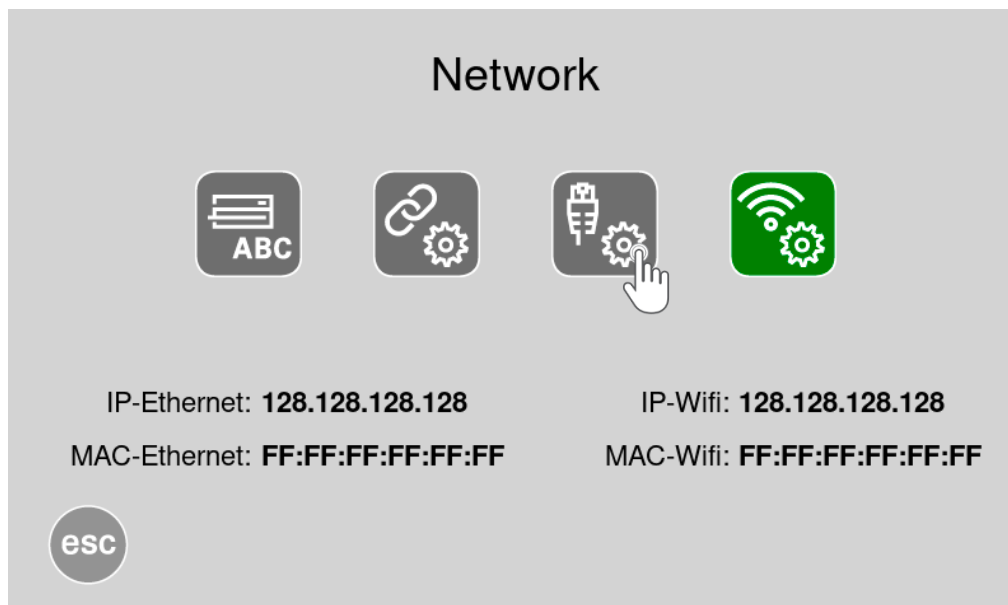
 Save changes  Discard changes and exit menu	The port is entered using the keyboard.  If a port number greater than 0 has been entered, the socket connection is active.  Port = 0  Port > 0
--	---

4.1.3 Ethernet settings



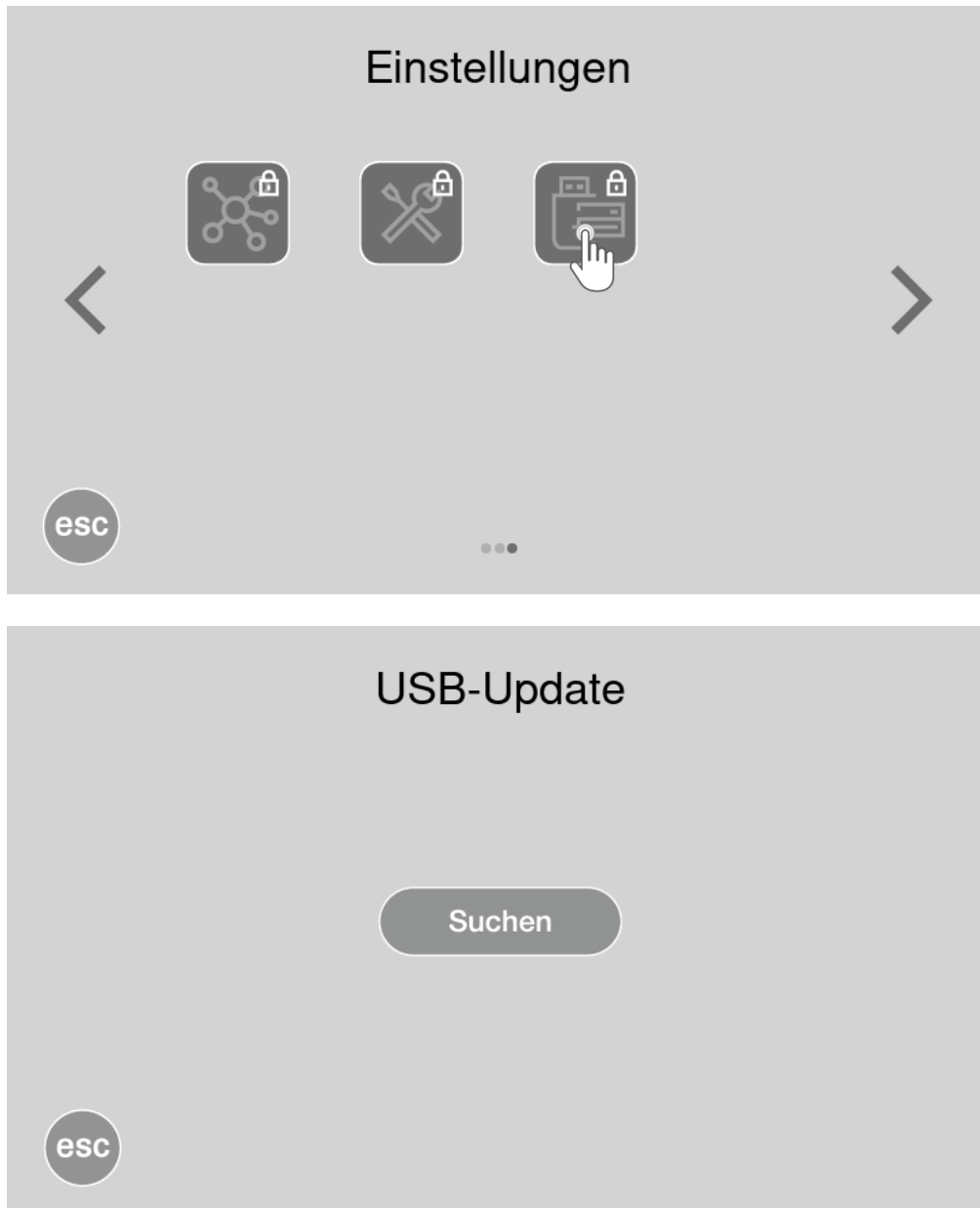
 Save changes  Discard changes and exit menu	The data are entered using the keyboard. 
---	--

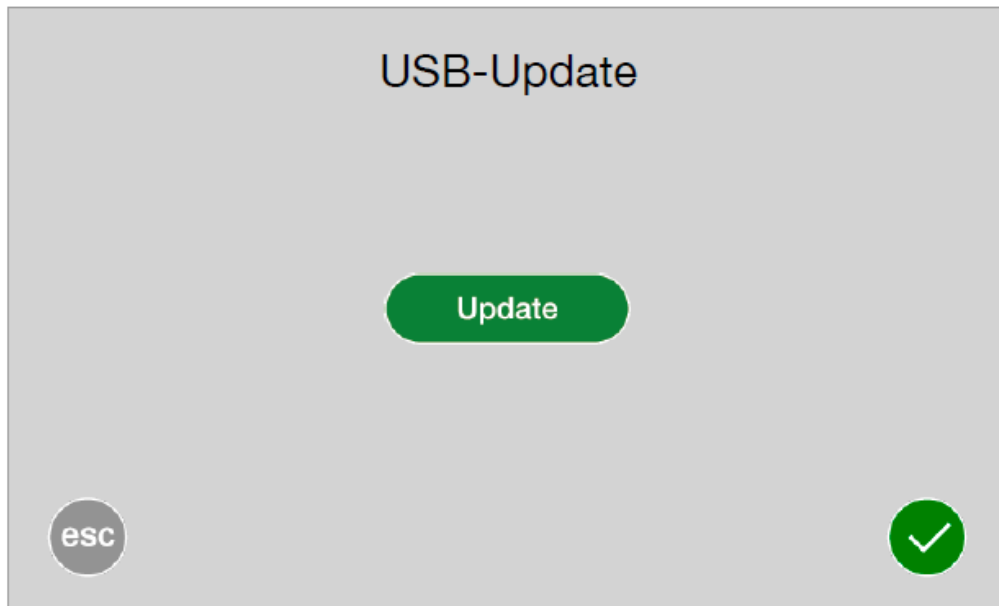
4.1.4 Wi-Fi settings



- Save changes - Discard changes and exit - Create new SSID - Delete SSID - Active - not active	Activation / deactivation is carried out by pressing and holding the Wi-Fi symbol The data are entered using the keyboard 
--	--

4.2 Update





 Save changes	After inserting a USB stick with update data, an update search can be started by pressing the button.
 Discard changes and exit menu	
 Suchen Search for update	
	 kein Update No update or no new update
	 Update Start update

5 Troubleshooting and maintenance

5.1 Troubleshooting checklist



The troubleshooting suggestions marked with an * may only be carried out by the manufacturer or by a service partner authorized by the manufacturer.

Malfunction	Possible cause	Remedy
The sealing machine cannot be switched on. No data on the display	Power supply unit -power supply unit not plugged in	Check the mains connection and, if necessary, plug the cable into another socket
	-mains cable defective	Replace mains cable
	Touch control defective	Replace temperature controller*
The sealing machine does not heat up	Setpoint temperature is too low	Increase setpoint temperature
	Temperature limiter activated	Switch off the sealing machine, let it cool down and inform your service partner.
	Temperature sensor	Replace temperature sensor*
	Heating cartridge	Check heating cartridges and replace if necessary*
No transport	Control defective	Replace control*
	Conveyor belt -damaged -no transport	Replace conveyor belt Check belt tension
	Motor start sensor	Replace light barrier*
	Motor	Replace motor*
	Control defective	Replace control*
	Front flap sensor	Check or replace reed contacts

Malfunction	Possible cause	Remedy
Uneven material transport or loud running noise	Conveyor belt guide	Replace PTFE strip on the guide Renew rail
	Conveyor belt -damaged -no transport	Replace conveyor belt Check belt tension
	Motor	Replace motor*
Seal seam does not hold	Temperature too low	Increase temperature
	Contact pressure too low	Adjust the contact pressure of the sealing roller or replace the sealing roller*
	Sealing dies Distance between the sealing dies too large	Set the distance of the sealing dies to 0.5 mm*
Seal seam distorted	Contact pressure too high	Adjust the contact pressure of the sealing roller or replace the sealing roller*
Paper side of the packaging discoloured or side gusset melted	Temperature too high	Reduce temperature
Printout too faint	Ink ribbon used up	Replace ink ribbon
No printout	Internal printer switched off	Set print start correctly
	Optical sensor „printer start“ misaligned or defective	Adjust optical sensor
Printout too faint	Ink ribbon used up	Replace ink ribbon
	Ink ribbon is not transported	Ink ribbon not engaged Check the function of the ink ribbon motor

5.2 Customer service



Your hawa customer service team is available to you Mon-Fri between 8:00 and 17:00 at the following telephone number:

+49 (0) 6261 9770-0.

You are also welcome to send your inquiries to the following email address: service@hawa.com

6 Maintenance, calibration, validation

This chapter contains general information on the Maintenance, Calibration as well as Validation and Requalification of the sealing device, in order to ensure safe and intended use.

If, for the operation of the sealing device, statutory or regulatory requirements exist, these must be complied with.

The responsibility for the planning, execution and documentation of the described measures lies with the operator.

6.1 Maintenance

The maintenance of the sealing device serves to maintain safe function as well as long-term operational readiness.

The operator is responsible for determining the type, scope and frequency of maintenance.

It is recommended to have maintenance work carried out by the manufacturer or by a manufacturer- authorized service partner. This recommendation serves to ensure proper execution as well as to avoid unintentional influence on the device function due to improper interventions. Improper maintenance or repair work can impair the safety and function of the sealing device.

After maintenance work has been carried out, the applicable statutory and safety-relevant requirements for the product must be observed. This can include, for example, electrical safety tests or comparable measures, provided that these are prescribed for the respective area of application.

For standard operation of our sealing devices, we recommend scheduled maintenance at an interval of 12 months. This interval takes into account typical operating conditions, frequency of use as well as environmental factors for standard applications.

For specific projects or special operating conditions (e.g. increased intensity of use, special environmental conditions or differing operational requirements), differing maintenance intervals can be appropriate.

Finally, it is recommended, after completion of maintenance work, to carry out a calibration of the sealing device, in order to ensure that the device continues to be operated within the intended process parameters.

6.2 Calibration

Sealing devices must be properly installed and calibrated, in order to ensure a reproducible and standard-compliant sealing process.

The determination of the intervals for the calibration of the sealing device is the responsibility of the operator.

When determining suitable calibration intervals, the following aspects can be taken into account, among others:

- Intensity of use and number of sealing cycles
- Operating hours
- Operating and environmental conditions
- Results from monitoring as well as previous operating experience

Irrespective of this, applicable standards, directives, statutory requirements as well as national or professional recommendations must be taken into account, provided that they are relevant for the respective area of application.

As an example of such professional guidance, the DGSV (**Deutsche Gesellschaft für Sterilgutversorgung**) provides corresponding guidelines and orientation aids. These documents are available free of charge on the website of the DGSV and can be used for support if needed.

The responsibility for the selection, application and implementation of suitable calibration intervals remains with the operator in any case.

6.3 Validation / Renewed performance qualification (requalification)

The sealing device described here meets the technical requirements for carrying out a process validation in accordance with the applicable normative requirements.

The sealing device described here monitors the following Process variables:

- Temperature
- Contact force
- Throughput speed (dwell time).

The sealing device described here is equipped with an alarm system that informs the user in the event of deviations in the process parameters and interrupts the sealing process. These monitoring and safety functions create the prerequisite for a standard-compliant process validation.

On this basis, the sealing process can be validated .

The planning, execution and maintenance of the validated state is the responsibility of the operator.

Requalifications are to be defined on an event- and risk-based basis, for example in the case of:

- changes to the sealing device or to process-relevant assemblies,
- changes to the packaging material,
- significant changes to the process parameters or the process management.

International standards do not specify any fixed time intervals for renewed performance qualifications (requalifications). To support the definition of suitable procedures, professional guidelines and orientation aids can be consulted, for example the documents published by the Deutsche Gesellschaft für Sterilgutversorgung (DGSV), which are available free of charge on the website of the DGSV.

The responsibility for the scope, frequency and implementation of validation and requalification measures remains with the operator.

6.4 Spare parts service



Simply order parts:

- Enter machine number.
- Enter machine type.
- Enter address as well as fax and order number.
- Mark the required items.
- Enter the required quantity.
- Sign the order.
- Fax the order.



7 Technical data sheet

Connection data

Mains connection	[V _{AC}]	100 – 240 ~
Supply voltage	[V _{DC}]	24 =
Mains frequency	[Hz]	50 / 60

Mechanics

Dimensions (length x width x height) [mm] <i>Without feed aid</i>		510 x 255 x 155
<i>With feed aid</i>		610 x 255 x 155
Housing		Powder-coated / stainless steel AISI 304
Weight	[kg]	15,0
Sealing distance to the edge	[mm]	0 – 35
Seal seam width	[mm]	12 +/-0,5
Sealing system		SealPeak (hawaFlex)
Seal seam length	[mm]	Unlimited
Distance to the medical product	[mm]	>30 (in accordance with DIN 58953-7)

Process variables / sealing parameters

Sealing temperature	max.	[°C]	210
Sealing temperature tolerance		[°C]	± 2 - 5
Contact pressure		[N]	100
Contact pressure deactivation tolerance		[%]	± 20
Throughput speed		[m / min]	5 -13
Shut-off tolerance throughput speed		[%]	± 10
Temperature ranges			3
Standard temperature tolerance		[°C]	±2

Electronics and communication systems

System		Microprocessor
Interfaces		2 x RS-232 2 x USB-A 1 x RJ45 Wi-Fi
Transmission speed (baud rate)	[Bd]	9.600
Serial RS 232 interfaces and Ethernet		
Electrical protection class	(in accordance with DIN EN 61140 / VDE 0140-1)	3
Degree of protection	(in accordance with DIN EN 60529)	IP 20

Environmental parameters

Ambient temperature	[°C]	+5 to +40
Heat emission	[kJ/s]	0,1
Relative humidity	max. [%]	80 non-condensing
Noise intensity in accordance with the Machinery Directive 2006/42/EC Annex I 1.7.4.2 u.)	[dB(A)]	<45 +/- 10
Combined power consumption	[W]	67.5 - 90 W ¹
Power consumption in normal operation	[W]	27 - 32 W ²
Max. noise emission	[dB]	65

¹ Depending on the temperature setting; may vary during the heat-up phase (280.08 W max.).

² Depending on the temperature setting; „normal operation“ means 25% operating mode and 75% Standby + mode

8 Declaration of conformity

8.1 CE Declaration of Conformity

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration "CE" de Conformité Declaración de conformidad de la C.E. Dichiarazione di conformità - Declaração de conformidade	9.694.053C
Gültig ab: 01.07.2026 Valid from: 01.07.2026	Seite 1/1 Version 1.02	
Hiermit erklären wir, daß die Folienschweissmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: Dichiariamo con la presente che le macchine per saldatura di fogli: Por este meio se declara que as máquinas de selagem de folhas de plástico:		
hd 650 DCT-V ECOPAK 07/07S		
folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: correspondre 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:		
EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle macchine nella versione Directiva da UE relativa a maquinaria	2006/42/EG	
EMV-Richtlinie Directive CEM Direttiva CEM	EMC-directive Directiva de CEM Directiva CEM	2014/30/EU
WEEE-Richtlinie Directive WEEE Direttiva WEEE	WEEE-directive Directiva de WEEE Directiva WEEE	2012/19/EU
RoHS-Richtlinie Directive RoHS Direttiva RoHS	RoHS-directive Directiva de RoHS Directiva RoHS	2015/863/EU
Harmonisierte Normen Standard harmonise Norme armonizzate	Harmonized standards Las normas armonizadas Normas harmonizadas	EN ISO 12100:2010 EN ISO 13857:2019 EN IEC 63000:2018 EN 60204-1:2018 EN IEC 61000-6-1:2019 EN IEC 61000-6-3:2021
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		
 hawa GmbH 74847 Obrigheim/Germany T +49 (0) 6261 / 9770-0 info@hawa.com		
Torsten Ehrhardt Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany		
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.

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8.2 Declaration of conformity ISO 11607-2 / KRINKO / BfArM / DIN 58953-7

 74847 Obrigheim / Germany	Konformitätserklärung – Declaration of Conformity Déclaration de Conformité Declaración de conformidad Dichiarazione di conformità - Declaração de conformidade	9.694.053D						
Gültig ab: 01.07.2026 Valid from: 01.07.2026	Seite 1/1 Version 1.02							
Hiermit erklären wir, daß die Folienschweissmaschinen: Herewith we declare that the Foil sealing unit: Par la présente, nous déclarons que la gamme de Soudeuse de films plastique: Por la presente certificamos que las máquinas embolsadoras modelos: Dichiariamo con la presente che le macchine per saldatura di fogli: Por este meio se declara que as máquinas de selagem de folhas de plástico: hd 650 DCT-V ECOPAK 07/07S 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: <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top; width: 50%;"> 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) </td> <td style="vertical-align: top; width: 50%;"> KRINKO / BfArM Bundesgesundheitsblatt 2012 55:1244-1310 </td> </tr> <tr> <td style="vertical-align: top;"> 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 </td> <td style="vertical-align: top;"> ISO 11607-2:2019 </td> </tr> <tr> <td style="vertical-align: top;"> Sterilisation – Sterilgutversorgung – Teil 7: Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und –schläuchen Sterilization – Sterile supply – Part 7: Use of sterilizaiton paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels Stérilisation – Approvisionnement en produits stériles – Partie 7: Utilisation de papier pour stérilisation, de matériaux d'enveloppe en non-tissé, matériaux textiles tissés, de sacs en papier, de sachets et gaines scellables </td> <td style="vertical-align: top;"> DIN 58953-7:2020 </td> </tr> </table>  hawa GmbH 74847 Obrigheim/Germany T +49 (0) 6261 / 9770-0 info@hawa.com Torsten Ehrhardt Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany			Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention(KRINKO) beim Robert Koch-Institut(RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte(BfArM)	KRINKO / BfArM Bundesgesundheitsblatt 2012 55:1244-1310	Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens Packaging for terminally sterilized medical devcies – Part 2: Validation requirements for forming, sealing and assembly processes Emballages des dispositifs médicaux stérilisés au stade terminal – Partie 2: Exigences relatives aux procédés de mise en forme, de fermeture et d'assemblage	ISO 11607-2:2019	Sterilisation – Sterilgutversorgung – Teil 7: Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und –schläuchen Sterilization – Sterile supply – Part 7: Use of sterilizaiton paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels Stérilisation – Approvisionnement en produits stériles – Partie 7: Utilisation de papier pour stérilisation, de matériaux d'enveloppe en non-tissé, matériaux textiles tissés, de sacs en papier, de sachets et gaines scellables	DIN 58953-7:2020
Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention(KRINKO) beim Robert Koch-Institut(RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte(BfArM)	KRINKO / BfArM Bundesgesundheitsblatt 2012 55:1244-1310							
Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens Packaging for terminally sterilized medical devcies – Part 2: Validation requirements for forming, sealing and assembly processes Emballages des dispositifs médicaux stérilisés au stade terminal – Partie 2: Exigences relatives aux procédés de mise en forme, de fermeture et d'assemblage	ISO 11607-2:2019							
Sterilisation – Sterilgutversorgung – Teil 7: Anwendungstechnik von Sterilisationspapier, Vliesstoffen, gewebten textilen Materialien, Papierbeuteln und siegelfähigen Klarsichtbeuteln und –schläuchen Sterilization – Sterile supply – Part 7: Use of sterilizaiton paper, nonwoven wrapping material, textile materials, paper bags and sealable pouches and reels Stérilisation – Approvisionnement en produits stériles – Partie 7: Utilisation de papier pour stérilisation, de matériaux d'enveloppe en non-tissé, matériaux textiles tissés, de sacs en papier, de sachets et gaines scellables	DIN 58953-7:2020							
hawa GmbH Obere Au 2-4 74847 Obrigheim / Germany	T + 49 (0) 6261 / 9770-0 F + 49 (0) 6261 / 62015 info@hawa.com www.hawa.com	Amtsgericht Mannheim: HRB 441011 Geschäftsführer: Christian Wolf Firmensitz: Obrigheim						
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