



HD 650 DE-V

EcoPak 06

TRANSLATION OF THE ORIGINAL OPERATING INSTRUCTION

Valid for device software versions 10-0505-01-01 / 10-0496-02-02

1	INTRODUCTION	3
1.1	PREFACE	3
1.2	LEGEND	3
1.3	IMPORTANT NOTICE	4
1.4	CLEANING	4
1.5	SAFETY INSTRUCTIONS	5
2	BEFORE COMMISSIONING	7
2.1	INTENDED USE	7
2.2	SETUP AND FUNCTIONS.....	8
	2.2.1 Sealing procedure sequence.....	8
2.3	SETUP	9
2.4	INSPECTION OF THE DEVICE.....	9
2.5	OPERATION.....	10
3	BASIC FUNCTIONS.....	11
3.1	SWITCH ON DEVICE.....	11
3.2	PROCESS VARIABLES	11
3.3	EXPLANATIONS OF THE HOME SCREEN.....	12
3.4	TEMPERATURE SETTING.....	13
3.5	CONTROL CENTRE	14
	3.5.1 Monitoring display	14
	3.5.2 Device's operating data display.....	14
3.6	SEALING SEAM INSPECTION – "SEAL CHECK".....	15
3.7	SETTINGS 01.....	16
	3.7.1 DataMatic	17
	3.7.2 List of names.....	18
	3.7.3 Scanner function	19
	3.7.4 Batch counter.....	20
	3.7.5 Test intervals.....	21
	3.7.6 Standby	22
	3.7.7 Operator standby	23
3.8	SETTINGS 02.....	24
	3.8.1 Date/time.....	25
	3.8.2 Expiry date	26
	3.8.3 Unit of measurement.....	28
	3.8.5 Language	29
	3.8.6 Network settings (IP).....	30
	3.8.6.1 Device name	32
	3.8.6.2 Connection settings.....	33
	3.8.6.3 Ethernet settings	34
	3.8.7 Update.....	35
4	TROUBLESHOOTING AND MAINTENANCE	36
4.1	TROUBLESHOOTING CHECKLIST	36
4.2	CUSTOMER SERVICE.....	37
5	ALARM FUNCTIONS AND ERROR DISPLAYS	38
5.1	MAINTENANCE/CALIBRATION.....	38
5.2	SPARE PARTS SERVICE	38
6	TECHNICAL DATA SHEET	39
7	DECLARATION OF CONFORMITY.....	40
7.1	CE DECLARATION OF CONFORMITY	40
7.2	DECLARATION OF CONFORMITY ISO 11607-2 / KRINKO / BfARM / DIN 58953-7	41

1 Introduction

1.1 Preface

Thank you for purchasing this sealing device.




These instructions contain information on the use, maintenance and care of the device.

This sealing device is a microprocessor controlled rotary sealer for packaging sealable transparent pouches and reels (medical packaging).



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

1.2 Legend

	The exclamation mark in the triangle draws your attention to important notes in the operating instructions, which must absolutely be observed.
	This warning sign refers to measures that could pose a risk to human health if not observed. It is compulsory to observe it.
	Tips with a hand symbol next to it refer to everyday practice.

1.3 Important notice



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

The Medical Devices Directive 93/42/EEC and the Medical Device Regulation 2017/745 (MDR) do not apply to sealing devices.
The limit values of IEC 60601-1 must not therefore be used for repeated electrical inspections.

The manufacturer does not accept any liability for damage caused by tests according to standards that are not listed in the declaration of conformity.

If the device is modified or tampered with without the manufacturer's express permission, the warranty is invalidated and any liability for physical or material damage is transferred to the operator.

Note

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

These operating instructions apply to products in the EcoPak 06 series.

1.4 Cleaning

Before cleaning, pull the mains plug out of the socket and disconnect the device from the power supply unit with the plug. Clean the device only with a dry or slightly damp soft cloth and a mild cleaning agent. (For example: Isopropanol, spirit, etc.) Prevent water from finding its way into the device.

Caution! Never wet clean the device!

1.5 Safety instructions



1. In terms of their safety technology, our products are in perfect condition when they leave our factory.
2. In order to maintain this condition, the contents of these safety instructions as well as the type plates, labelling and safety information attached to the device must be observed during handling of the device (transport, storage, setup, commissioning, operation and maintenance).
3. This device is suitable for processing sealable pouches and reels. See "Intended use".
4. Please check the packaging and report any defects to the carrier or parcel service immediately before setting up the device.
5. Before commissioning, make sure that the device shows no signs of damage. If in doubt, please contact the manufacturer or an authorised service partner appointed by the manufacturer.
6. Do not use the device if the mains cable, mains plug or power supply unit 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 machine is damaged, it must be repaired by the manufacturer or one of the manufacturer's authorised service partners.
7. The device needs to be connected to an earthed socket with a stable voltage using the mains cable supplied. Use in IT networks is not permitted.
8. Place the device on a stable surface.
9. The device may only be installed and operated in dry, non-potentially explosive areas.
10. Condensation may form if the sealing device is brought directly from a cold environment into a warm environment. Wait until temperature equalisation has taken place.
11. Repairs and the replacement of wear parts/spare parts may only be performed by the manufacturer or one of the manufacturer's authorised service partners.
12. Switch off the device when it is not in use and disconnect the mains plug from the socket.
13. Do not use the device if you have any doubts about its safety.
14. Do not insert pointed or flat items into the import slot of the device. This can result in damage to the device and the instruments as well as an electric shock.
15. The device must not be installed or operated by persons under 14 years of age.
16. The device must not be operated unsupervised.
17. It is forbidden to operate the device when under the influence of drugs or alcohol.
18. Keep hair, clothing and gloves away from moving parts! Loose clothing, jewellery or long hair can get caught in moving parts.





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

2 Before commissioning

2.1 Intended use

SEALABLE MATERIALS

Sealable paper pouches in accordance with EN ISO 11607-1/EN 868-4	x
Sealable pouches and reels made of film in accordance with EN ISO 11607-1/EN 868-5 and made of paper in accordance with EN 868-3	x
Sealable pouches and reels made of film in accordance with ISO EN 11607-1/EN 868-5 and uncoated materials made of polyolefins in accordance with EN 868-9 (e.g. Tyvek® ¹)	x
Sealable pouches and reels in accordance with ISO 11606-1/EN 868-5 made of PP fleece or PP textile composite material	x ²
Aluminium laminated film	x ²

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 Release and / or testing required

The device is also intended

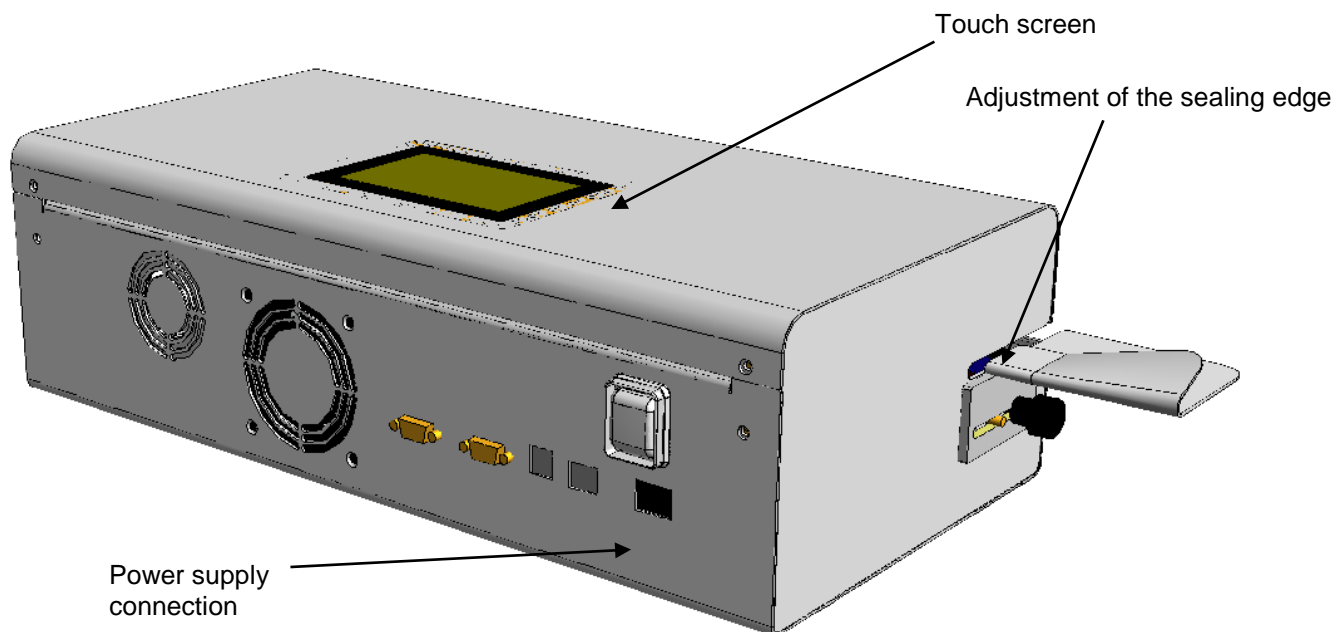
- a) For use at work
- b) For use by persons aged 14 years and over
- c) For operation by instructed persons

The packaging of foodstuffs and hazardous substances (substances hazardous to health, in particular toxic, corrosive, highly flammable and explosive substances) is not intended.

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



2.2 Setup and functions



2.2.1 Sealing procedure sequence

- Step 1:** After the med. packaging has been inserted, the feed is automatically switched on.
- Step 2:** The med. packaging is now fed and the sealing seam area is heated to the set sealing temperature by the heating elements fitted at the top and bottom.
- Step 3:** The sealing seam, which is now heated, is pressed together by the sealing rollers and sealed.
- Step 4:** The finished med. packaging is transported to the extraction side.
- Step 5:** If no further med. packaging is fed, the feed switches off automatically after 10 seconds.

2.3 Setup



The setup or operation of the device in potentially explosive atmospheres is not permitted.

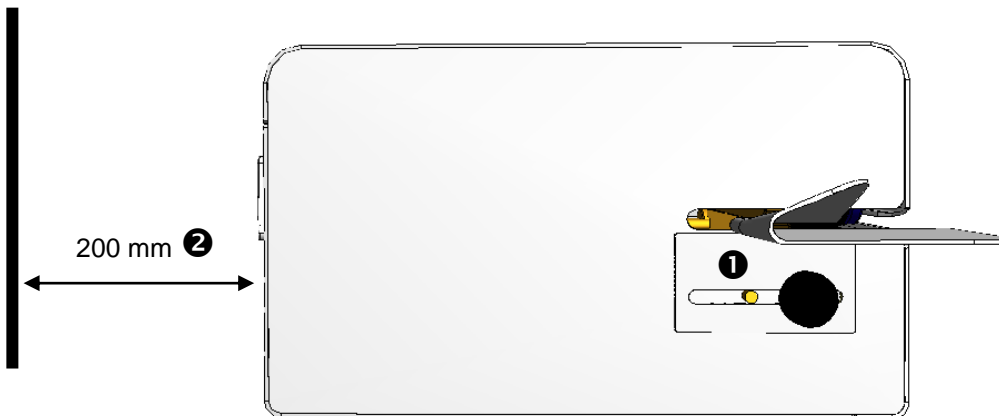
Only use sockets that are equipped with a protective earth conductor and connected to a stable mains voltage.



The device may only be installed in a dry environment. The function is impaired by high levels of dust and vapour as well as dripping or splashing water.

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

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



2.4 Inspection of the device

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

Sealing device

Power supply unit

Insertion plate

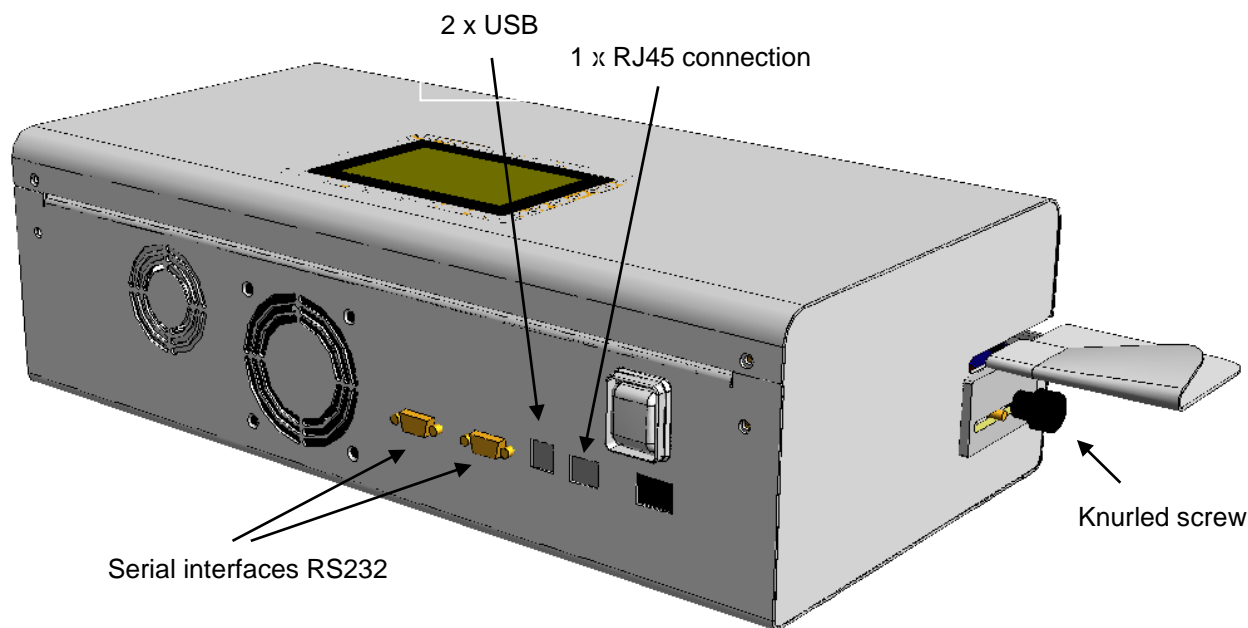
Power cable

Operating instructions

Test report



2.5 Operation



- Step 1** Set the desired width of the sealing edge. After loosening the knurled screw, the insertion plate can be infinitely adjusted to sealing edge widths between 0 and 30 mm.
- Step 2** Insert the packaging into the device from the left via the insertion plate.
- Step 3** Remove the sealed packaging from the outlet side and allow it to cool briefly.



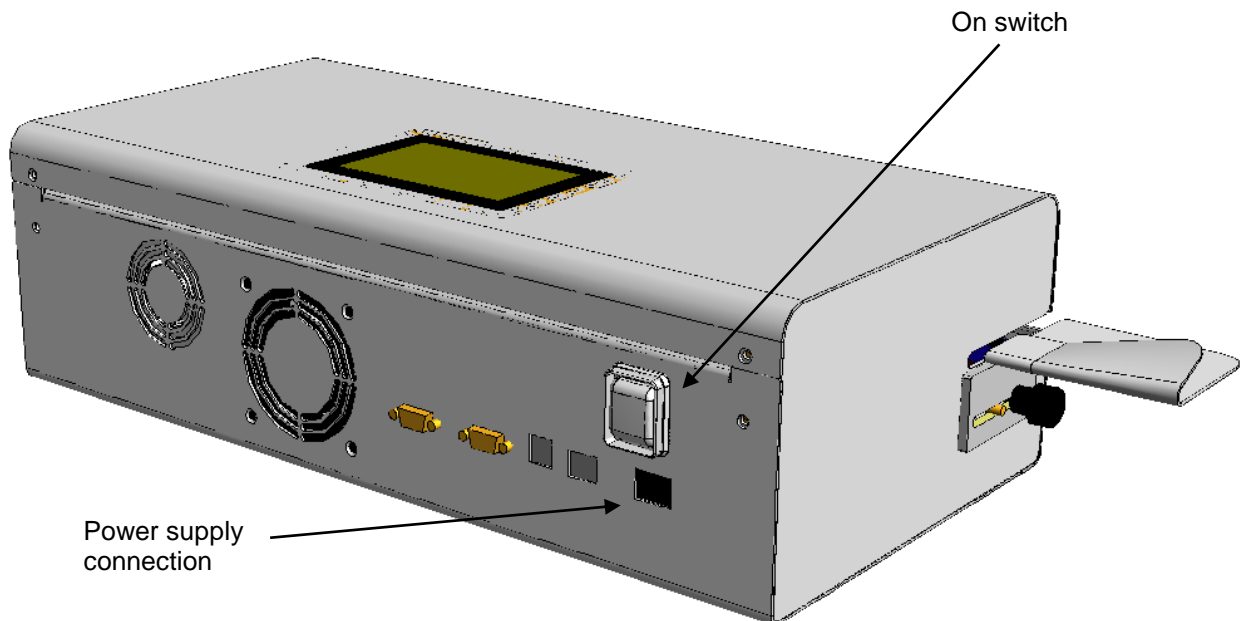
Testing the sealing seam (see Sealing seam test chapter)

The sealing temperature must be increased in case of leaks. If the film melts, the set temperature is too high.

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

3 Basic functions

3.1 Switch on device



Plug the power supply unit into the device's power supply connection.

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

Switch the device on by setting the on switch to position "1".

Set the desired sealing temperature on the temperature controller.

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

3.2 Process variables

Sealing temperature

The temperature is monitored electronically by means of a temperature sensor.

If the temperature deviates from the set value by 5°C (specifications in accordance with DIN 58953-7), the drive is disabled.

Contact pressure

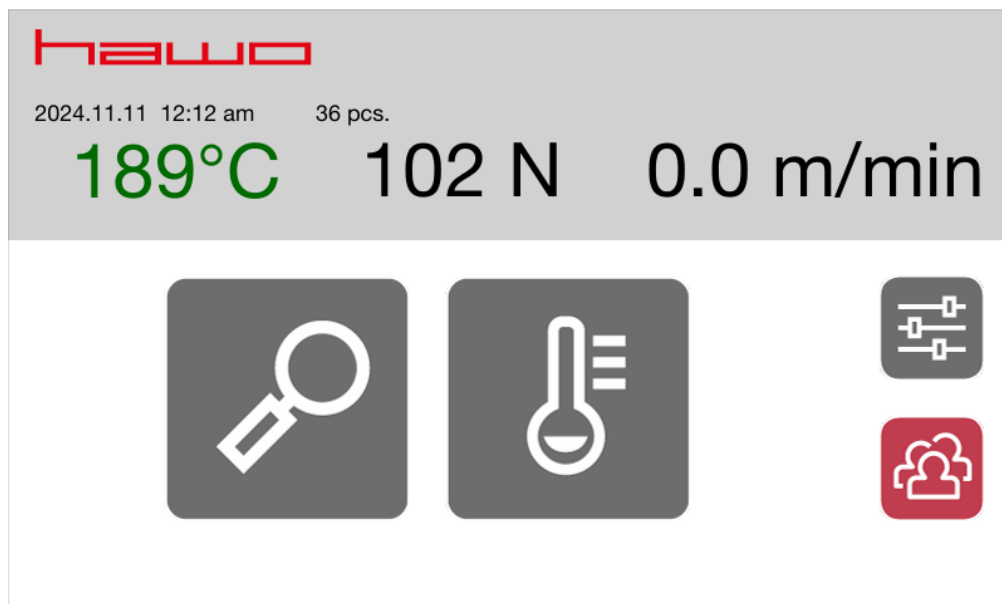
The contact pressure is monitored electronically by means of a strain gauge.





If the set value deviates within the tolerance range of +/-20%, an alarm message is issued (as specified in DIN 58953-7) and the sealing process is blocked.

Sealing speed (holding time)

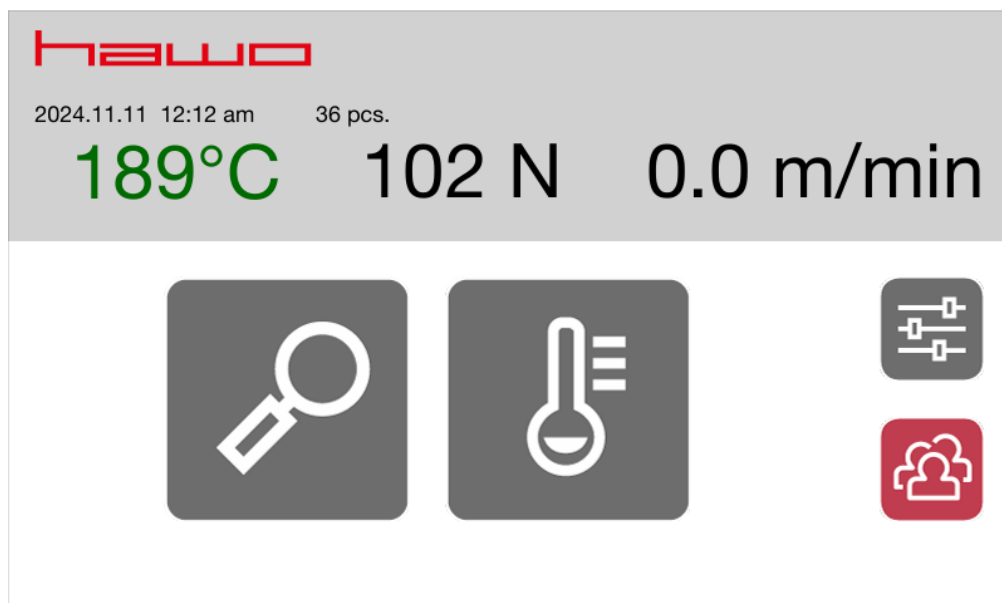
The sealing speed (exposure time) is monitored electronically by means of a speed sensor. An alarm message is issued if the value deviates +/-10% from 10m/min, (as specified in DIN 58953-7) and the sealing process is blocked.





3.3 Explanations of the home screen



Symbol	Function	Note
189°C	Display of the current sealing temperature	
102 N	Displays the current pressing force	
0.0 m/min	Displays the current throughput speed	Value > 0 only when the motor is running
	Log in	Log in/out user (see Operator chapter)
	Control centre	Check of the heating, DMS module and motor functions as well as the device operating data
8 pcs.	Display of the total batch counter / the set quantity	
	Seal test	
	Selection of the sealing parameters used	

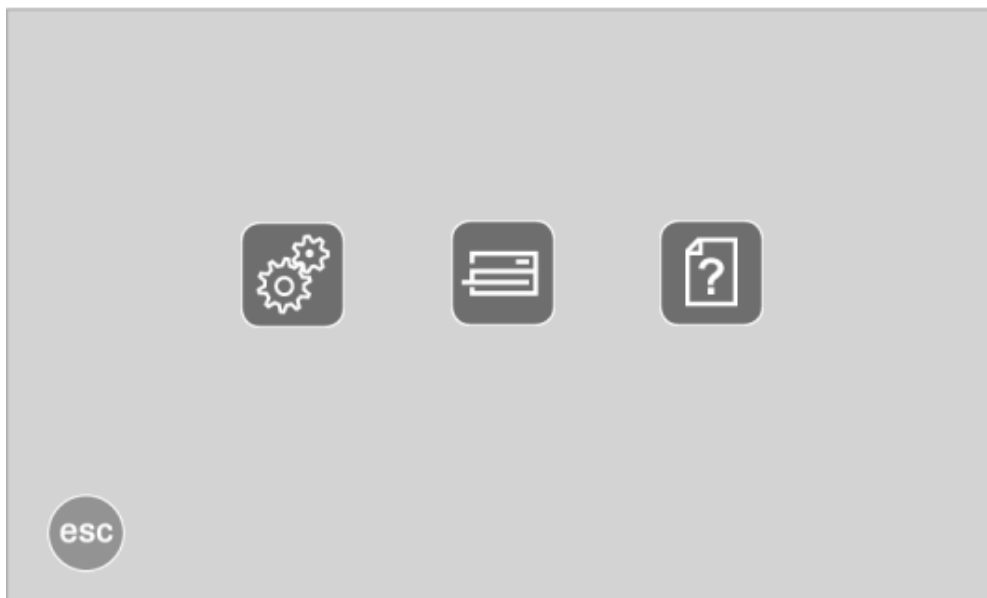
3.4 Temperature setting



Symbol	Function	Note
	Temperature setting	Press and hold one of the buttons 1, 2 or 3 to change the corresponding settings.
 	Temperature selected by tapping Temperature not selected	A temperature must be selected.
	Colour selection for the different temperatures	The colour changes each time the button is pressed.



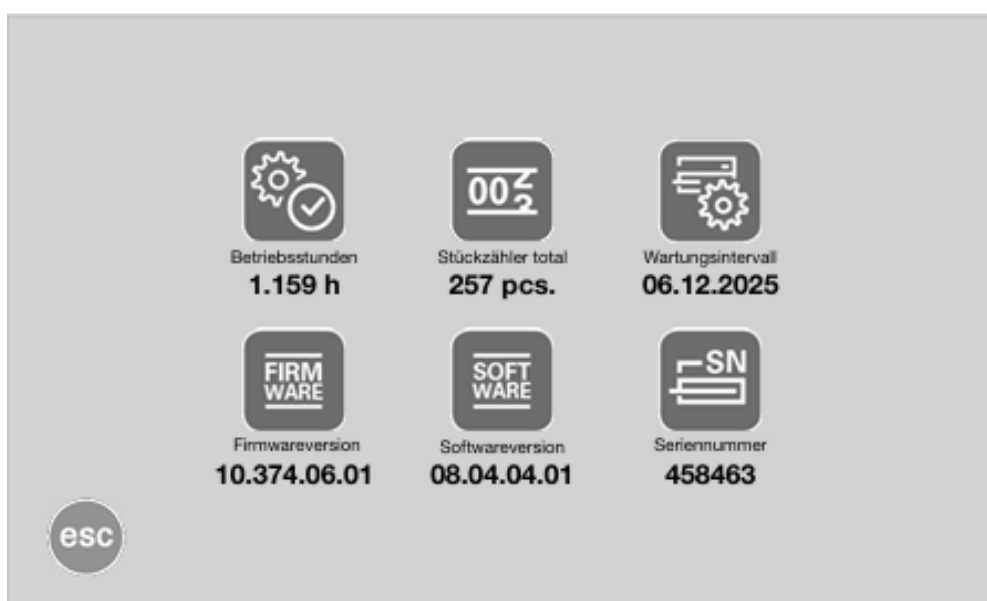
3.5 Control centre



3.5.1 Monitoring display

Symbol	Function	Note
	Monitoring of the temperature	Monitoring of the process variables: The symbols indicate whether the device's respective sensors are working. By tapping one of the 3 symbols, the sensor status of all 3 values is queried and the respective symbol is then labelled as "red" or "green".
	Monitoring of the contact pressure	
	Monitoring of the speed (dwell)	

3.5.2 Device's operating data display.



3.6 Sealing seam inspection – "Seal Check"

Check the process variables (temperature, contact pressure and sealing time [holding time]) using the "SEAL CHECK" function.



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

This test should be performed and documented before and after the daily working process and/or before/after each batch.

It is recommended to use the sealing device's SEAL CHECK function in addition to the SEAL CHECK sealing indicator.

Before the test, the sealing device must be ready for operation and the set temperature must have been reached.

Symbol	Function	Note
	Seal test	Execution of a routine test Seal test, ink test or peel test

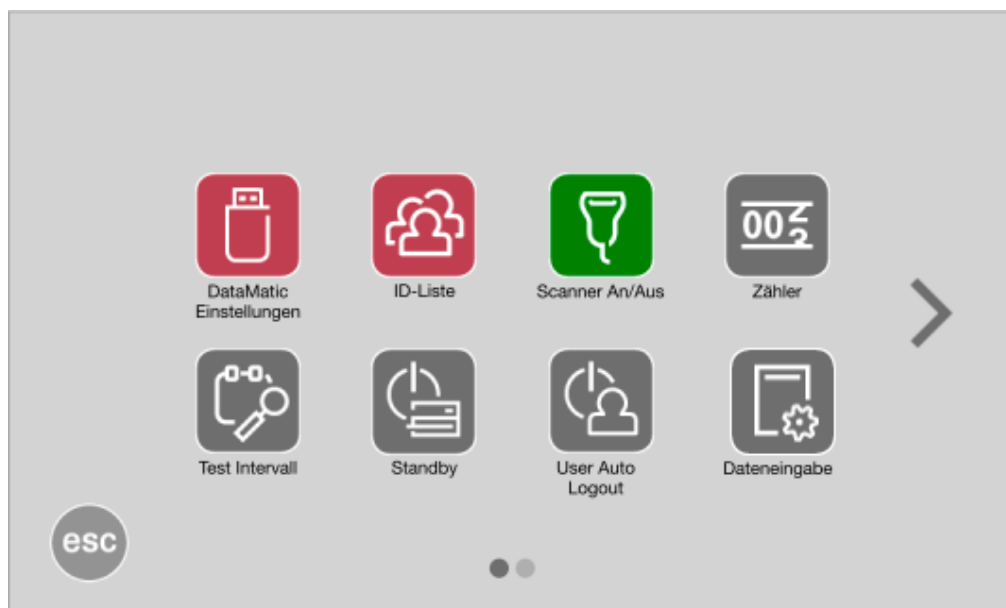
Activation and start of the sealing seam test









1. Activate sealing seam test
2. Select type of sealing seam test
3. Insert med. packaging with a minimum width of 200 mm and start the Seal Check.

This key is used to cancel the function

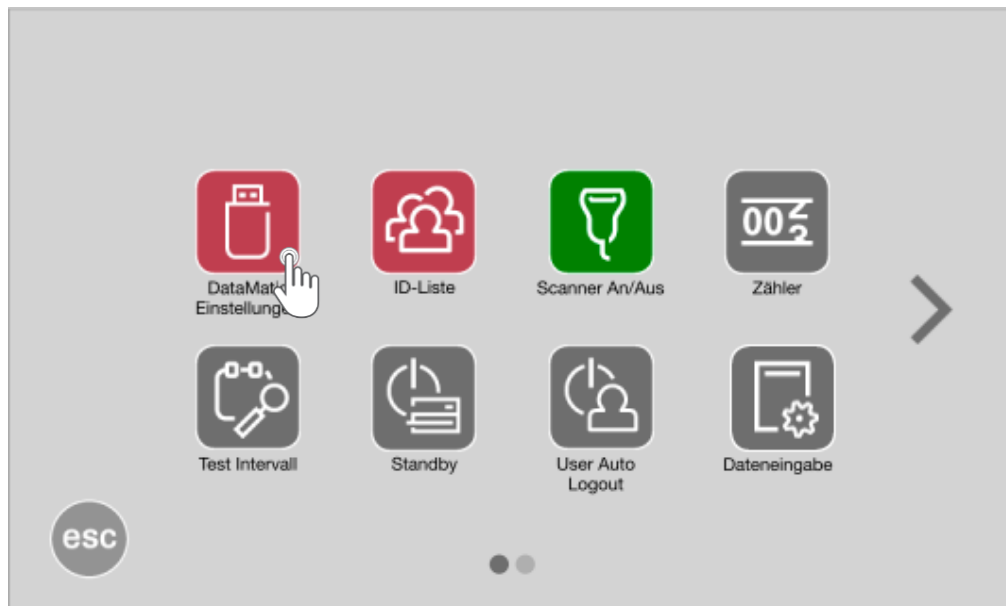
4. Evaluate the result of the sealing seam and confirm the question with the respective button.

3.7 Settings 01



Symbol	Function	Note
	DataMatic	Selection of individual DataMatic data: Date, time, temperature, contact pressure, sealing speed, total batch counter and serial number are fixed default values.
	Name list	Creating, editing and deleting users
	Scanner	Assignment of scanned data to other functions.
	Batch counter	Setting the batch counter for counting up/down
	Test intervals	Setting different intervals for seal test, ink test and peel test.
	Standby	After the selected time, the device reduces the heat output and cools down to 80°C.
	User standby	After a selected period of time, a logged-in user is logged out automatically.
	Data input	Enter the information for LOT, CE, Info, REF and Steri

3.7.1 DataMatic



Activating the individual DataMatic function

Press and hold the button

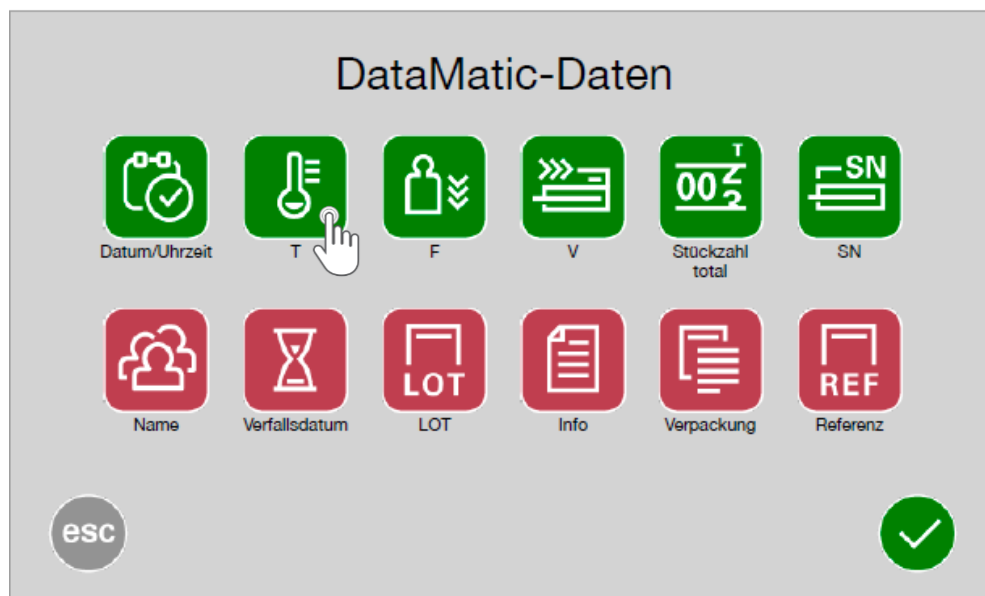


DataMatic **not** active



DataMatic active

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



You can activate the saving and recording of the respective data by tapping the symbol.



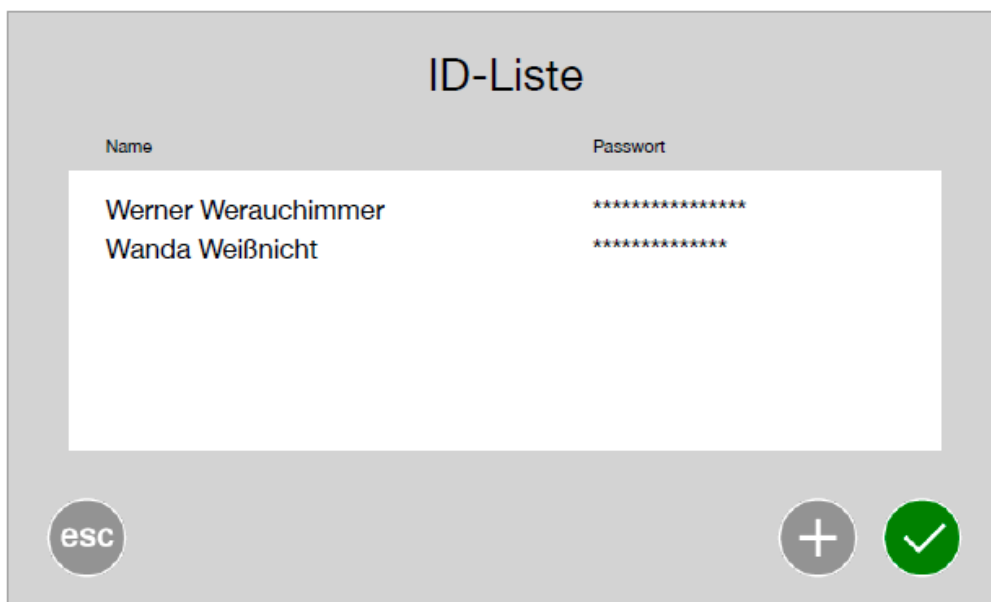
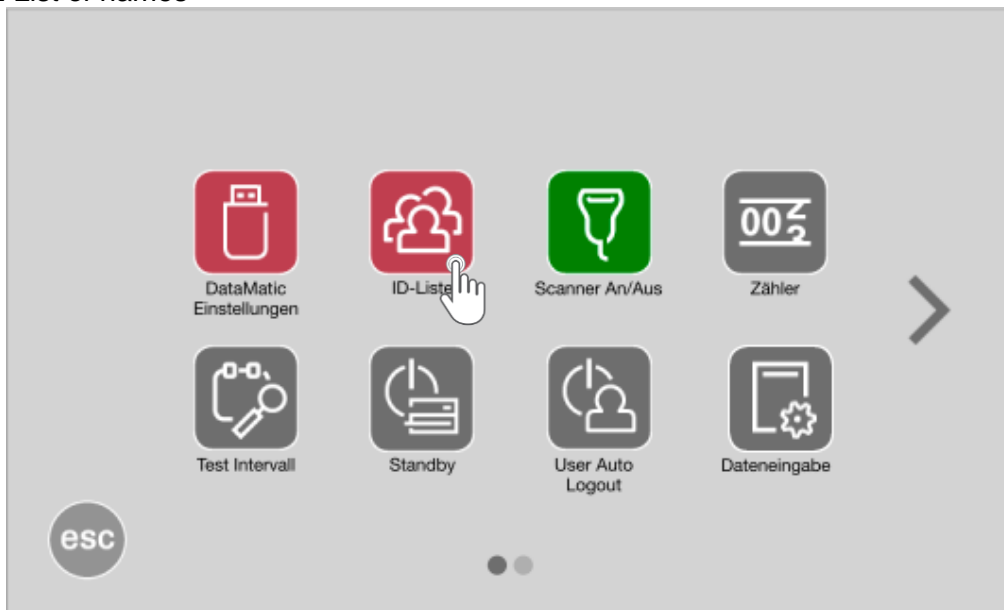
Recording **not** active



Recording active

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

3.7.2 List of names



Create a new operator



Save changes

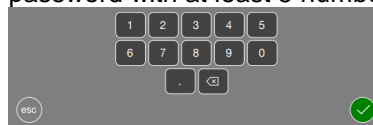


Discard changes and exit menu

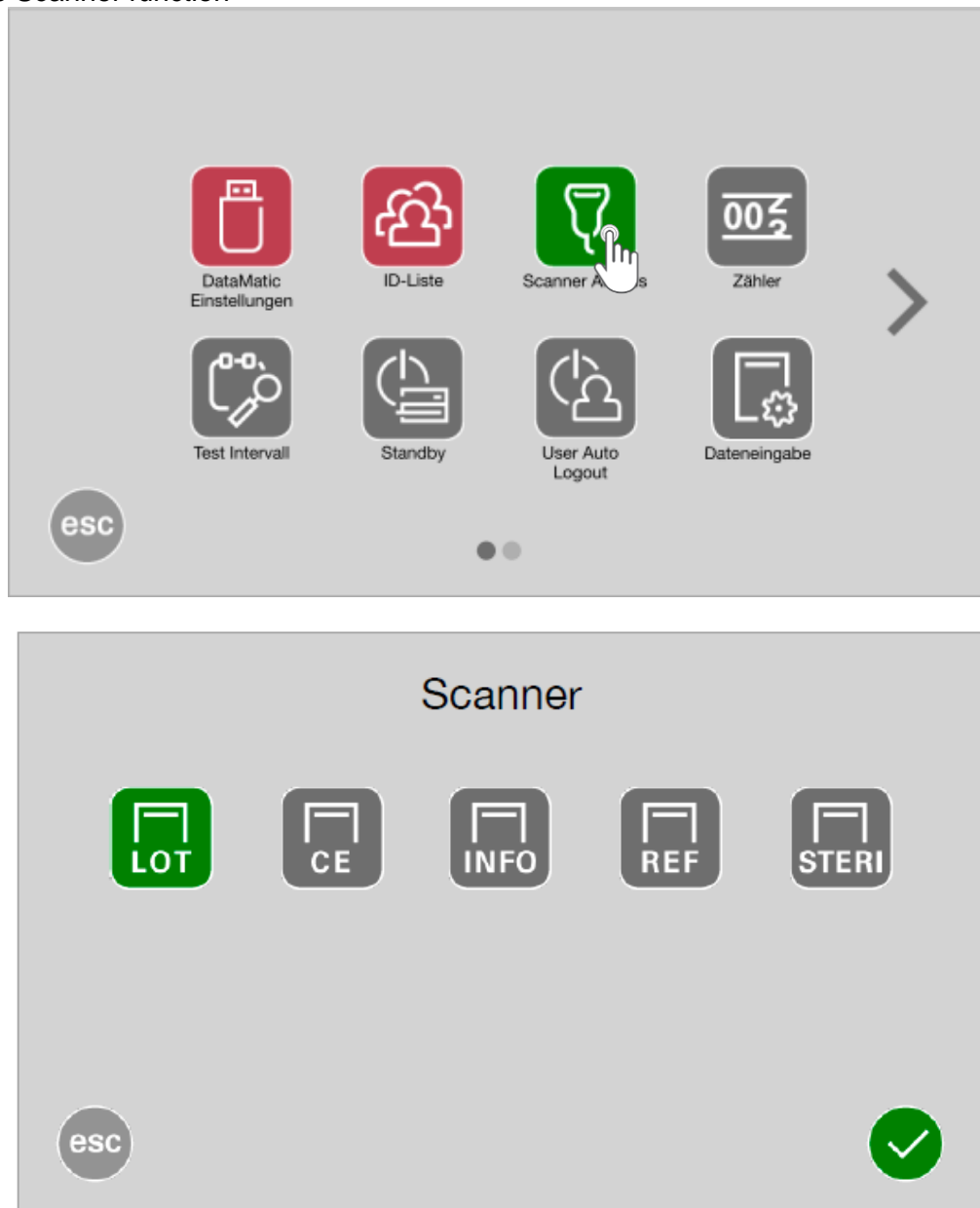
A new operator is entered using the keyboard that appears. Alternatively, a USB keyboard can be used.



After entering the name, the system requires a numerical password with at least 5 numbers.



3.7.3 Scanner function



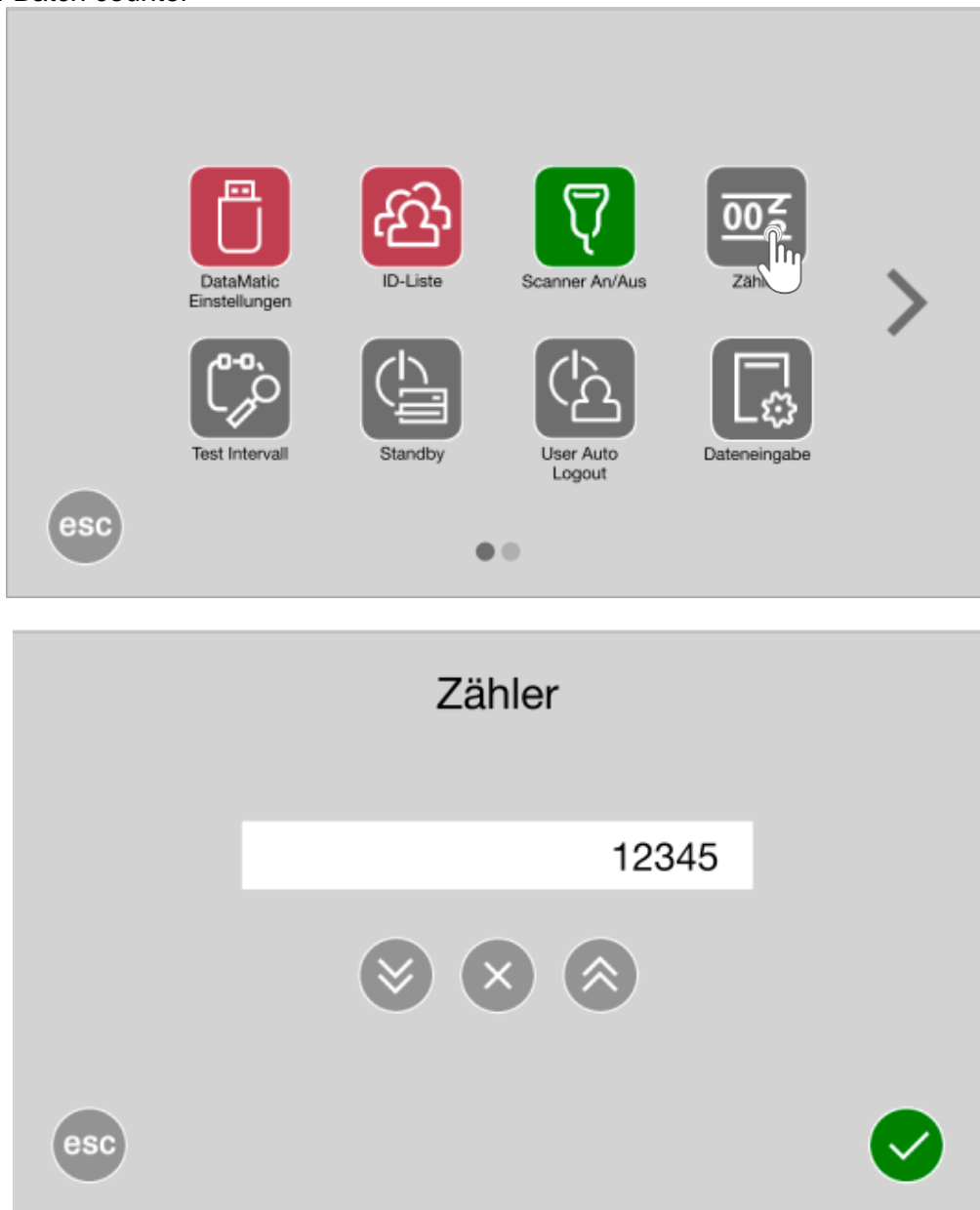
Activating the scanner function

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




Scanned data is assigned to the sterilisation information.

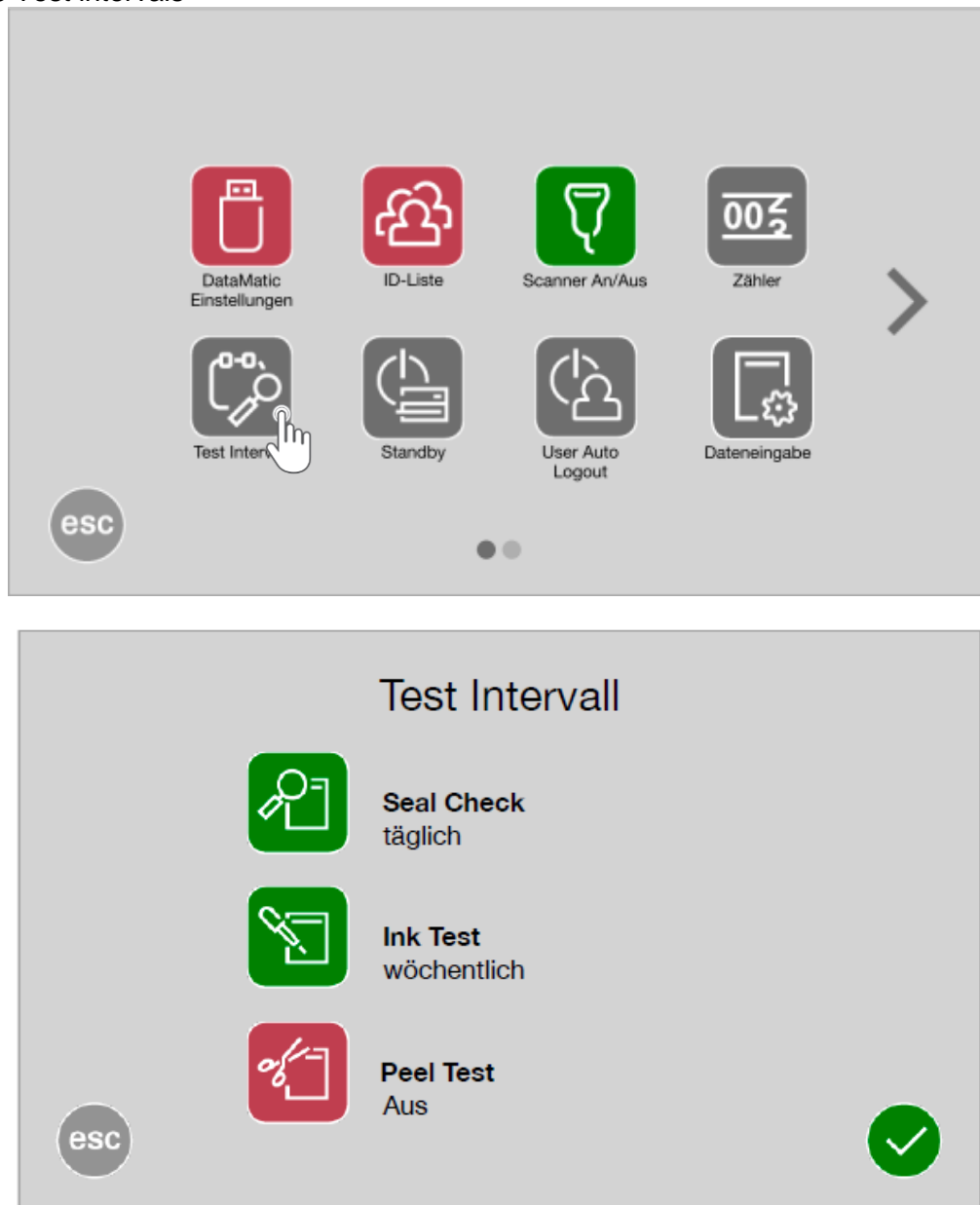
3.7.4 Batch counter



Activating the counter function

<p>✓ Save changes</p> <p>esc Discard changes and exit menu</p>	<p>< > Batch counter counts down or up</p> <p>× Set batch counter to zero</p> <p>The batch counter is entered using the displayed keyboard.</p> 
--	--

3.7.5 Test intervals



Activating the scanner function

The respective test interval can be set by tapping the button.

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



Save changes



Discard changes and exit menu

Adjustable test intervals:

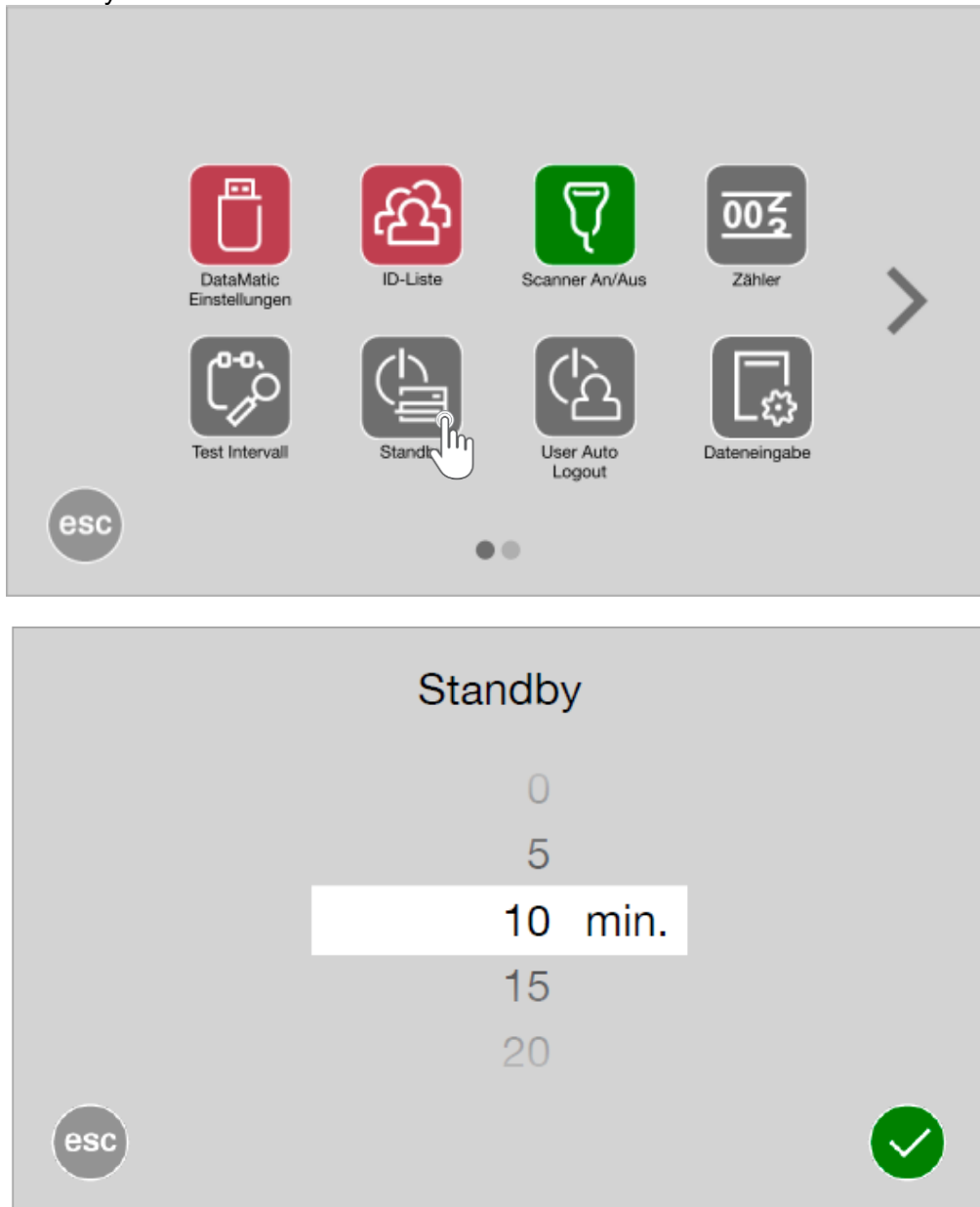
- OFF
- Daily
- Weekly
- Monthly

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

Example for the selection "daily":

- ➔ Selection on 18 February 2025 at 08:00
- ➔ Reminder on 19 February 2025 at 08:00

3.7.6 Standby



Activating the standby function

The standby function reduces the heat output after a set time and regulates the device to a temperature of 80°C.



Save changes



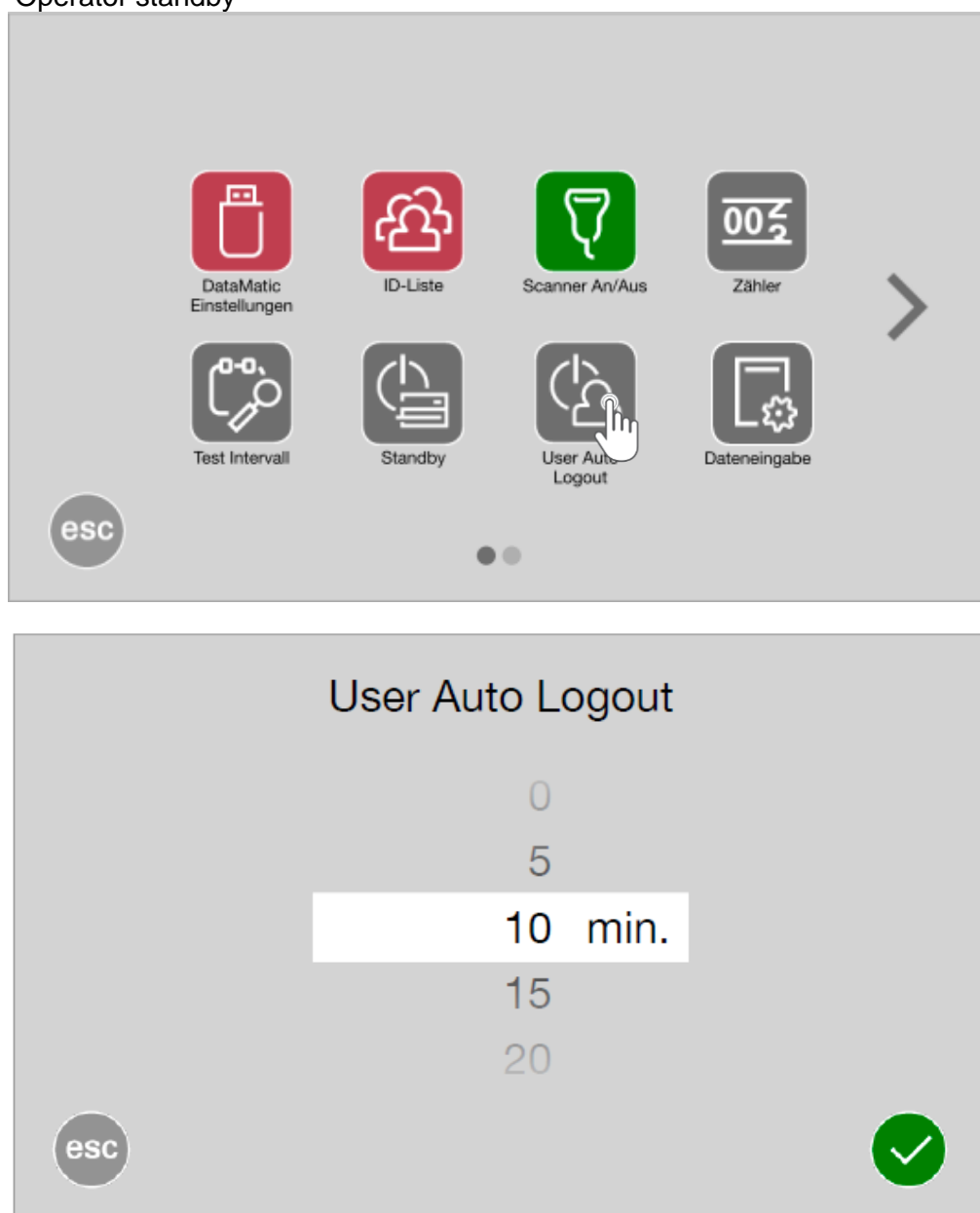
Discard changes and exit menu

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 device heats up again to the preset value. Sealing is not possible during this time!

3.7.7 Operator standby



Activating the operator logout function

The standby automatically logs off the currently logged on operator after the set time.



Save changes

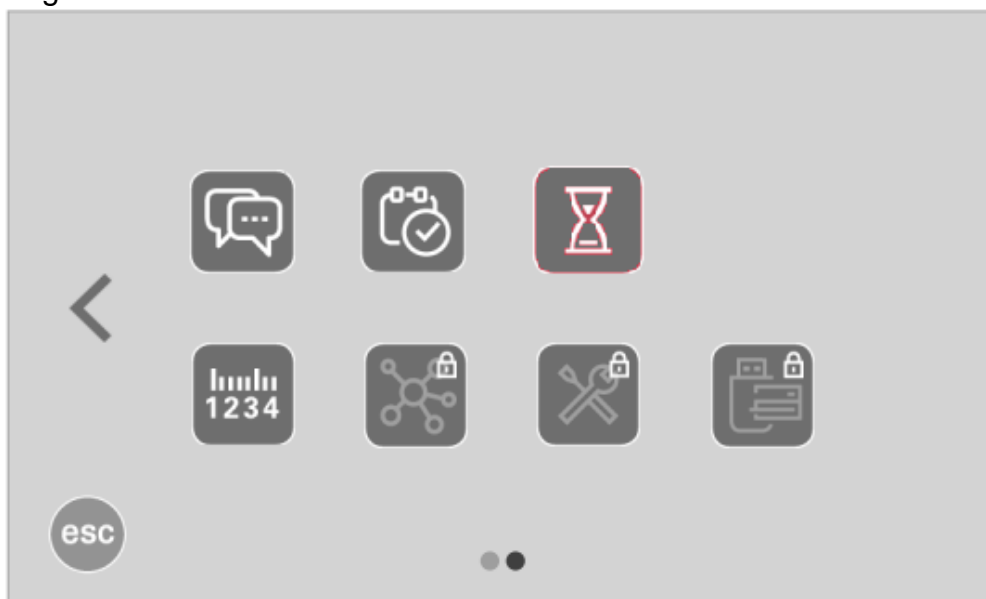









Discard changes and exit menu

Adjustable times:

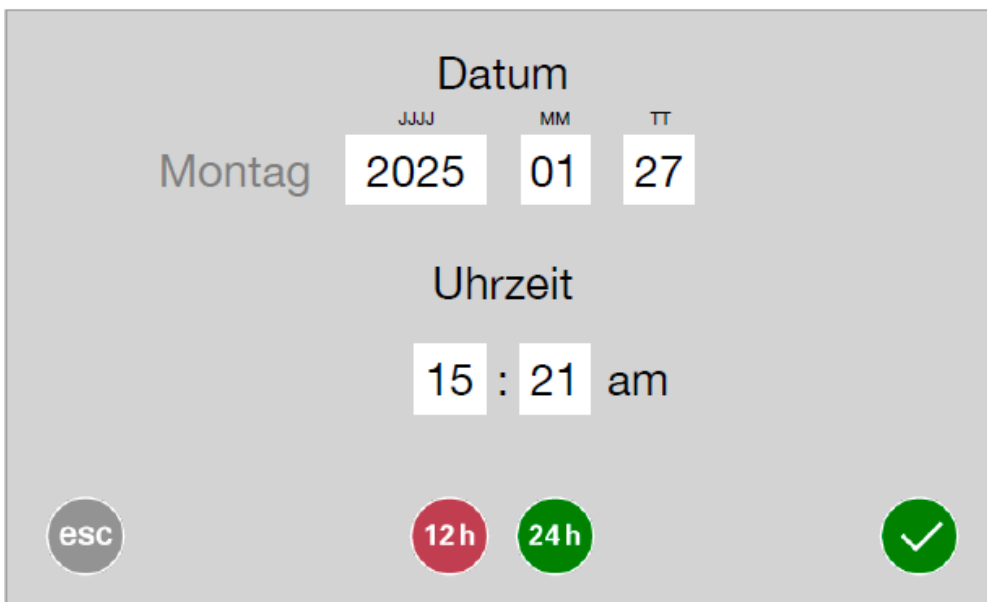
- 0 = OFF
- 5 min.
- 10 min.
- 15 min.
- 20 min.
-
- 60 min.

3.8 Settings 02








Symbol	Function	Note
	Date/time	Current date and time setting
	Expiry date setting	Enter the expiry date in days, months or as an individual entry with a fixed date
	Unit of measurement	Conversion of the units of measurement from si T[°C] ● F[N] ● v[m/min] fps T[°F] ● F[lbf] ● v[ft/min]
	Language	Defining the three languages that can be preselected via the start menu
	Network settings (IP)	Password-protected menu level for network settings
	Service settings	Password-protected menu for maintenance personnel
	Update	Performance of software updates via USB stick

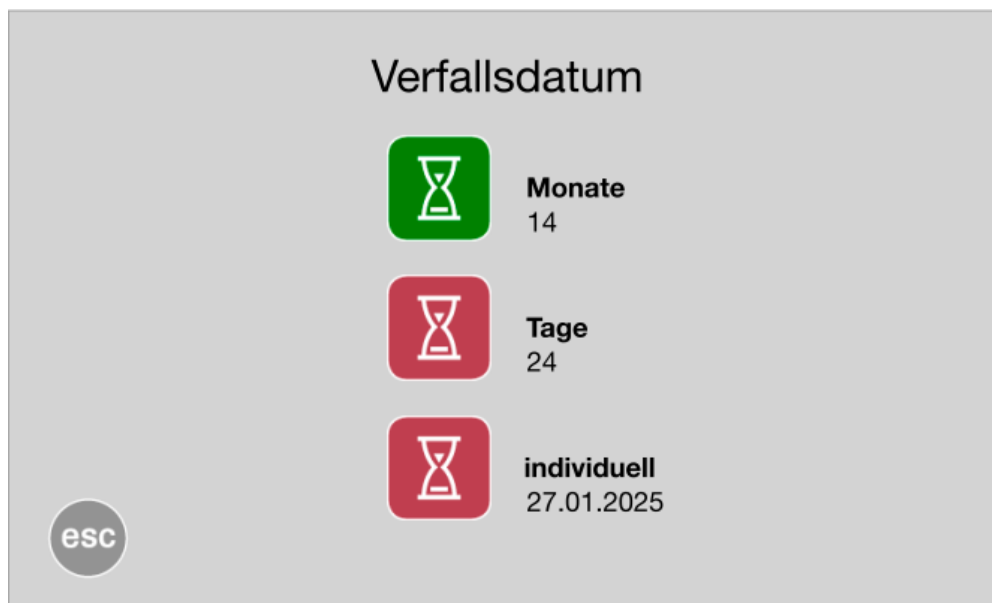
3.8.1 Date/time



Activating the operator logout function

 Save changes	 12 hours [am / pm] selection
 Discard changes and exit menu	 24 hours selection
	<p>The individual data is entered by selecting the digits to be changed and entering them using the keyboard.</p> 

3.8.2 Expiry date



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

Verfallsdatum

Tage: 22
23
24
25
26

esc

✓

To enter the individual date, use the keyboard

Verfallsdatum

individuell: JJJJ MM TT
2025 01 27

esc

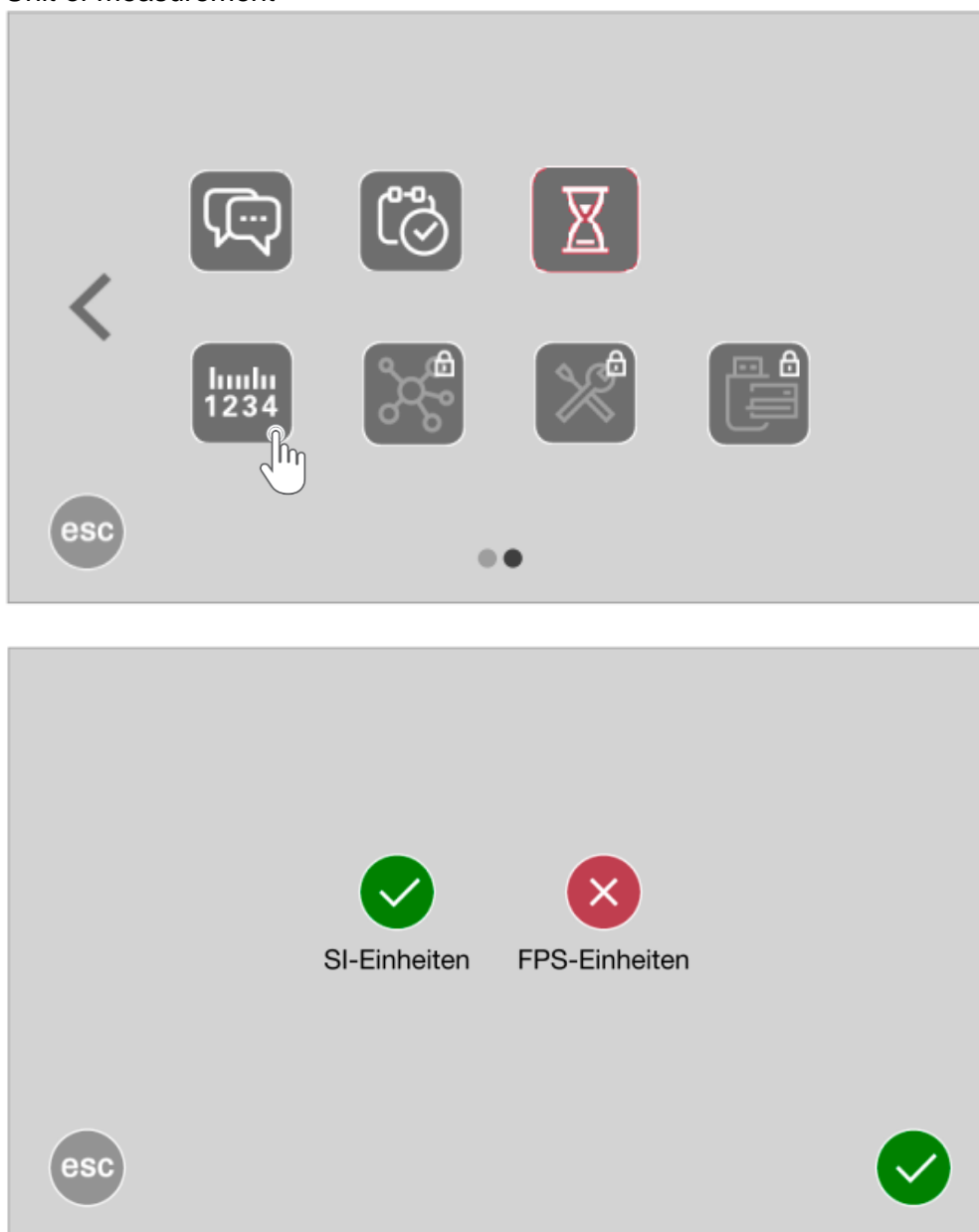
✓

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





1 2 3 4 5
6 7 8 9 0
.
esc

✓

3.8.3 Unit of measurement



Changing the units of measurement

 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]

3.8.5 Language



Save changes



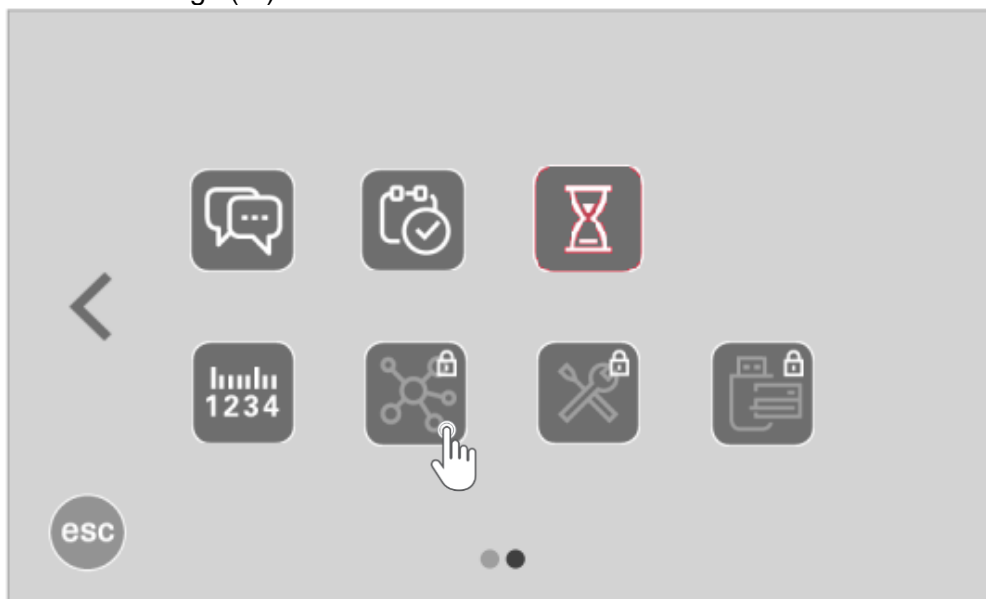
Discard changes and exit menu

Customisable languages

- German
- English
- Spanish
- French
- Portugese

(subject to change)

3.8.6 Network settings (IP)

**Important information about the network settings**




→ Please read and observe this information in advance

If you have any questions in this regard, please get in contact with an authorised service team.

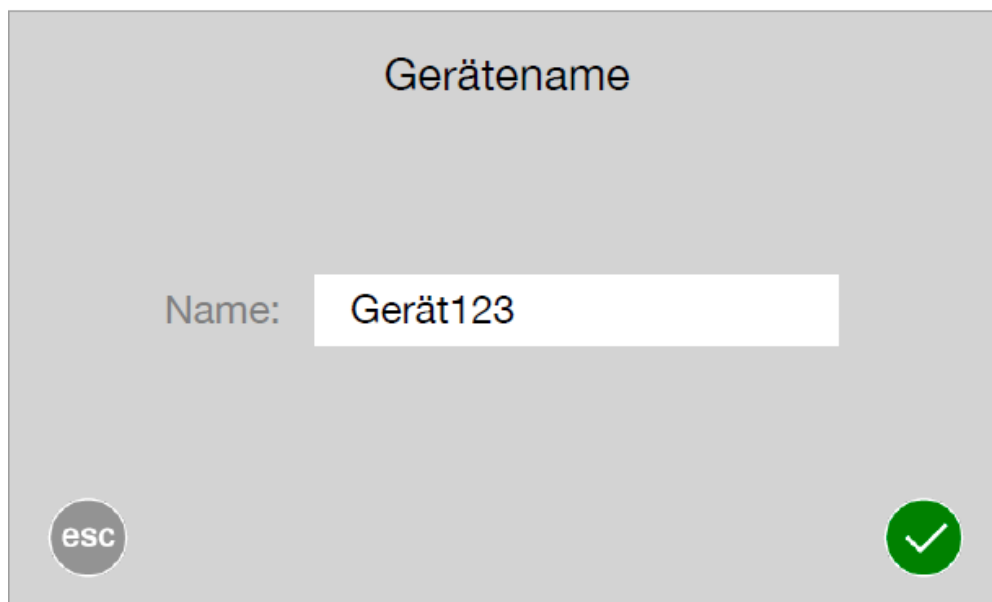
The adjustable network data, IP addresses and ports should be set by trained personnel.

When activating the Wi-Fi function, a check should be carried out in advance to legitimise the use of this interface.



Symbol	Function	Note
	Entering the device name (Hostname)	Facilitates subsequent assignment of devices in the network
	Network port settings	Entering and activating / deactivating the socket connection
	Ethernet settings	Entering the IP address, gateway and subnet address

3.8.6.1 Device name



Save changes

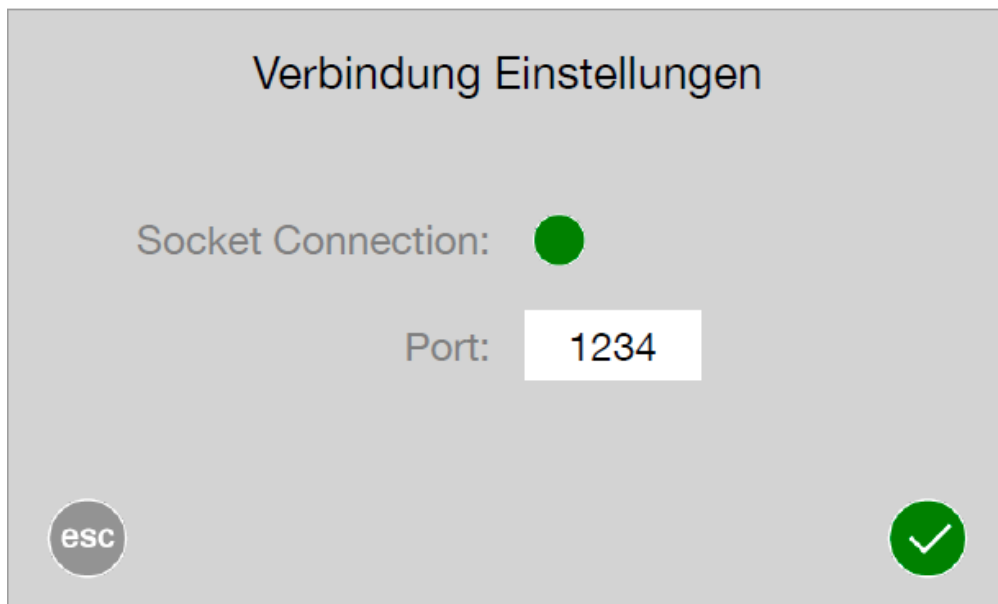


Discard changes and exit menu

The name is entered using the keyboard in alphanumeric form.



3.8.6.2 Connection settings

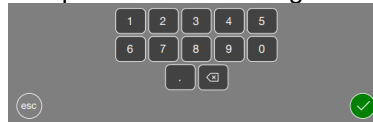


Save changes



Discard changes and exit menu

The port is entered using the keyboard.



If a port number greater than > 0 was entered, the socket connection is active.

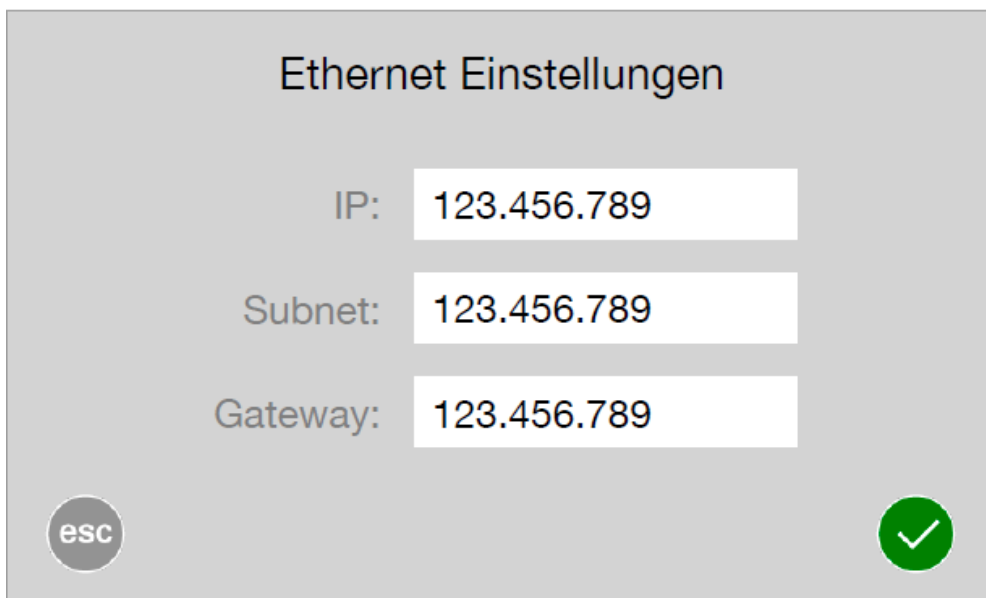


Port setting = 0



Port setting > 0

3.8.6.3 Ethernet settings

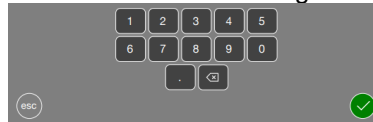


Save changes

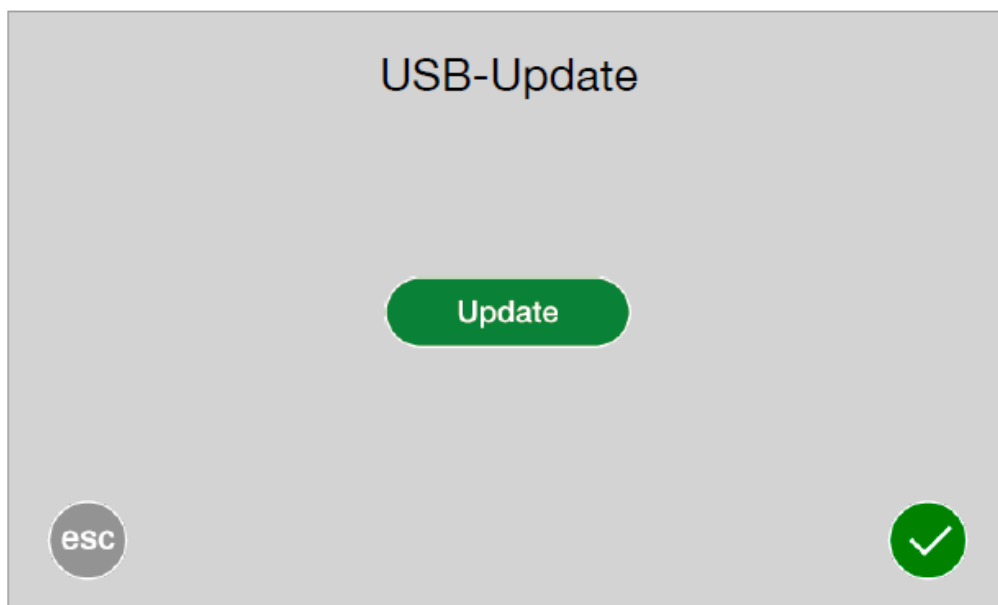
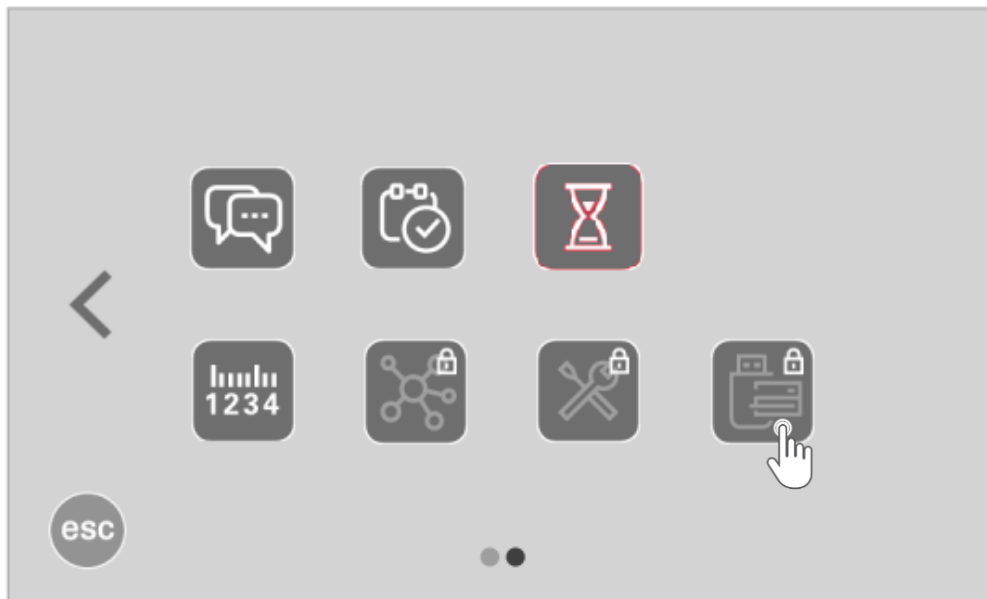







Discard changes and exit menu

The data is entered using the keyboard.



3.8.7 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		
			Search for update
			No / no new update
			Start update

4 Troubleshooting and maintenance

4.1 Troubleshooting checklist



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

Malfunction	Possible cause	Remedy
The sealing device cannot be switched on. No data on the display	Power supply unit -Power supply unit not plugged in	Check the mains connection and plug the cable into a different socket if necessary
	-Power cable defective	Replace mains cable
	Touch control defective	Replace temperature controller*
The sealing device does not heat up	Set temperature is too low	Increase set temperature
	Temperature limit activated	Switch off the sealing device, allow it to cool down and inform your service partner.
	Temperature sensor	Replace temperature sensor*
	Heating cartridge	Check heating cartridges and replace if necessary*
	Control defective	Replace control*
No transport	Conveyor belt -Damaged -No transport	Replace conveyor belt Check belt tension
	Motor start sensor	Replace light barrier*
	Motor	Replace motor*
	Control defective	Replace control*

Malfunction	Possible cause	Remedy
Uneven material transport or loud running noise	Conveyor belt guide Conveyor belt -Damaged -No transport Motor	Replace PTFE strips on the guide Replace rail Replace conveyor belt Check belt tension Replace motor*
Sealing seam will not hold	Temperature too low Pressure applied too low Sealing die Distance between the sealing dies too great	Increase temperature Adjust contact pressure of the sealing roller or replace sealing roller* Set distance between the sealing dies to 0.5 mm*
Sealing seam distorted	Contact pressure too high	Adjust contact pressure of the sealing roller or replace sealing roller*
Paper side of the packaging is discoloured or side fold melted	Temperature too high	Lower temperature

4.2 Customer service



Your hawa customer service team is available Mon-Fri between 08:00 and 17:00 on the following telephone number:

+49 (0)6261 9770 -0.








You can also send your enquiries to the following e-mail address: service@hawa.com

5 Alarm functions and error displays

5.1 Maintenance/calibration



Like all technical devices, your device is also subject to technical wear. In order to ensure that your device is always ready for use, it should be checked regularly by a qualified person and serviced and calibrated at least every 24 months by the manufacturer or one of the manufacturer's authorised service partners.

Maintenance cycle	PTFE strip guide die	Pressure roller	Toothed belt	Sealing stamp distance	Calibration of the process variables
At least every 3 months					
As required, but at least every 24 months					

Explanation of symbols:



Test



Replace



Adjust



Measure

5.2 Spare parts service



Simply order parts:

- Enter device number.
- Enter device type.
- Enter address, fax and order number.
- Mark items required.
- Enter quantity required.
- Sign order.
- Fax order.



6 Technical data sheet

Connection data

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

Mechanical system

Dimensions ¹	Length [mm]	565
¹ Including slot	Width	255
	Height	155
Housing		Powder-coated / stainless steel AISI 304
Weight	[kg]	13.5
Sealing distance to edge	[mm]	0 – 35
Sealing seam width	[mm]	12 +/-0.5
Sealing system		SealPeak (hawaFlex)
Sealing seam length	[mm]	Unlimited
Distance to medical product	[mm]	>30 (in accordance with DIN 58953-7)

Process variables/sealing parameters

Sealing temperature	Max.	[°C]	210
Sealing temperature tolerance		[°C]	± 5
Contact pressure		[N]	100
Contact pressure deactivation tolerance		[%]	± 20
Throughput speed		[m / min]	5 -13
Throughput speed switch-off tolerance		[%]	± 10
Temperature ranges			3
Temperature standard tolerance		[%]	±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]	9600
Serial RS 232 interfaces and Ethernet		
Electrical protection class	(in accordance with DIN EN 61140 / VDE 0140-1)	3
Protection class	(in accordance with DIN EN 60529)	IP 20

Environmental parameters



Ambient temperature	[°C]	+5 to +40
Heat output	[kJ/s]	0.1
Relative humidity	Max. [%]	80 non-condensing
Noise intensity in accordance with the Machinery Directive 2006/42/EC Appendix I 1.7.4.2 u.)	[dB/ A]	<45 +/- 10
Power consumption combined	[W]	67.5 - 90 W ¹
Power consumption in normal operation	[W]	27 - 32 W ²
Max. noise development	[db]	65

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



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

7 Declaration of conformity

7.1 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		9.694.052C																				
Gültig ab: 25.11.2024 Valid from: 25.11.2024		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;">hd 650 DE-V ECOPAK 06/06S</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: correspondre aux dispositions suivantes et standards harmonise: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <table border="0"> <tr> <td>EG - Maschinenrichtlinie Machinery directive Directive "CE" rel. aux machines Directiva de Maquinaria de la CE Direttiva CE sulle macchine nella versione Directiva da UE relativa a maquinaria</td> <td>2006/42/EG</td> <td colspan="2"></td> </tr> <tr> <td>EMV-Richtlinie Directive CEM Direttiva CEM</td> <td>EMC-directive Directiva de CEM Directiva CEM</td> <td>2014/30/EU</td> <td></td> </tr> <tr> <td>WEEE-Richtlinie Directive WEEE Direttiva WEEE</td> <td>WEEE-directive Directiva de WEEE Directiva WEEE</td> <td>2012/19/EU</td> <td></td> </tr> <tr> <td>RoHS-Richtlinie Directive RoHS Direttiva RoHS</td> <td>RoHS-directive Directiva de RoHS Directiva RoHS</td> <td>2015/863/EU</td> <td></td> </tr> <tr> <td>Harmonisierte Normen Standard harmonise Norme armonizzate</td> <td>Harmonized standards Las normas armonizadas Normas harmonizadas</td> <td>EN ISO 12100:2010 EN ISO 13857:2019 EN IEC 61000-6-1:2019 EN IEC 63000:2018</td> <td>EN 60204-1:2018 EN 61010-1:2010+A1:2019 EN IEC 61000-6-3:2021</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> <div style="text-align: center;">  Torsten Ehrhardt Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany </div>				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 61000-6-1:2019 EN IEC 63000:2018	EN 60204-1:2018 EN 61010-1:2010+A1:2019 EN IEC 61000-6-3:2021
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 61000-6-1:2019 EN IEC 63000:2018	EN 60204-1:2018 EN 61010-1:2010+A1:2019 EN IEC 61000-6-3:2021																				
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.																				

7.2 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	9.694.052D						
Gültig ab: 28.11.2024 Valid from: 28.11.2024	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;">hd 650 DE-V ECOPAK 06/06S</p> <p>folgenden einschlägigen Bestimmungen und harmonisierten Normen entsprechen: complies with the requirements of the following regulations and harmonised standards: corresponde aux dispositions suivantes et standards harmonise: objeto de esta Declaración cumple con las siguientes disposiciones: Sono conformi alle seguenti disposizioni in materia nonché alle seguenti norme armonizzate: correspondem às seguintes determinações e normas harmonizadas:</p> <table border="0" 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 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 </td> <td style="vertical-align: top;"> DIN 58953-7:2020 </td> </tr> </table> <div style="text-align: center; margin-top: 20px;">  hawa GmbH 74847 Obrigheim/Germany T +49 (0) 6261 / 9770-0 info@hawa.com </div> <p>Torsten Ehrhardt Prokurist / authorized officer hawa GmbH, Obere Au 2, D-74847 Obrigheim, Germany</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)	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 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	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 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	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						

9.610.007 Version 2.01

This document and its 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.



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

hawo USA
150 North Michigan Avenue
35th Floor
Chicago IL 60601
T +1 312 585 8329
F +1 312 644 0738
info@hawo-usa.com
www.hawo-usa.com

hawo ASIEN
25 International Business Park
#03-105 German Centre
Singapore 609916
T +65 6433 5339
F +65 6433 5359
info@hawo-asia.com
www.hawo-asia.com