

Instruction Manual

EM 40 / EM 24



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medical

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1 Safety instructions

Key:



Important information to avoid danger or damage and malfunctions.



ATTENTION! Danger of electric shock.



Read the following safety instructions before use.

Our products leave the factory in perfectly safe condition.

In order to preserve this condition, the contents of these safety instructions and type plates, labels and safety instructions attached to the device must be observed when handling the device (transport, storage, installation, commissioning, operation, maintenance, disassembly), as people's safety may be endangered and the product itself and other facilities damaged otherwise.

These safety instructions apply in the Federal Republic of Germany. The relevant national regulations must be observed if the product is used in other countries.

If the information contained in these safety instructions is not sufficient, the manufacturer can be contacted at the address provided at any time.

- Please check the packaging and report any damage to the freight forwarder immediately.
- Ensure that the device is not damaged before operating it. In case of doubt, please consult an electrician or contact the address given below.
- Before operating the device, please check whether the mains voltage of the unit is identical to the power supply in your country.
- The device may only be connected to a mains socket with the power cord supplied. Operation on IT networks is not permitted.
- Please place the device on a stable surface.
- If the sealer is moved directly into a warm environment from a cold environment, condensation can occur. Wait until the temperature has stabilised. Using the device with condensation can be fatal!
- This appliance is not intended for use by persons with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the appliance by a person responsible for their safety.
- Only authorised personnel may exchange fuses and do repairs. Please contact the address below.
- Switch off the mains before cleaning! Use only a dry or dampened soft cloth with a mild detergent to clean the device. Never allow water to enter the unit.
- Use the device only in dry conditions at temperatures between 15 and 30 ° C. Using the device outside of the specified parameters may cause malfunction or damage to the unit. Allow the device to reach room temperature before using it for the first time.

- Only seal suitable materials. If you have any questions, please contact the manufacturer or your dealer.
- Never seal polyethylene bags or similar items. This will damage the device.
- Do not insert pointed or flat objects into the insertion slot of the device. This can damage the device and the instruments.
- The device may only be opened by trained personnel. Always unplug the mains plug before opening the device.
- Do not insert objects into the ventilation slots of the unit: you may suffer electric shock or damage the device.
- Operate the device only within the specified voltage limits.
- Have the device serviced at least once a year and check for electrical safety.
- Do not use the device if you're unsure of the safety.
- The user is responsible for ensuring that seals work properly. Check the seals regularly. Have the sealing process validated.
- Always disconnect the mains plug before opening the device cover.
- Always fasten the device flap with the screw after opening it, to avoid accidental opening during operation and therefore injury.

Intended Use:

This device is intended to be used only as a Sealing device for medical purposes. Any other use is not allowed and can reduce the safety level provided by this device.

Disposal:



This product must not be disposed of together with domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substances, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner. Remove the batteries before disposing of the device/unit. Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop. Consult your municipal authority or your dealer for information about disposal.

Battery disposal & safety instructions:



The battery is permanently installed in the device, it can only be changed or removed by the dealer. Do not throw used batteries into the household refuse; put them in a hazardous waste container or take them to a battery collection point, at the shop where they were purchased!

Technical support

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2 Connections, control and setting devices



3 Technical specifications

Rated voltage range:	115V or 230V~ ±10%	Depending on specification on the type plate
Total current rating:	0,2 – 6,5A	
Frequency range:	48 - 62Hz	
Rated input:	800 VA	
Fuse: 	6,3AF	5 x 20 mm
Fuse (internal):	8AT	5 x 20 mm
Battery	3V Lithium manganese	CR 2032 (210mA)
Ambient temperature range	+15...+30°C	
Storage temperature range:	-10 ...+50°C	
Climate:	60% r.F. at +30°C	No condensation allowed
Protection:	IP20	
Electrical safety	EN 61010-1	
Protection class:	I	
Pollution grade:	2	

Dimensions (W x H x D):	(560 x 120 x 280) mm	
Weight:	11,7kg	
COM connection:	9 pol.	

4 Operating the device

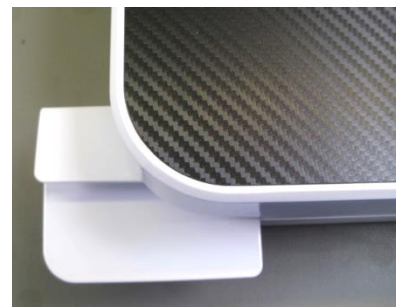
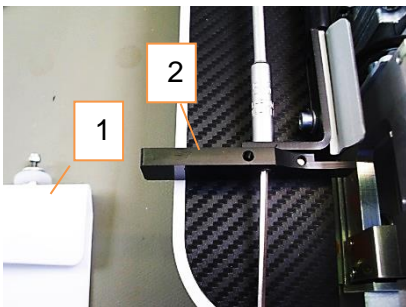


Read the safety instructions before switching on!

The unit is supplied with disassembled housing feet. The housing feet can be found in the accessory box. Please screw the housing feet to the bottom of the device. Then place the device on a stable flat surface.



For devices from model year 05/2018 an enlarged infeed guide (1) is attached. If you want to use this, unscrew the black infeed guide (2) and mount the enlarged infeed guide. Use a 2.5mm hex key and a 5.5mm socket wrench. (not included)



When transporting always unscrew both the housing feet and the enlarged infeed guide to prevent damage.



Before putting the device into operation, remove the protective film from the cartridge and insert it. To do this, open the housing cover and remove the printer cartridge. The chapter "Changing the cartridge" describes how to do this.

Use the ON/OFF switch on the back of the device to switch it on.

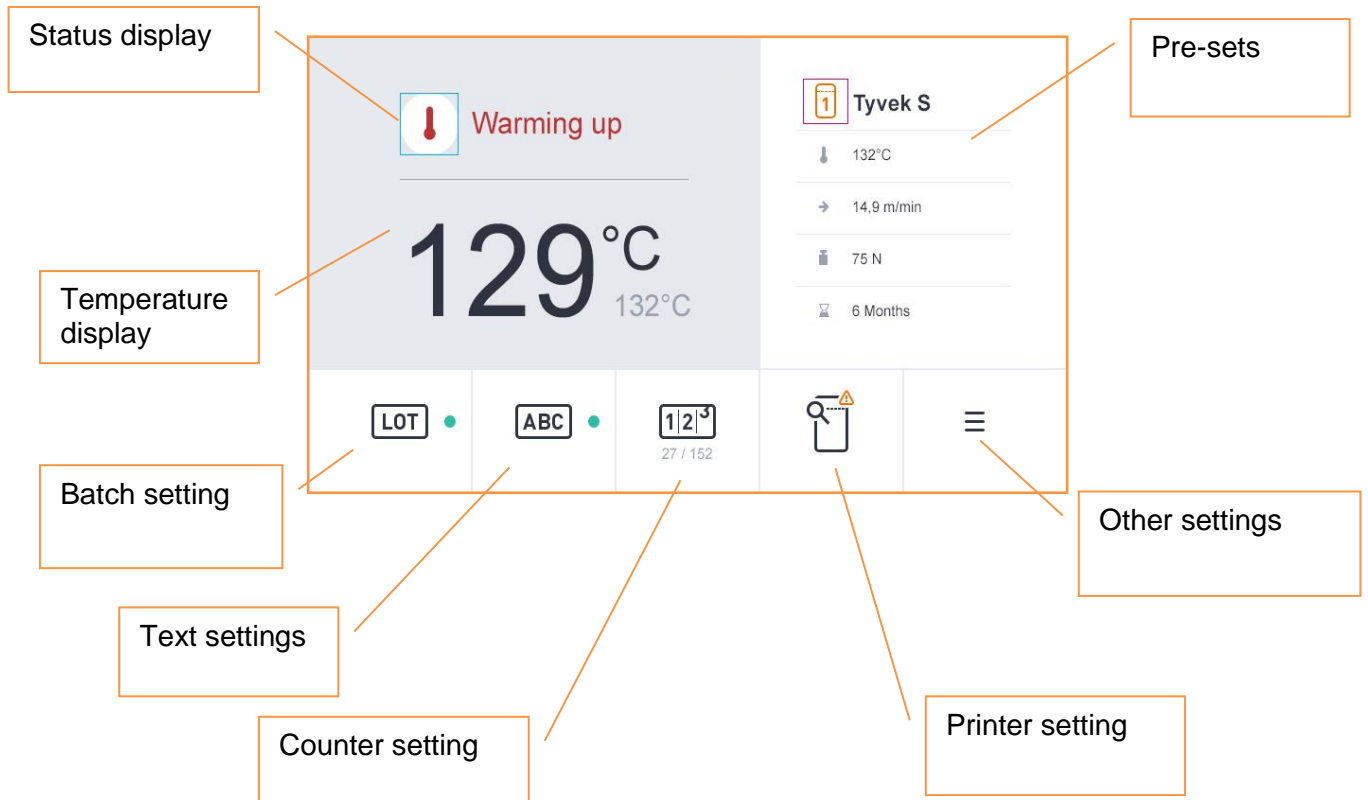


The device is suitable for operation on a network with the specifications indicated on the type plate.

The device is ready for use shortly after switching on. This is indicated by the display and by a short sound signal.

5 The EM 40 Main Menu

(Pre-set in English)

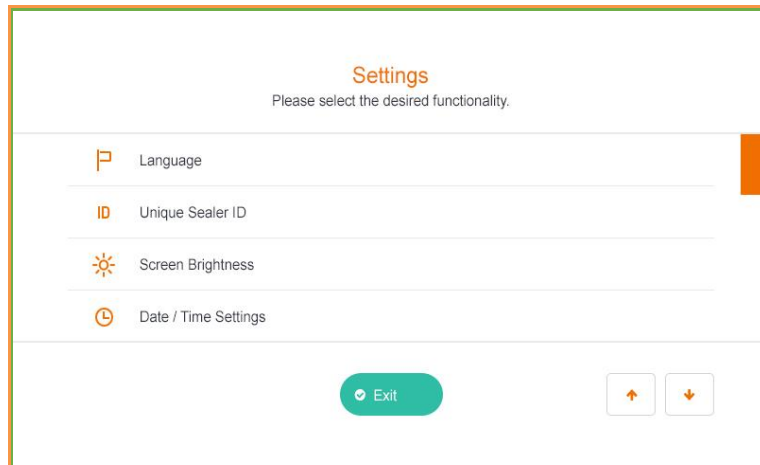


The device can be adjusted and operated via the touchscreen. When a field is touched, a new menu opens. The screen reacts to light pressure and can thus also be operated with gloves.

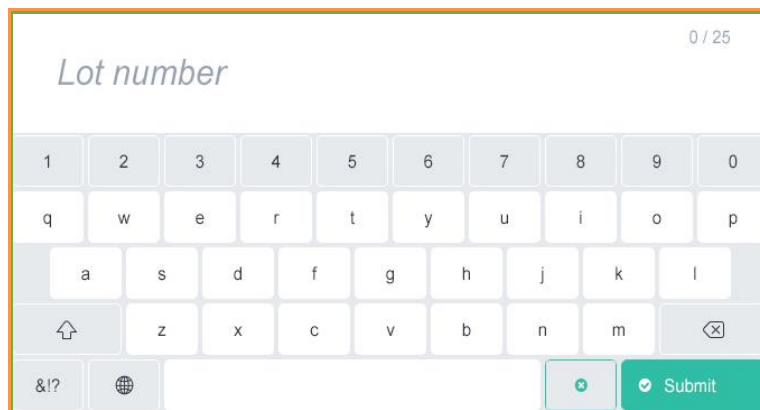
The operation of the EM 24 and EM 40 is the same. Since the EM 24 has no printer, the printer menu items are disabled and displayed in light gray.


There are different ways of operating the menus:

1. Selecting from a list
Use the up / down arrow keys to scroll to the desired option.
Select the option. The selected option is highlighted.



2. Entering text
Touch the entry area. A keyboard screen will open.
Enter the desired text.
- 3.



Press  to confirm the selection or  to return without change.

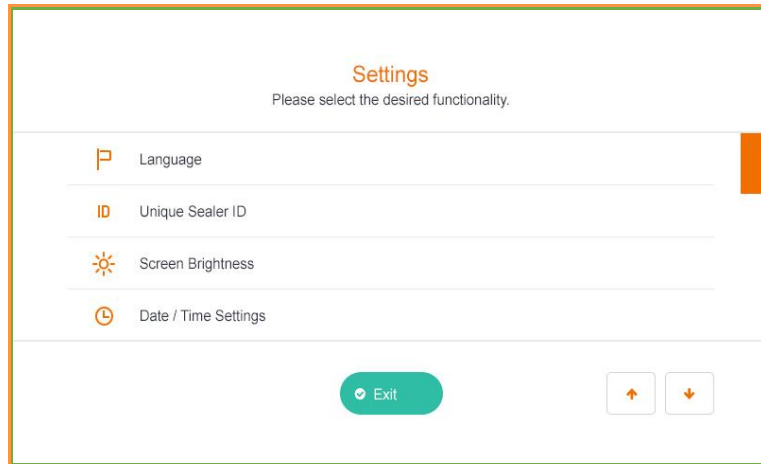
6 Basic settings

Before you use the device you must set certain basic settings or check them.

These settings remain saved in the device and will not be lost even if the device is disconnected from the mains.

After pressing on „Other settings“ in the main menu you will reach the following menu.

The operation is largely self-explanatory and takes place as described above by selecting an option or by entering text.

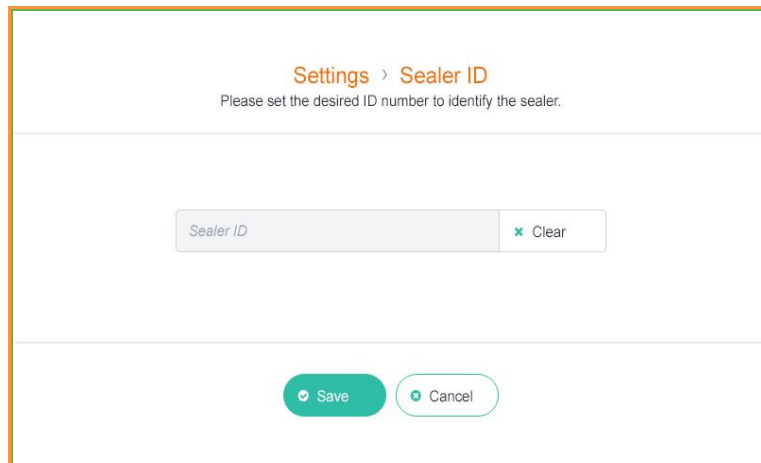


6.1 Language

Here you can select from the available menu languages.

6.2 Unique sealer ID

If you use several sealers, enter a sealer identifier to distinguish between them.

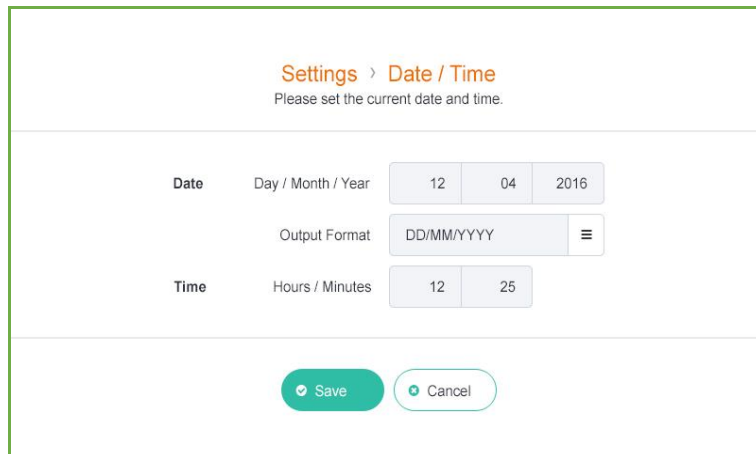


6.3 Screen brightness

Adjust the screen brightness here.

6.4 Setting the date

Check the date, clock time and format and correct them if necessary.



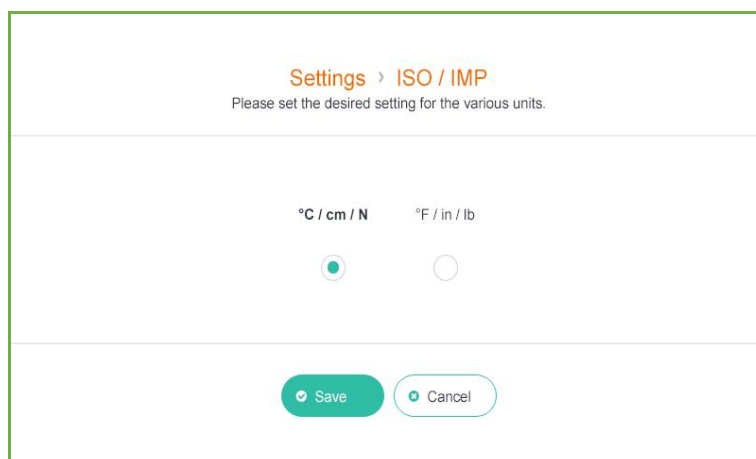
Settings > Date / Time
Please set the current date and time.

Date	Day / Month / Year	12	04	2016
	Output Format	DD/MM/YYYY		
Time	Hours / Minutes	12	25	

Save Cancel

6.5 Setting up the unit system

Check the unit system and correct it if necessary.



Settings > ISO / IMP
Please set the desired setting for the various units.

°C / cm / N °F / in / lb

Save Cancel

6.6 Setting the Standby and Login options

Here you can define the time after which the password input and the entry of the personal code should expire.

In this way, you can prevent unauthorised persons from working with the device under your name after the password was entered.


Set the time to 0 min to switch off this function.

After activation of the standby function the device takes some time to reach its sealing temperature again. A low set-back temperature saves most energy. A higher one will cause the unit to return to operating temperature faster.

Settings > Stand By / Log Out
Please set the desired stand-by and log-out times.


Stand By After minutes of inactivity
 at °C

Log Out After minutes of inactivity.


Scheduled Ink Test
 An ink test has to be performed.


6.7 Setting the test interval


If you have defined a test interval, a sealtest and / or an ink required when rebotting the sealer before you can seal. Set test interval to "0" in order not to be reminded to perform a


Scheduled Seal Test
 A seal test has to be performed.

test is the test.

Settings > Test Interval
Please set the desired interval for periodical tests.

Seal Test Every days, starting on 

Ink Test Every days, starting on 

6.8 User settings

6.8.1 Setting up user profiles

Here you can define different user profiles and assigned rights to assign them to the different users later. The profile administrator has all the rights. Profiles cannot be changed.

Settings > Users
Please edit or view the desired user profile.

+ Add user

Profile 1	Administrator	Edit	Users (2)
Profile 2	Head CSSD	Edit	Users (7)
Profile 1	Employees	Edit	Users (9)

+ Return

Settings > Users > Edit Profile 2
Please set the desired permissions for the profile.

Title Head CSSD

Seal Presets

View Seal Preset

Change Seal Preset

Edit Seal Preset

+ Save
+ Cancel
↑
↓

6.8.2 Changing and deleting users

Give every user a personnel number and a password and assign a user profile to each user.

The personnel number can be printed on the packaging material.

The password prevents someone else from sealing and printing your personnel number.

By assigning a user profile, the supervisor can grant or deny employees certain rights.

A password can only be assigned to one user.



As soon as a user has been created, sealing is only possible when the person is logged in.

Settings > Users > 'Head CSSD'
Please edit or delete the desired user.

	Add user
123456789	Edit Delete
345678912	Edit Delete
567891234	Edit Delete

Return

Settings > Users > Edit User 2
Please set the desired properties for the user.

User profile: Head CSSD

Personal number: 123456789

Passcode: 1234 Generate

Save Cancel

6.9 CE number

Please enter the following text for the CE symbol to print it. (Number of notified body)

6.10 Service

This field is only accessible to trained service employees

6.11 System information

Here you can view different types of information, such as the next SERVABOX maintenance date.

6.12 Temperature

The temperature of some components for service purposes is shown here.

6.13 Manufacturer

Enter the name of the manufacturer here to print it next to the manufacturer symbol.

6.14 Reference

Enter the product reference here to print it next to the REF symbol.

6.15 Network settings

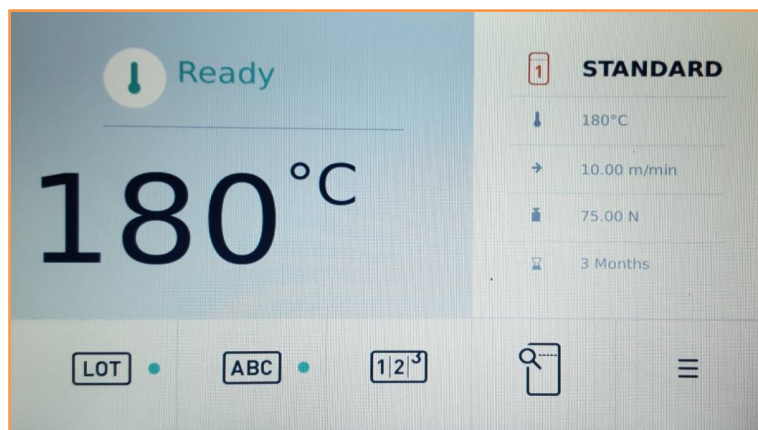
Set the desired network settings here.

6.16 Setting up a print layout

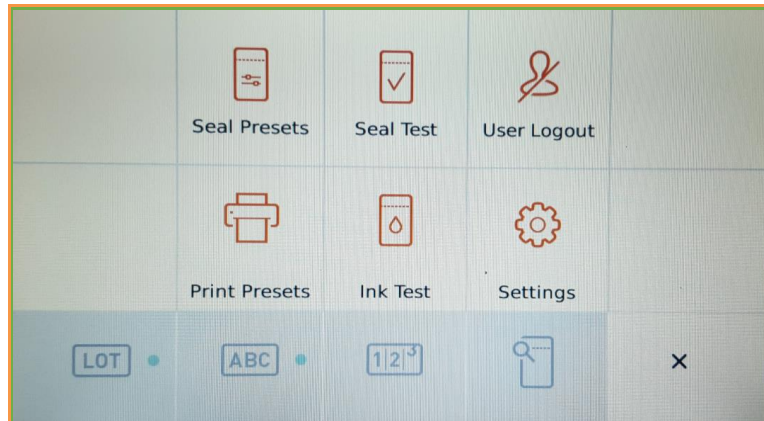
The EM 40 is equipped with a multi-line printer. Various print layouts can be created and selected for different requirements. Since the print-out is multi-lined, a lot of information can be printed on narrow bags.

Of course, you can also print in single or double spacing.

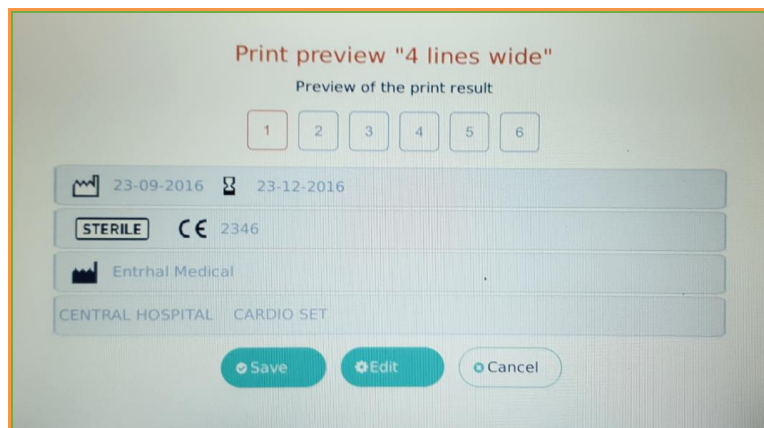
Proceed as follows to create a print layout:



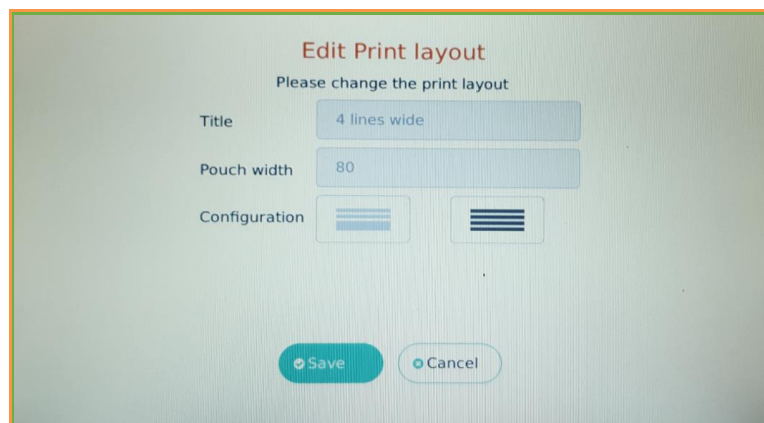
Touch the "Settings" field in the lower right corner of the main screen.



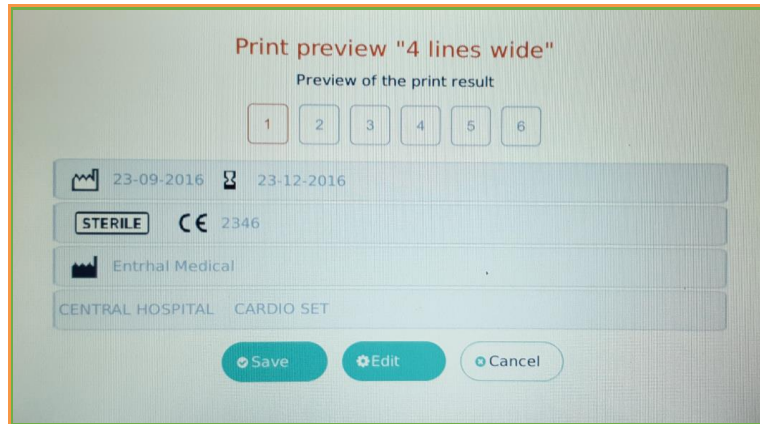
Touch the field „Print Presets“



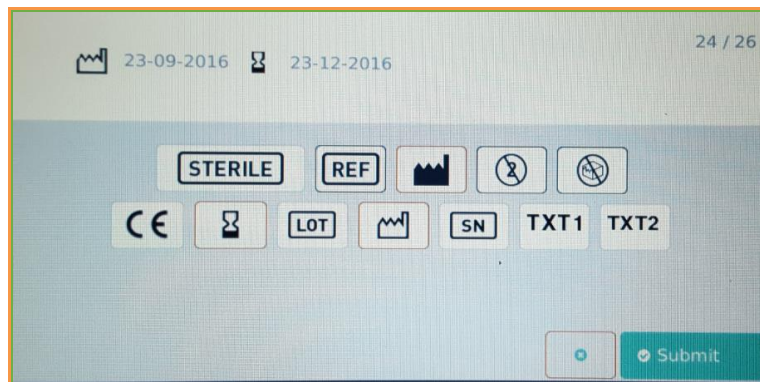
Now you can define up to 6 different print layouts. First select one of the six memory locations by touching



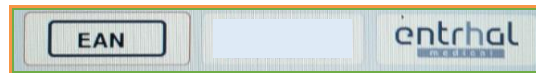
1. Give the layout a suitable name.
2. Select the smallest bag width 40/ 60/ 80mm
3. Select three or four-line printing.
(a bar code or graph can be used with three-line printing)
4. Press „Save“ to save or otherwise „Cancel“



To change, touch the corresponding line.



Select the information to be printed. Press the corresponding logo to select and deselect the print information. Selected print information is orange bordered, selectable black, and not selectable without border. In the upper right corner you can see how much of the available print length has already been used up. Confirm your selection with "Submit". Change the other lines in the same way. (For 3-line layout, you can also select a bar code and a logo.)



6.17 Selecting the sealing edge

Set the paper guide to the desired depth on the left side. This adjusts the edge distance of the seal seam. Slide the stopper to the desired position.



Make sure that the packaging is smooth, and inserted no deeper than the insertion plate. If packing material is inserted too deep or wrinkled, it can lead to material jams. Please also note that if the marginal distance is too small, the packaging cannot be opened properly and all the printing may not be printed on the packaging.

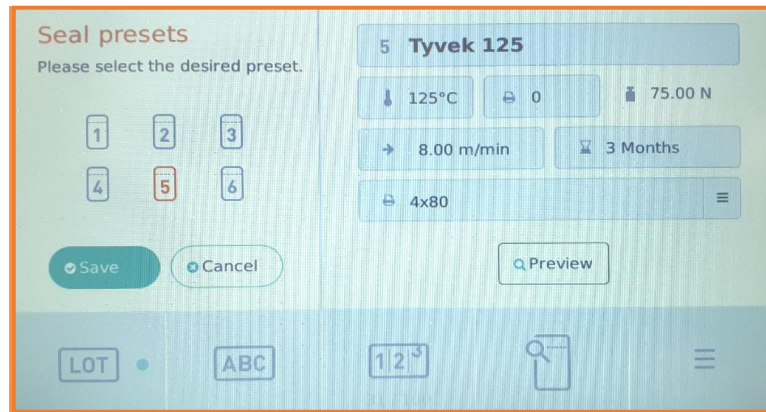
If the bags have not inserted deeply enough repeatedly, the ink may contaminate the sealer and subsequently the packaging. In this case, the device must be opened and cleaned. We therefore recommend setting the maximum sealing edge.

6.18 Configuring a seal pre-set

In order to simplify the variety of setting options, these are now combined into packaging-specific seal pre-setting.

These included temperature, speed, expiry time and printing settings.

Up to 6 different configurations can be set.



How to create a seal pre-set:

1. Select one of the six save locations
2. Enter a name that is easy to remember
3. Set the sealing temperature (see 6.9.1)
4. Set the sealing speed (see 6.9.1)
5. Set the storage time
6. Select the pre-set print layout
7. Set Number of seals per print (0 means printer is off)
8. Save the seal configuration.

How to select a seal pre-set:

1. Press on „preset“ in the main menu
2. Select the desired pre-set 1-6
3. Adjust the text, the batch number or the counter setting if necessary
4. Press Preview to view the printout.

6.18.1 Sealing parameters

For a good sealing result, it is important to set the correct sealing parameters.

The sealing pressure is already set optimally for all standard materials by the factory. All you need to do is set the temperature and the sealing speed. Use the instructions provided by the manufacturer as a first guideline.

The following information may be used as a first guide:

Material	Temperature	Speed
Transparent material (paper/ multilayer film)	160 to 190 °C	9-10 m/min
Transparent material (crepe/ multilayer film)	160 to 190 °C	9-10 m/min
Tyvek® material	120 to 130 °C	8-10 m/min
Amcor Ultra®	140 to 160°C	8-10 m/min



Do not use polyethylene packaging or other unsuitable materials under any circumstances. This could damage the device. In case of doubt, please contact the sealer manufacturer.

Set the device in such a way that the sealing seam cannot open during sterilisation and, on the other hand, fibre-free peeling is possible.

6.19 Initial validation of the sealing process

Packaging with heat seal bags is a safe but complex process.

Safety at the correct process setting and proper sealing constitute validation of the sealing process. It should take place at the end of commissioning.

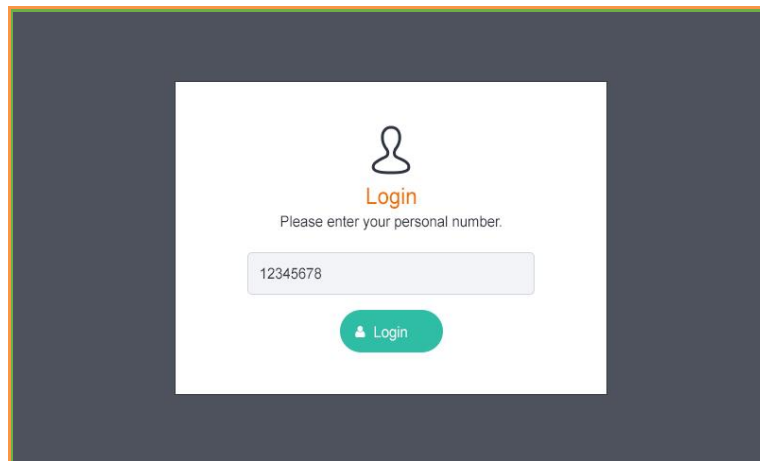
We recommend performing the initial validation according to the current edition of the guideline of the DGSV.

Changes to the process require revalidation. (See chapter on Revalidation)

7 Daily operation of the device

7.1 User login

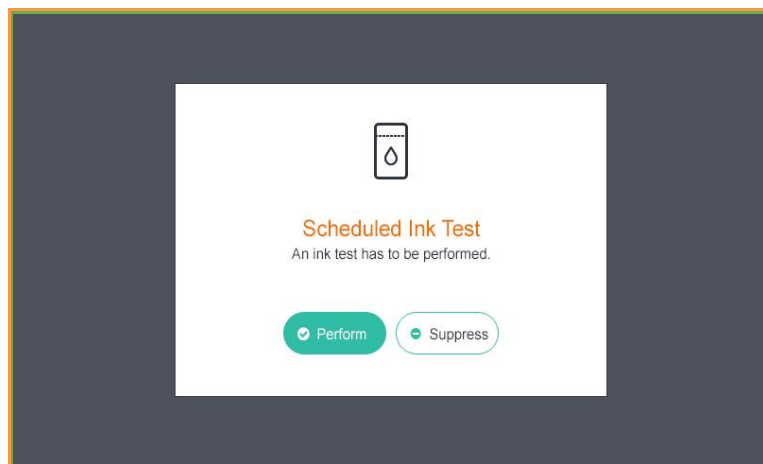
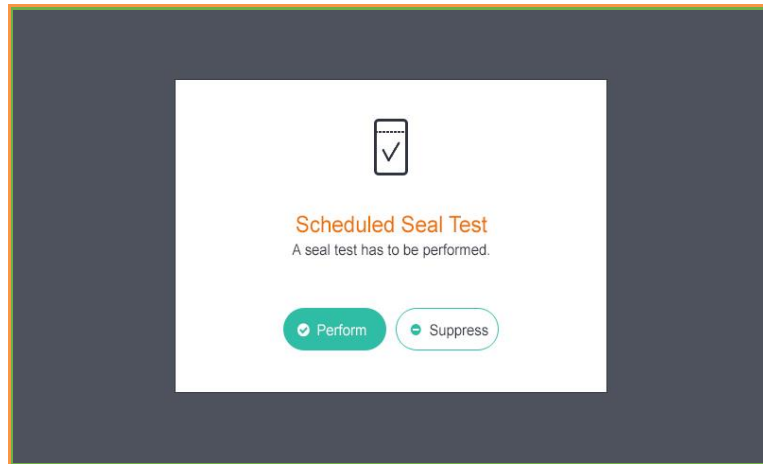
If a password has been defined it will be required at every operation insofar as it hasn't expired since the last operation.



If no password is defined, operating all functions other than service functions is possible.

7.2 Performing the seal test

If performing a seal test and/or ink test has been defined, the user is required to perform a seal test and approve it. Press on „Perform“ to carry out the test or „Suppress“ to skip this step.



7.3 Sealing

Check that you have the correct pre-set for the packaging and adjust it if necessary.

If the device is in stand-by mode, press any key or insert a bag on the left side. It will then heat up and start the transport drive after reaching the set sealing temperature.

If the device is ready for sealing, insert the packaging on the left side. A sensor will detect it and start the drive. The material is captured and drawn to the right by the device. Another sensor counts the seal. When it exits the device, the material is sealed. This can be seen in three continuous strips.

Make sure that the material is inserted flat, as it may not be properly sealed otherwise.

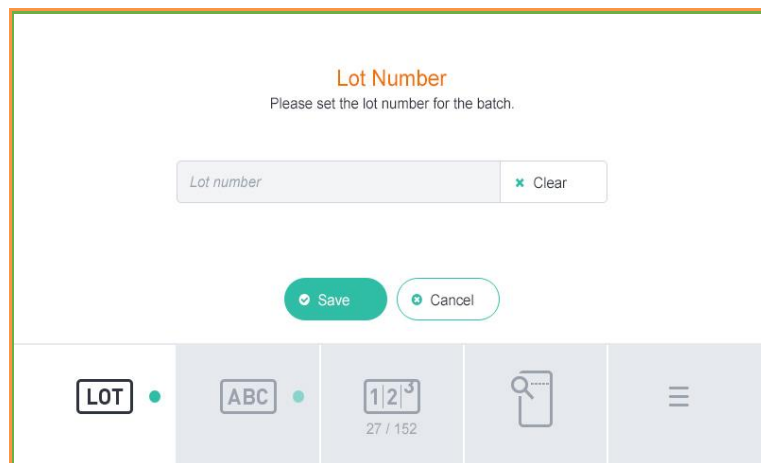
Also pay attention to the regulations of standards, especially those relating to filling (bags must be filled to a maximum of 2/3). This is to avoid the unintended insertion of objects.

If packaging material or an object is still caught in the unit, press the return button. The material is transported to the left side.

7.4 Setting the batch name

Enter the batch code that must be printed on the packaging here.

The batch number is also registered in the process documentation.



Lot Number
Please set the lot number for the batch.

Lot number Clear

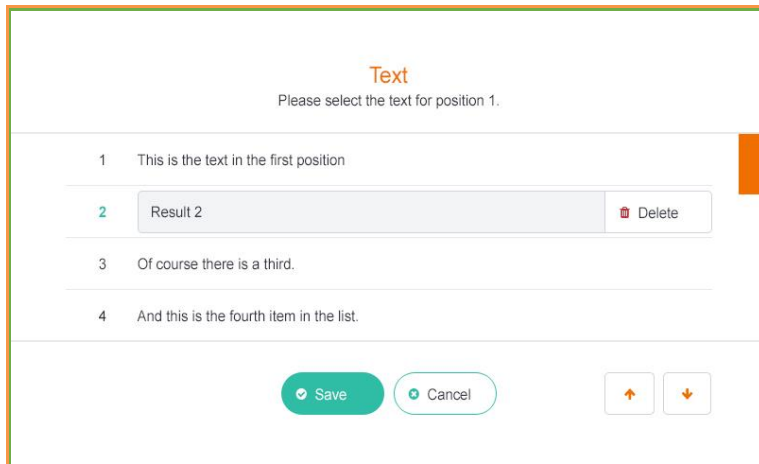
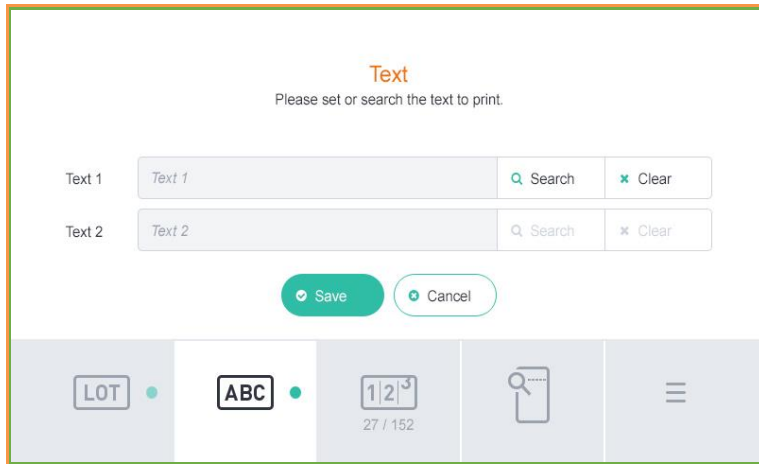
Save Cancel

LOT • ABC • 1|2|3
27 / 152

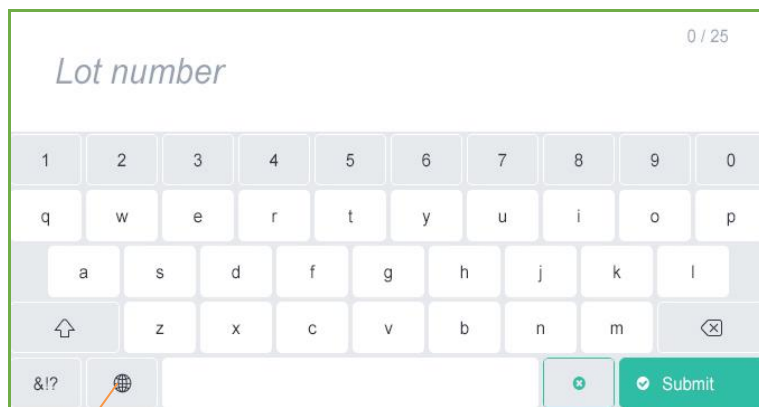
7.5 Text entry and selection

The text to be printed is entered here. With the EM 40, you now have the option to select two different texts for printing. Press „Search“ to select a saved text. A selection list will open. If you want to search more specifically, enter the first letters of the text you are looking for. „Clear“ removes the text from the selection.

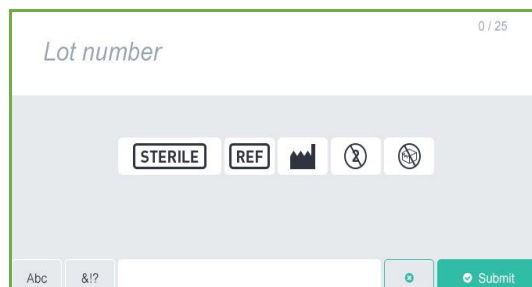
Then press „Save“ to save the changes or „Cancel“ to exit the menu without changes.



Text is entered via a keyboard that appears when a text input field is touched. Additional symbols can be integrated into the text via the symbol button.



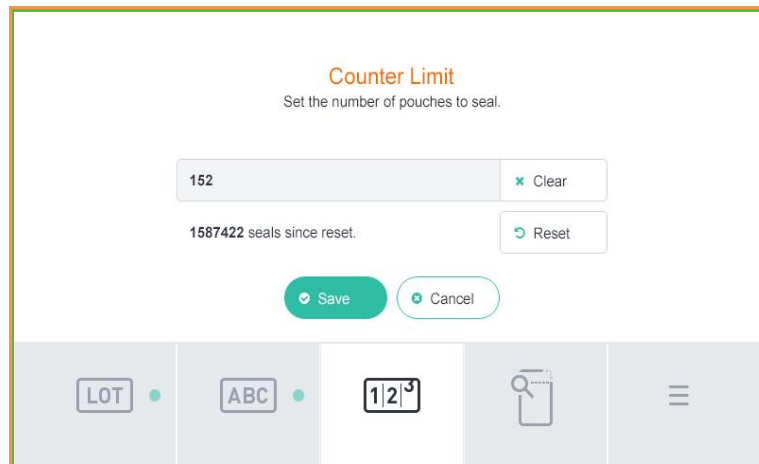
Symbol button



7.6 Setting the counter

Enter the number of seals to be produced, and the sealer will inform you when that number is reached.

You can view or reset the current counter status here.



8 Computer connection

The sealer can be connected to a computer for documentation of the sealing process via the RS232 interface.

Use a 1:1 wired cable with a male side and a female side for this.

If you use an interface converter, follow the manufacturer's instructions.

The COM port settings must be as follows:

8 Data Bits / 1 Stop bit / Flow control none / Baud rate 38400 Hz.

If necessary, ask your dealer which other connection types are available.

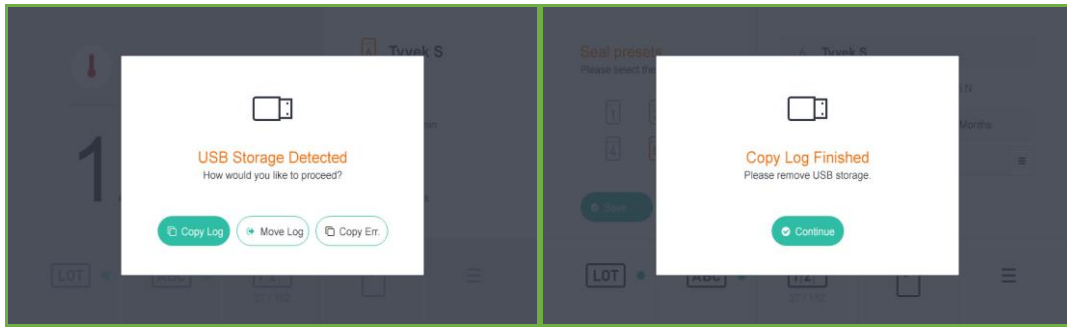
8.1 Documenting the sealing process with a USB stick

The sealing parameters are saved in the device. You can transfer the saved data to a USB stick for documentation.

Insert the USB stick into the USB port on the back of the device.

The device recognises the USB stick. The data can now be copied or moved to the USB stick.

After confirming successful transfer of the data the USB stick can be removed.



8.2 Documentation with CSSD documentation system

You can transfer the sealing parameters temperature, pressure and speed, a sequential number per seal, date of manufacture, expiry date, batch name, personal code and text during the sealing process to the PC. The serial number is formed from the total count by the pre-set device identifier. The serial number can be printed on each bag.

The interface is fully programmed and documented so that a programmer can integrate the data into his CSSD documentation system.

8.3 Controlling the sealer via web server

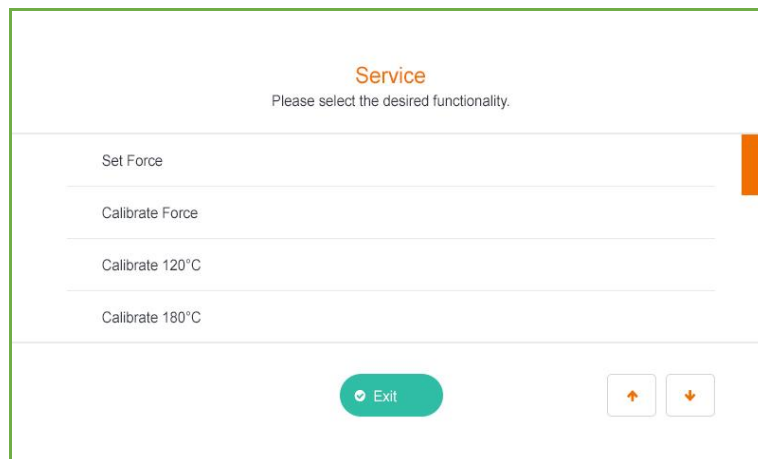
This function is being prepared.

9 Service options



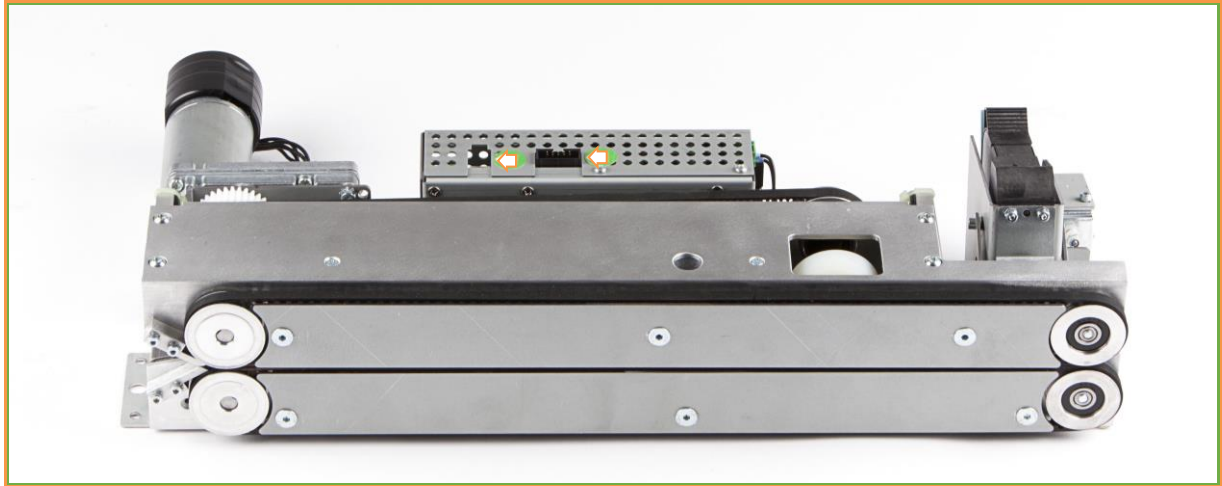
The service menu is only accessible to authorised persons with the service password. Changing settings here can lead to malfunctions.

Please consult your dealer or the manufacturer if necessary.



10 Service / SERVABOX

This sealer is equipped with the utility model protected SERVABOX.



With SERVABOX technology the complete sealing unit (SERVABOX) is replaced. Each SERVABOX is serviced and calibrated and delivered with a one-year warranty. The SERVABOX that you returned after the exchange is processed and calibrated in the factory and is then available to the next customer.

Thanks to this system, maintenance and calibration can be carried out in the shortest possible time by your company technician. Transport costs are reduced when compare to leased equipment. Repairs can also be done faster.

The sealer controller recognizes the new SERVABOX after it has been installed and restarts the service counter.

TIP: Set up a spare SERVABOX and thus increase the availability of your devices and avoid an interruption in your CSSD.

10.1 SERVABOX exchange process:

It is cheaper to exchange the SERVABOX than to buy/acquire.

Therefore, please return your old SERVABOX within 2 weeks after receipt of the new one.

If this does not happen, we assume that you want to buy the old SERVABOX and we calculate the difference to the purchase price.

If the returned SERVABOX has been used for more than one year or if it has been damaged by improper use, we reserve the right to be reimbursed the additional repair costs.

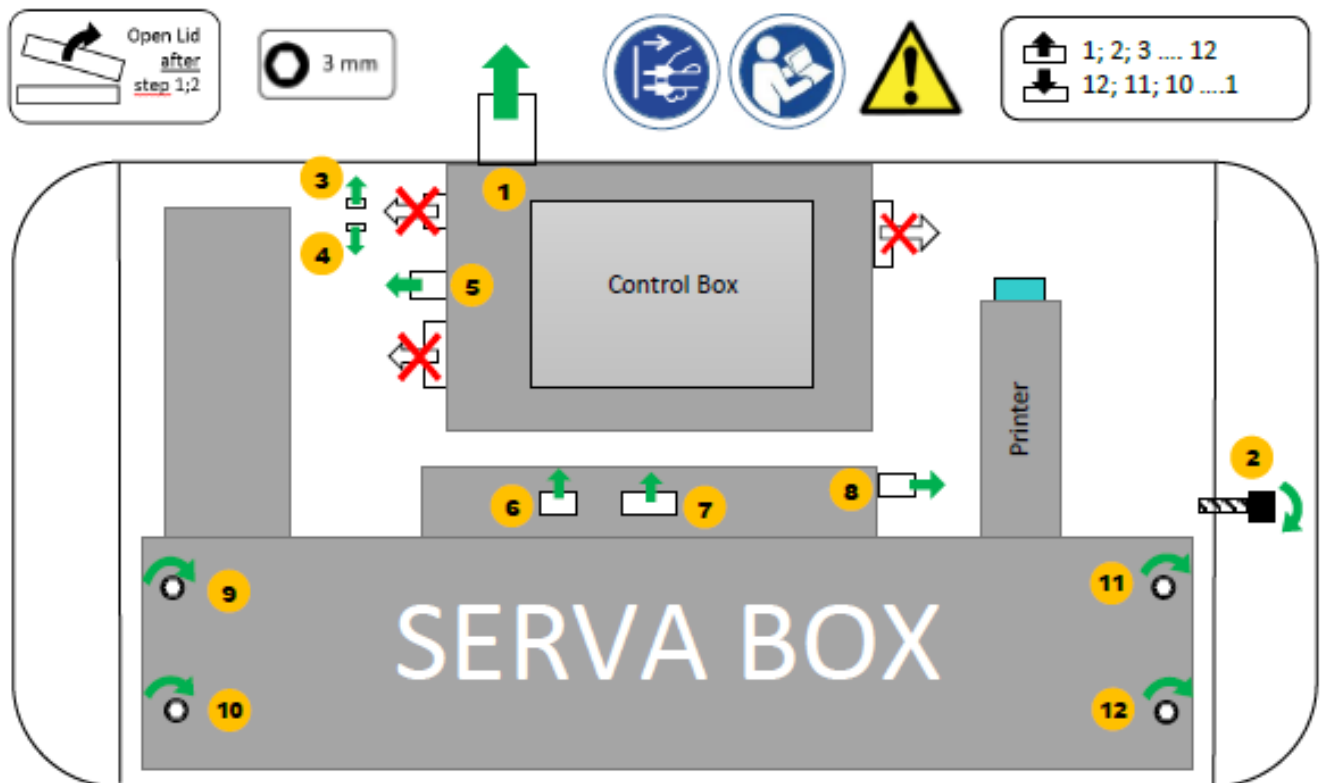
10.2 Replacing the SERVABOX

Changing the SERVABOX is very easy. All screws and connectors to be loosened are marked with an orange dot.

The green arrows on the schematic illustration mean that a screw or a plug connector has to be removed. The red X means that these connectors must not be loosened.



The housing must only be opened when the mains plug is pulled out and the device cooled down! In case of non-observance there is a risk of injury due to open gear parts and hot surfaces. The electronic components can also be damaged if the mains plug is not pulled out.



1. Press the ON/OFF button and wait till the device has come to a stop.
2. Pull out the network plug (1) and any other plugs at the back of the device.
3. Loosen the screw (2) marked with an orange dot in the slot on the right short side of the unit with the supplied 3mm hex wrench until the cover can be opened.
4. Flip the housing cover backwards.
5. Disconnect all marked connectors in numerical order (3,4,5,6,7,8).
6. Loosen the marked screws on the SERVABOX (9,10,11,12).
7. Replace the SERVABOX with a new one and screw it back into position with the screws (9,10,11,12).
8. Connect all the marked connectors in the device (3,4,5,6,7,8).
9. Close the housing and tighten screw (2).

10. Connect all the plugs at the back of the device.
11. Switch the device on again.
12. The device now recognises the new SERVABOX and restarts the service counter.
13. The sealer is now freshly serviced and calibrated.
14. You can now perform the new performance qualification according to EN ISO 11607. Please contact the Entrhal Validation service.

TIP:

To obtain a seamlessly validated process, produce the bags for the new performance qualification with the new SERVABOX. Work with the re-installed old SERVABOX until the validation documents for the new SERVABOX are available. Then continue working with the new SERVABOX.

Serious contamination of the electronics by dust can shorten the life of the device. Therefore, devices should be sent in for cleaning at least once every five years or more often in case of a heavy dirt load.



In order to avoid damage by electrostatic discharge or electric shock, opening the inner electronics housing is not permitted. If a housing is opened in spite of this, the warranty will expire.

10.3 Revalidation of the sealing process

According to the guidelines of the DGXV, revalidation should take place when there are changes to the sealing process (material / sealing parameters / sterilisation process) or after one year.

By replacing your SERVABOX in the exchange process, the maintenance and calibration is done quickly and simply.

After your SERVABOX has been exchanged by the company technician, you only need to seal and sterilise some bags and return them together with the completed list.

The validation report is then prepared based on your data and the test results of the bags.

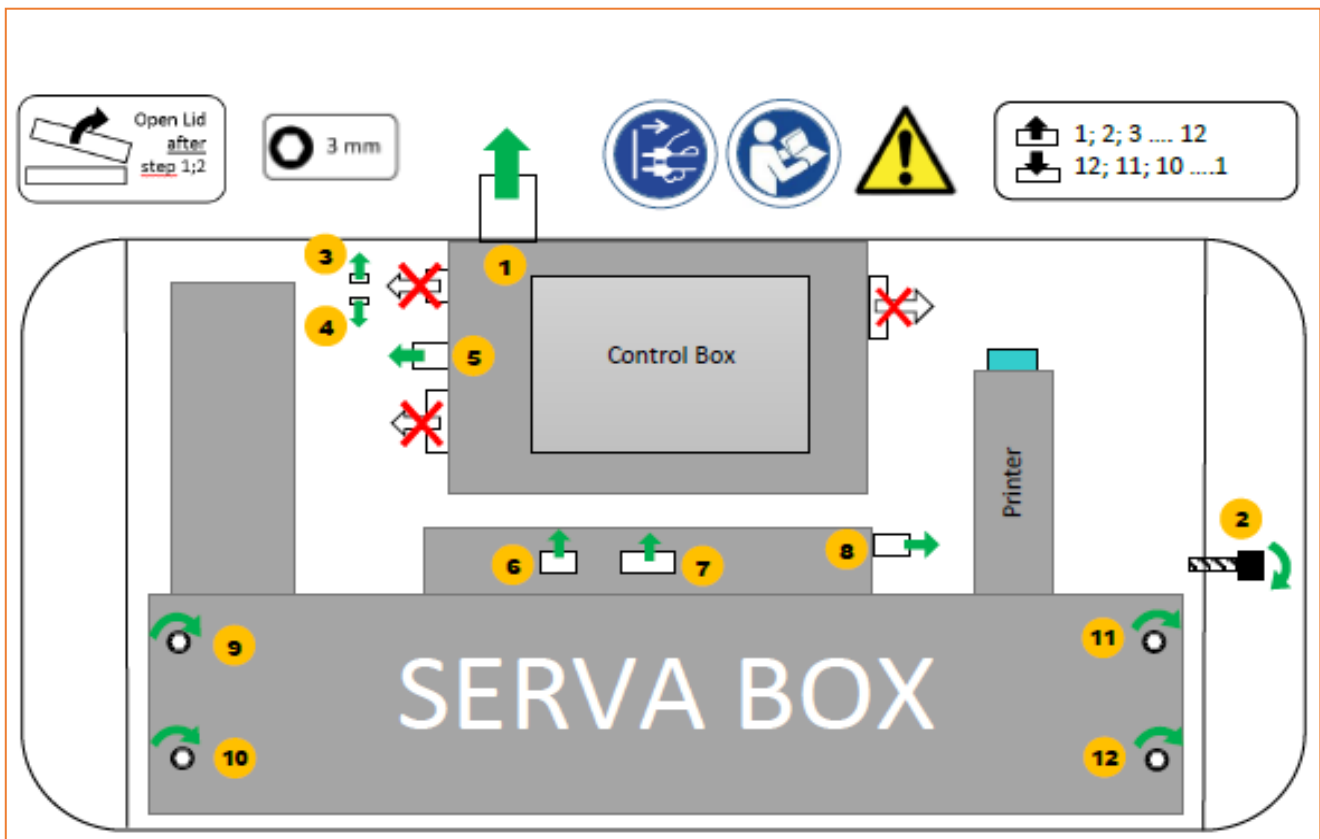
10.4 Maintaining and changing the cartridge

The built-in industrial inkjet printing system is very reliable and robust when properly maintained.

To keep the cartridge in usable condition, it needs regular maintenance. To do this, remove the printer cartridge and clean it regularly. We recommend cleaning the print head of the cartridge every day before switching it on, but at least weekly.

If the print cartridge no longer prints, a new one must be inserted. If it becomes necessary to exchange print cartridges between service intervals, it can be done as follows:

1. Turn the sealer off and allow it to cool sufficiently so that you don't touch hot surfaces.
2. Remove the network plug (1) from the back of the device.
3. Loosen the orange-marked screw (2) on the right short side of the unit until the lid can be flipped backwards.



4. Pull the turquoise lever on the printer right back and pull the print cartridge out towards the back.
5. To clean the print head, a cleaning set is available. (see spare part list) Wipe lightly with a lint-free soft cotton cloth soaked with cleaning fluid as shown in the figure below.

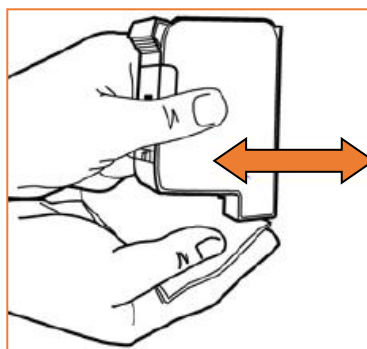


Do not use any other cleaning agents, nor paper or pulp cloths nor sponges. Residues can damage the nozzles.

6. To install a new cartridge or start up a new device, remove the protective film from the new cartridge.
7. Insert the cleaned / new cartridge and flip the lever back up.
8. Close the housing and screw it back in again by screwing the orange marked screw (2) on the right short side of the appliance.
9. Reconnect the device and turn it back on.
10. Do a trial print.
11. Only use original print cartridges as these ensure the high and sterilisation-proof quality of the printint.



Removing the cartridge



Cleaning



Inserting the cartridge

11 Warranty

The warranty for this device is 2 years from the date of commissioning.

The warranty is subject to the annual maintenance of the device in the form of an authorised service by Entrhal Medical GmbH or by an annual exchange of the SERVABOX by an electrotechnically trained person.

By participating in the exchange procedure, you extend your warranty on the most wear-resistant parts of the sealer by an additional year.

The guarantee does not cover faults caused by transport, improper use, pollution or non-observance of these operating instructions.

Also excluded are all wearing parts, in particular sliding belts, toothed belts. (Except yearly replacement of SERVABOX)

All consumable print cartridges are not covered by the warranty.

All claims beyond the repair and replacement of defective parts are excluded in principle.

12 Troubleshooting

The following information will help users to help themselves with some problems. Check the following to start with:

No display

Power supply connected? Sealer switched on? Has the sealer been switched off and on again?

The motor doesn't start:

Power supply connected? Sealer switched on? User logged in? Is the message „ready to seal“ displayed? Material inserted deep enough??

The printer doesn't print:

Printer switched off? Printing information activated? Print head empty or dirty or not inserted correctly? Bag inserted deep enough?

Seal too weak/strong:

Material suitable for heat sealing in accordance with EN 868? Temperature and speed set for the material according to validation? Material inserted correctly?

Material melted/burnt:

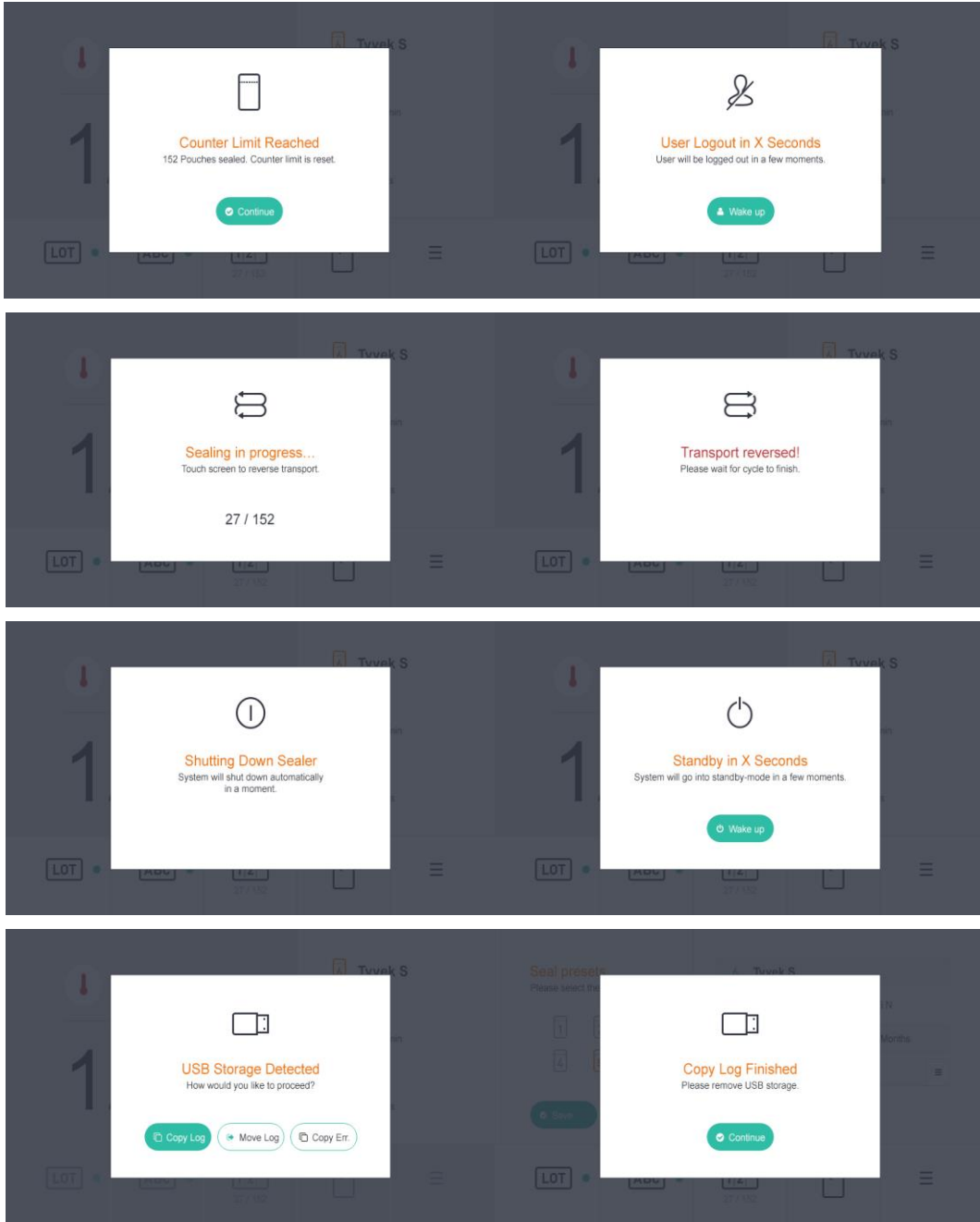
Material suitable for heat sealing in accordance with EN 868? Temperature and speed set for the material according to validation?

A list of past error messages can be printed via the web server or the service menu.

13 Status messages

When in use the device may display the following status messages.

These are largely self-explanatory and serve to inform the user.



14 Replacement and spare parts

Order number	Description	Quantity
8880984	SERVA BOX 24 KCS (buy)	1 piece
8880986	SERVA BOX 24 KCS (exchange)*	1 piece
8880946	SERVA BOX 40 KCS (buy)	1 piece
8880952	SERVA BOX 40 KCS (exchange)*	1 piece
8801163	Cartridge EM 40 black	1 piece
8880982	Cleaning set for ink jet cartridge	1 piece

* If you exchange the SERVABOX, you will get a lower price than the purchase price. Please return your old SERVABOX within 2 weeks of receipt. If this does not happen, we assume that you want to keep the SERVABOX and we will calculate the difference to the purchase price.

You can obtain other spare parts on request.