

Operating Instructions

CertoClav Vacuum Pro 8-22L

Laboratory autoclave

(User manual English: page 55)



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CE declaration of conformity

This is to certify that the **CERTOCLAV** autoclaves of type CV-Vac-Pro-8L, CV-Vac-Pro 12L, CV-Vac-Pro-18L, and CV-Vac-Pro-22L comply with the following EU Directives:

2014/35/EU Low Voltage Directive

Related standards:

EN 61010-2-040:2015 Safety requirements for electrical equipment for measurement, control and laboratory use
Laboratory equipment – Part 2-040: Particular requirements for sterilizers and cleaning machines
Disinfection devices for the treatment of medical material
EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control and laboratory use
– Part 1: General requirements

The autoclave is designed according to the low voltage directive 2014/35/EU.

2014/30/EU Electromagnetic compatibility / EMC Directive

Related standards:

EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1:
General requirements
EN 61000-3-3:2013 Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage
fluctuations and flicker in public low-voltage supply networks for devices with a rated current ≤ 16 A per conductor that
are not subject to any special connection conditions

2011/65/EU Restriction of the use of certain hazardous substances (RoHS) Directive / Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Related standards:

EN 50581:2012 Technical documentation for the assessment of electrical and electronic equipment regarding the
restriction of hazardous substances

Manufacturing quality:

CertoClav manufactures according to modern production methods using high quality materials. Decades of experience and experienced employees guarantee high quality products and maximum customer service. All devices are subject to 100% testing for functionality and quality.

Manufacturer:

CERTOCLAV Sterilizer GmbH, A-4060 Leonding, Austria



Michael Dirix
Managing Partner

Leonding, March 2020

1 Validity of the operating instructions

| | |
|---|---|
|  | This manual is only valid for CertoClav Vacuum Pro Series autoclaves with the model designations CV-08-V-Pro, CV-12-V-Pro, CV-18-V-Pro and CV-22-V-Pro. |
|  | Please read this operating manual before the initial operation of the autoclave. |
|  | Strictly adhere to all safety instructions in this operating manual. |
|  | Keep these operating instructions within easy reach of the autoclave. |
|  | If there are questions or problems with the autoclave, contact your dealer or the manufacturer. |
|  | Operation and maintenance of the autoclave may only be carried out by trained personnel. |

2 Meaning of the labels

| | |
|---|--|
|  | ATTENTION! |
|  | PROTECTIVE GROUND WIRE CONNECTION |
|  | Hot surface, keep away |
|  | ENVIRONMENTAL PROTECTION – Do not dispose of electronic waste together with household waste. Contact your dealer or a local recycling center to dispose of the waste properly. |
|  | MANUFACTURER |
|  | COMMUNAUTÉ EUROPÉENNE |
|  | DATE OF PRODUCTION |
|  | SERIAL NUMBER |
|  | THIS SIDE UP |
|  | SHELTER FROM RAIN |
|  | DO NOT ROLL |
|  | STACKING: MAX. 3 UNITS |
|  | ROOM TEMPERATURE: 5 °C~40 °C |
|  | RELATIVE HUMIDITY ≤ 80% |

3 General Safety Instructions

- ⚠ Only use the equipment in accordance with these instructions. Store this operating manual in a place that is easily accessible to all users.
- ⚠ Use a power outlet with a protective earth conductor and make sure that the protective earth conductor is well grounded.
- ⚠ Do NOT install the autoclave in a place where the power supply cannot be quickly disconnected.
- ⚠ Operate the autoclave exclusively with the supply voltage declared on the autoclave's type plate.
- ⚠ Do NOT touch the power plug or socket with wet hands.
- ⚠ Do NOT load, bend or twist the cables. Do NOT place heavy objects on the cables.
- ⚠ Do NOT autoclave pressure-tight containers; these containers could implode or explode.
- ⚠ Only fill the water tank with distilled or demineralized water.
- ⚠ Do NOT block the door of the autoclave.
- ⚠ Do NOT cover the ventilation openings at the back of the autoclave.
- ⚠ If you notice any unusual odors or noises during operation, immediately disconnect the autoclave from the power supply and contact your local dealer or the manufacturer by e-mail.
- ⚠ If you do NOT operate the autoclave for a long period of time, please disconnect the power supply and empty the internal water tanks.
- ⚠ Only connect original accessories to the autoclave.
- ⚠ Do NOT modify the device.
- ⚠ The autoclave must NOT be installed in an area, that is subject to the danger of explosions.
- ⚠ The autoclave may only be used in laboratories. It is NOT suitable for domestic use.
- ⚠ Please fill bottles and other containers only up to a maximum of half the volume with liquid.
- ⚠ Do NOT remove containers with liquids from the chamber until a liquid temperature of less than 80 °C is measured. Otherwise there is a danger of boiling delay of the liquid.
- ⚠ If the pressure is quickly released during autoclaving liquids due to an unscheduled program termination, there is a possibility of boiling delay of the liquid. Therefore, before opening the autoclave, always wait until the temperature of the medium has reached less than 80 °C.
- ⚠ The autoclave must NOT be transported when filled.
- ⚠ The autoclave must NOT be forced open.
- ⚠ This autoclave may only be serviced by trained dealers.
- ⚠ Only use original spare parts for maintenance.

4 Substances which must NOT be autoclaved

Never use the autoclave to sterilize any of the following materials or alkaline solutions. Sterilization of such substances can lead to explosion, corrosion of the sterilization chamber and piping, as well as attrition of the seals.

Explosive substances

Nitroglycol, nitroglycerine, nitrocellulose and other explosive nitric acid esters.

Trinitrobenzene, trinitrotoluene, picric acid and other explosive nitro compounds.

Peracetic acid, methyl ethyl ketone peroxide, benzoyl peroxide and other organic peroxides.

Flammable substances

Metallic lithium, potassium, sodium, yellow phosphorus, phosphorus sulfide and red phosphorus.

Celluloids, calcium carbide (carbide), calcium phosphide and magnesium powder.

Aluminum powder, magnesium powder and metal powder other than aluminum powder.

Sodium dithionite (or sodium hydrosulfite).

Oxidizing agent

Potassium chlorate, sodium chlorate, ammonium chlorate and other chlorates.

Potassium perchlorate, sodium perchlorate, ammonium perchlorate and other perchlorates.

Potassium peroxide, sodium peroxide, barium peroxide and other inorganic peroxides.

Potassium nitrate, sodium nitrate, ammonium nitrate and other nitrates.

Sodium chlorite and other chlorites.

Calcium hypochlorite and other hypochlorites.

Combustible materials

Ethyl ether, petrol, acetaldehyde, propylene oxide, carbon disulfide and other substances whose flash points are in the range of -30 to 0 °C.

Methanol, ethanol, xylene, benzyl acetate (or amyl acetate) and other substances whose flashpoints are between 0 and 30 °C.

Kerosene, gas oil, turpentine oil, isopentyl alcohol (or isoamyl alcohol), acetic acid and other substances with a flash point between 30 °C and 65 °C

Combustible gas (hydrogen, acetylene, ethylene, methane, ethane, propane, butane and other substances operating at a temperature of 60 °C at an absolute pressure of 0.2 bar)

If a saline solution has been spilled inside the chamber, remove all liquid from the chamber and wipe the liquid around the door seal. Clean the door seal using distilled or demineralized water.

5 Introduction

This autoclave is an automatic steam sterilizer with vacuum pump and steam generator. Depending on the program and settings, the sterilization temperature is between 105 °C and 134 °C. Solid materials and liquids can be sterilized. The autoclave is outfitted with a flexible media sensor, to measure the temperature directly within the medium. The program parameters and sterilization programs are displayed on the front LCD screen and on the mobile touch screen. If a problem is detected during the sterilization process, the autoclave automatically issues an error message. The autoclave is equipped with internal water tanks for fresh and process water.

5.1 Field of application

This autoclave is exclusively intended for the use in laboratories. For example, for the sterilization of liquids, solids, waste and textiles such as swabs, glasses, petri dishes, porous materials, powders, hollow bodies and instruments. No pressure-tight sealed containers may be sterilized.

5.2 Technical data

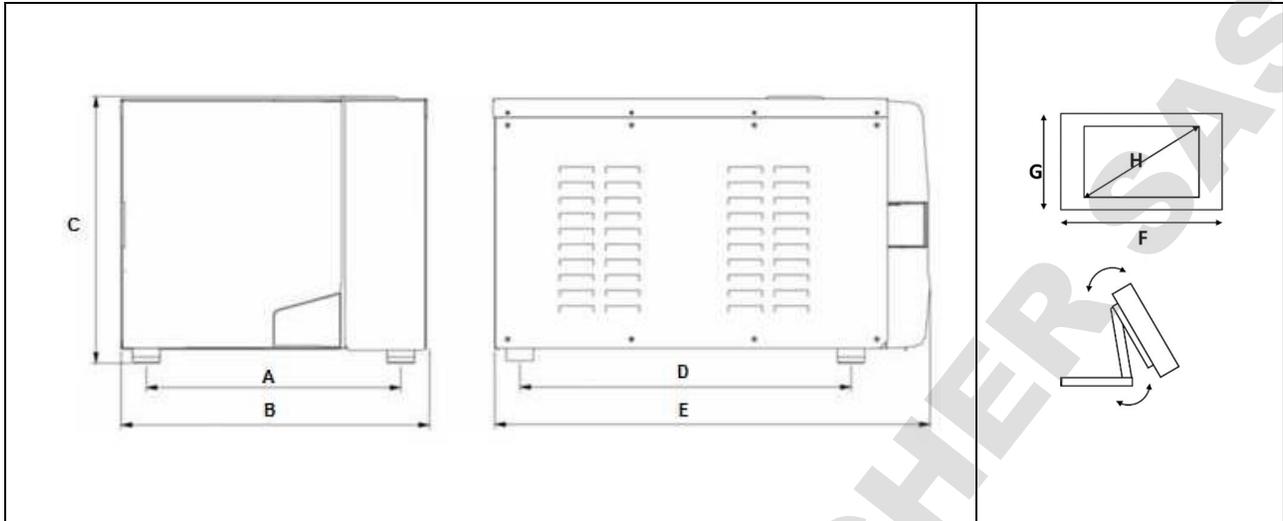
The working area of the autoclave:

- Ambient temperature: 5 °C – 40 °C
- Relative air humidity: ≤ 80%
- Air pressure: > 70kPa;
- Supply voltage: 230V AC, 50Hz, 2500VA
- Maximum working pressure: 0.21 ~ 0.23MPa
- Maximum operating temperature: 135 °C ~ 137 °C
- Expected life: 10+ years

5.3 Requirements for transport and storage

- Ambient temperature: 5 °C ~ 40 °C
- Relative air humidity: ≤80%.
- No corrosive gases in the environment

5.4 Dimensions and weight



| Model | A | B | C | D | E | F | G | H |
|----------------|-------|-------|-------|-------|-------|-------|-------|-------|
| CV-VAC-PRO-12L | 415mm | 503mm | 433mm | 540mm | 610mm | 200mm | 128mm | 178mm |
| CV-VAC-PRO-18L | 415mm | 503mm | 433mm | 540mm | 610mm | 200mm | 128mm | 178mm |
| CV-VAC-PRO-22L | 415mm | 503mm | 433mm | 640mm | 710mm | 200mm | 128mm | 178mm |

| Model | Chamber volume | Chamber diameter | Chamber depth | Net weight |
|----------------|----------------|------------------|---------------|------------|
| CV-VAC-PRO-12L | 12 liters | 200mm | 360mm | 51kg |
| CV-VAC-PRO-18L | 18 liters | 250mm | 350mm | 53kg |
| CV-VAC-PRO-22L | 22 liters | 250mm | 450mm | 55kg |

6 Scope of delivery

| Index | Description | Quantity |
|-------|---|----------|
| 1 | QuickConnect discharge hose | 1 |
| 2 | Drawer set consisting of: 1 x handle, 3 x drawers, 1 x drawer holder | 1 |
| 3 | Power cable for autoclaves | 1 |
| 4 | Operating instructions | 1 |
| 5 | Mobile touch screen | 1 |
| 6 | Power cable for touch screen | 1 |
| 7 | Base for touch screen with four fastening screws | 1 |
| 8 | Interface box for touch screen | 1 |
| 9 | Autoclave | 1 |
| 10 | Warranty card | 1 |
| 11 | Data cable (1m length) between autoclave and touch screen | 1 |

7 Installation of the autoclaves

7.1 Packaging

This autoclave is delivered in a wooden crate. To open, the metal flaps on the top of the box must be opened. Lift the autoclave vertically out of the box with the help of a second person at the two loops.

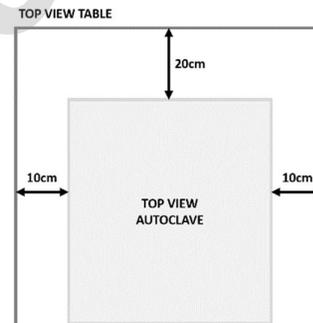
(see picture)



7.2 Installation

If you place this autoclave on a laboratory table, check that the table can support the weight of the autoclave. Please keep at least 10 cm of free space around the autoclave. Leave at least 20 cm of free space at the ventilation slots on the right side of the autoclave. Make sure that the room is well ventilated. Use a level to check that the autoclave is horizontally leveled.

Important: Place the autoclave at the front of the chamber 1.5 cm higher than the back, to achieve a slight tilt, so that the condensate in the chamber can flow towards the drain.



Open the door of the autoclave and remove the tray set including accessories. Remove the packing material.



Mount the base to the touch screen using the four screws provided.



Now, the touch screen with the base should look like the illustration on the right.



Connect the touch screen to the interface box.



Connect the power supply unit of the touch screen to the interface box.

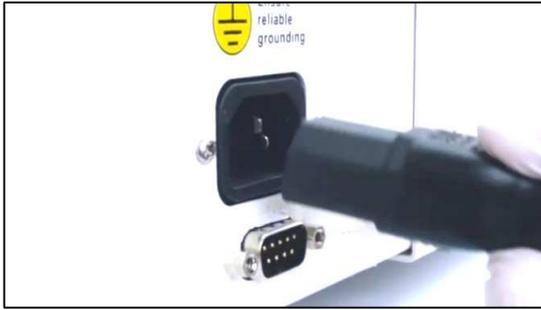


Only place the touch screen on flat, stable surfaces. You can also place the waterproof touch screen on top of or next to the autoclave.

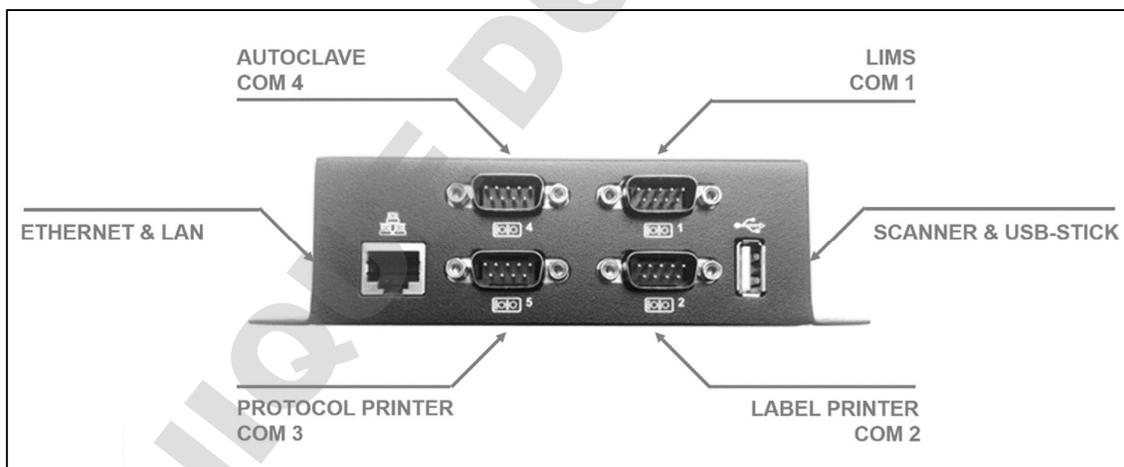


Make sure that the table can support the weight of the autoclave.

Connect the power cable to the device socket at the back of the autoclave. Note: Check, whether the information on the autoclave type plate matches the information on the voltage source. Check that the safety switch of the autoclave is in the upper position. Switch the autoclave on at the green rocker switch.



Connect the autoclave with the RS232 cable at the COM 4 connection of the interface box to the RS232 connection on the back of the autoclave.



Turn on the touch screen.

If a login window appears on the screen after a few seconds, the touch screen is correctly connected to the autoclave.

If a message about a connection termination with the autoclave appears on the screen, the touch screen and autoclave are not connected correctly. Check whether the autoclave is switched on and connected to the COM4 port of the interface box.

7.3 Installation of accessories

7.3.1 Connecting the log printer

Connect the log printer (thermal or dot matrix printer) to the COM 1 connection of the interface box. The connecting cable can be found in the carton of the log printer. Follow the operating instructions of the printer.



7.3.2 Connecting the barcode scanner

Connect the barcode scanner to the USB port of the interface box. You can take the connection cable from the carton of the scanner. Follow the operating instructions for the barcode scanner.



7.3.3 Connecting the label printer

Connect the label printer to the COM2 connection of the interface box. You can take the connecting cable from the carton of the label printer. Follow the operating instructions for the label printer.



7.3.4 Connecting the private CertoServer

If you do not have/ want access to the Internet and still want to use CertoCloud, it is recommended to connect the local CertoServer to the autoclave. In chapter 12.2.4 you will learn how to connect the CertoServer to the autoclave.

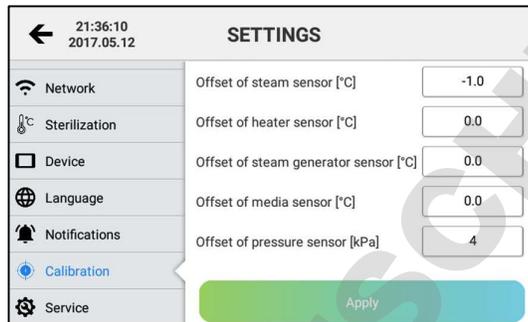


7.4 Pressure sensor calibration

Since the atmospheric pressure depends on the installation location, you should recalibrate the pressure sensor after changing the installation location.

Calibration instructions:

Switch on the autoclave and open the door. Log in to the administrator account. User account: Admin, password: "admin". If the pressure display shows a pressure that deviates from 0kPa, the pressure sensor offset should be corrected. Navigate to Settings->Calibration and enter a suitable offset for the pressure sensor in [kPa]. Example: The pressure display shows a pressure of +4 kPa when the door is open. Enter an offset of -4 kPa for correction and press the "Save" button. The parameters are permanently accepted.



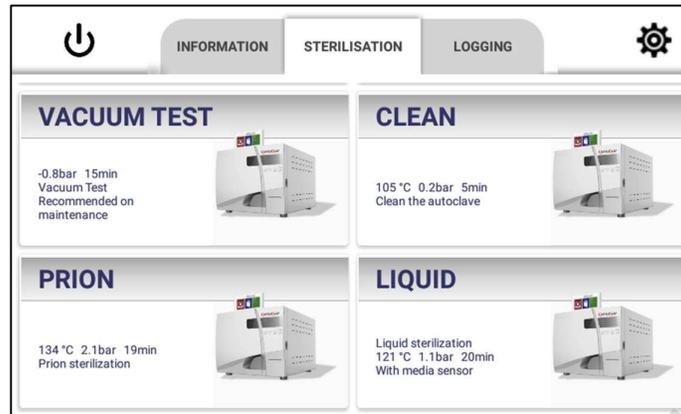
If the pressure sensor is not properly calibrated after the autoclave has been installed, the autoclave may refuse to start a program.

7.5 Validation and calibration

If you have any questions about validation and calibration of the instrument, please contact the manufacturer.

8 Sterilization programs

| Program | Vacuum phases | Sterilization time [min] | Sterilization temperature [°C] | Sterilization pressure [kPa] | Vacuum hold time [min] | Drying time [min] |
|-----------------|---------------|--------------------------|--------------------------------|------------------------------|------------------------|-------------------|
| 121 °C / SOLID | 1 | 20 | 121 | 110 | - | 3 |
| 121 °C / POROUS | 3 | 20 | 121 | 110 | - | 7 |
| 121 °C / HOLLOW | 3 | 20 | 121 | 110 | - | 10 |
| 134 °C / SOLID | 1 | 4 | 134 | 210 | - | 3 |
| 134 °C / POROUS | 3 | 4 | 134 | 210 | - | 7 |
| 134 °C / HOLLOW | 3 | 4 | 134 | 210 | - | 10 |
| USER-DEFINED | 1-10 | 1-60 | 105-134 | 20-210 | - | 1-40 |
| B-D TEST | 3 | 3.5 | 134 | 210 | - | 7 |
| VACUUM TEST | - | - | - | -80 | 15 | - |
| CLEAN PROCESS | 3 | 5 | 105 | 20 | - | 10 |
| PRIONS | 3 | 19 | 135 | 210 | - | 10 |
| LIQUID | - | 20 | 121 | 110 | - | 0 |

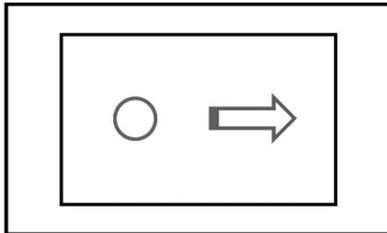


- The "121 °C" programs and the "134 °C" programs for the respective load type do not differ in the result. If the load is temperature sensitive and therefore, cannot be sterilized at 134 °C, please select the 121 °C program.
- The SOLID programs can only sterilize solids that are not packaged. Such as unpacked pliers, scissors, tweezers, bowls, etc.
- The "Porous" programs are specially designed for bodies made of porous material. Three venting steps, by means of the vacuum pump, ensure complete penetration with steam of the porous material. This is a necessary condition for an immaculate sterilization of porous materials.
- The "Hollow" programs can sterilize hollow bodies of type A and type B. These are for example glasses or cannulas.
- With the "User-defined" program you can set a user-defined program of your choice. However, it is not suitable for the sterilization of liquids, but only for solids, porous materials and hollow bodies.
- The "B&D/Helix" program tests hollow bodies of type A. The "B-D Test" and "Helix Test" programs are almost identical. The only difference is that the "B-D Test" program uses a B&D test package, while the "Helix Test" program uses a test device. (PCD: Process Challenge Device)
- The "Vacuum Test" program performs an air tightness test.
- The "Clean Program" program cleans the autoclave. If the autoclave displays the message "Need Clean", please run this program. This program can also be used to cleanse other bodies.
- The "Prion" program is especially suitable for the sterilization of prions on surfaces of all kinds.
- The "Liquid Program" is used to sterilize liquids in bottles and other open containers. It is recommended to use the built-in flexible media sensor for this program. The media sensor is placed in the liquid medium or a reference glass with distilled water during sterilization. The autoclave now adjusts the holding time during sterilization, so that the medium will have maintained the required sterilization temperature for at least 20 minutes. Note: For older models with firmware version < 10, the hold time is 17 minutes. If the media sensor is not used, the media temperature cannot be recorded during sterilization. ATTENTION: Never place pressure-sealed bottles, bags or containers; without a pressure equalization mechanism, in the autoclave. These could explode due to excess pressure during cooling. NOTE: Do not fill glasses more than half their max. capacity.

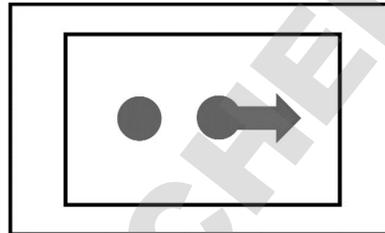
| | |
|---|---|
|  | Never place tightly closed bottles, bags or containers in the autoclave. These could explode due to excess pressure. |
|  | Please carry out a vacuum test every month. If the program does not complete successfully, contact your dealer or the manufacturer! |

9 Basic operation

Click and wipe

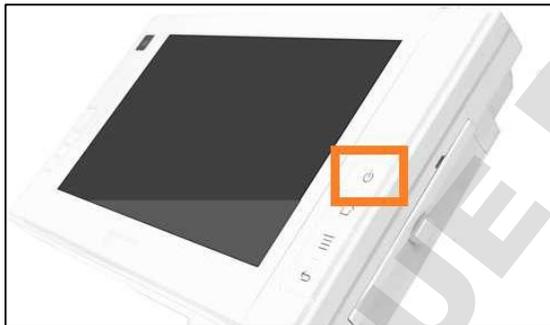


Long click and drag



9.1 Switching on the touch screen

1. Press and hold the -button on the front panel (to the right of the screen) for at least 3 seconds.
2. Switch on the autoclave at the green power switch.



9.2 Switching off the touch screen

Press the -button on the front panel (to the right of the screen) for at least 3 seconds. A notification will then appear on the screen. Select "Shutdown" to turn off the screen.

9.3 Stand-by

Briefly push the -button next to the screen. The backlight of the screen will then turn off. Push the -button again to reactivate the touch screen.

10 Instructions for daily use

10.1 Preparations before use

Switch on the autoclave at the green power switch. Switch on the touch screen directly on the screen. To do this, press the -button on the front of the screen (to the right of the screen) for at least 3 seconds. The autoclave's touch screen then switches on and displays the login window. The autoclave is ready for operation.

| | |
|---|--|
|  | Please ensure that the autoclave is grounded. |
|  | Before the first use, the touch screen displays the message "Please fill distilled water into the water tank". As soon as the tank is filled, the notification disappears, and the autoclave is ready for operation. |

10.2 Refilling of distilled water



When the message "Please fill distilled water into the water tank" appears on the screen, fill distilled water into the water tank at the top of the autoclave. As soon as the warning message disappears and a beep sounds, the minimum fill level of distilled water has been reached. Take care not to overfill the tank. The inlet to the water tank is located on the lid of the autoclave. Only distilled or demineralized water is suitable for the operation of the autoclave.

If the tank is overfilled, water can be drained with the QuickConnect hose connection at the front of the unit. If the message "Please fill distilled water into the water tank" appears on the screen during a sterilization run, you do not need to cancel the sterilization run. However, please fill distilled water into the tank before starting the next sterilization cycle.

| | |
|---|---|
|  | Neither the manufacturer nor your dealer is liable for damage caused by using contaminated water. |
|  | Before filling distilled water into the water tank, please switch on the autoclave and make sure that your autoclave is horizontally leveled. |
|  | Only fill demineralized or distilled water into the freshwater tank. A water quality sensor continuously monitors the quality of the water. If too impure water is filled into the tank, a warning message appears on the front integrated LCD screen and the touch screen. |

10.3 Steps to start a sterilization process

Before starting the program, first check whether the autoclave is ready for operation. If no warning or error message is displayed on the touch screen, the autoclave is ready for operation.

10.3.1 Loading of the autoclave

Please make sure that the total volume of the load is less than 70% of the volume of the sterilization chamber. If you put your load in or take it out of the sterilization chamber, please use the tool provided.

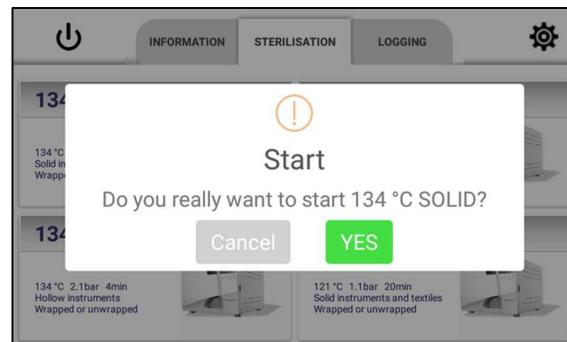
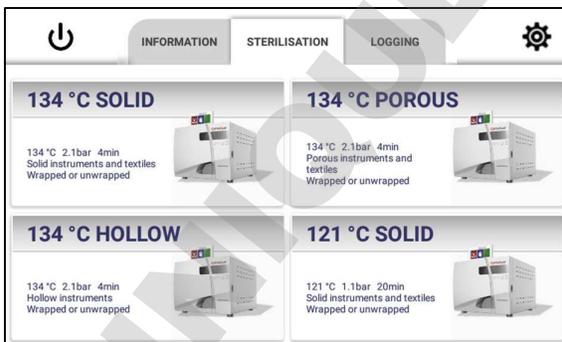
| | |
|---|--|
|  | Please leave at least 10 mm free space between the load and the sterilization chamber wall. |
|  | When running the B&D/Helix program, place the indicator in the inner center of the sterilization chamber. This way you get a reliable test result. |

10.3.2 Close autoclave door

| | |
|---|---|
|  | When the temperature in the sterilization chamber is high, the autoclave door is difficult to close. Wait 30 seconds before closing the door. |
|---|---|

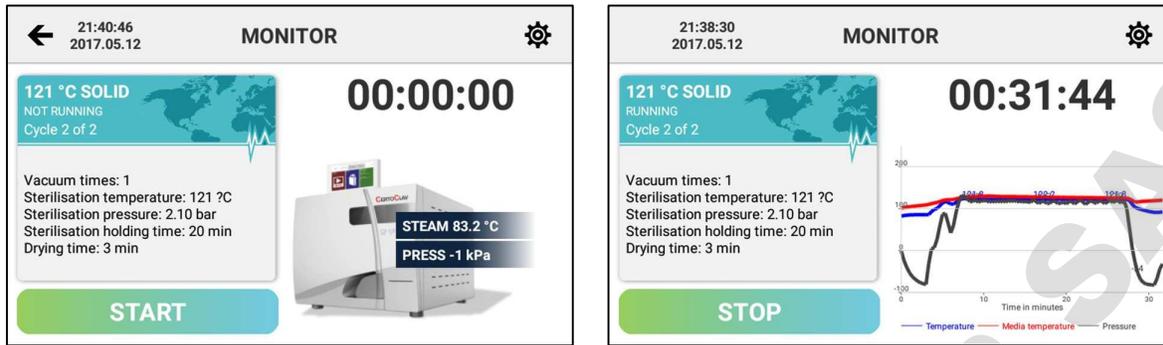
10.3.3 Select sterilization program on screen

1. After logging in (see section 11.1.) navigate to the sterilization menu.
2. In the middle 4 programs are visible. Scroll down the list to see all available programs.
3. Press one program to select it. Confirm that you want to start the program.
4. If enabled in the settings, step-by-step videos are displayed before the program starts.



10.3.4 Status screen

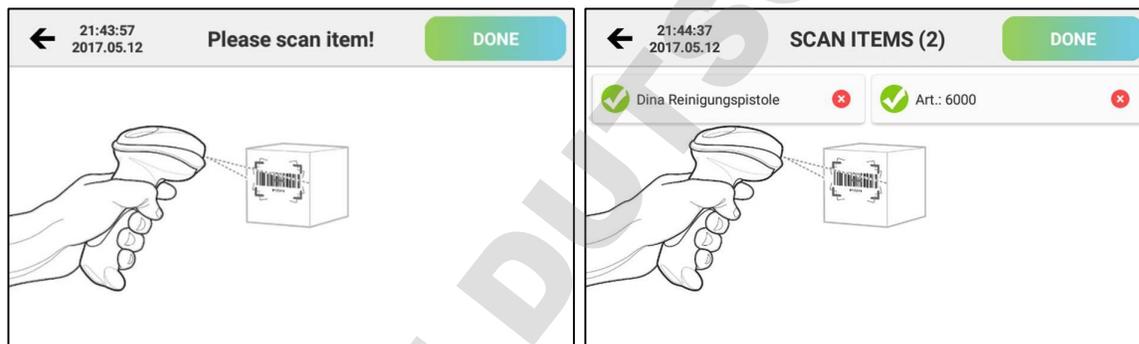
During the current cycle, the status screen is visible. On the left side, information about the current cycle is listed. On the right side of the screen, the current steam temperature and pressure are displayed. If the liquid program has been started, the liquid temperature is also visible. To display a graphical view of the temperature and pressure curve, hold and drag the autoclave icon to the left. Afterwards a graphical recording becomes visible.



10.3.5 CertoTrace – Documentation and loading management

CertoTrace is a software that enables simple and professional documentation of the entire sterilization process and traceability of sterilized goods.

- 1) If CertoTrace is enabled (Settings->Sterilization->CertoTrace Documentation), the CertoTrace wizard is executed immediately after a program is selected.
- 2) Scan the barcode of bottles, instruments or other items placed in the autoclave to trace their sterilization with CertoTrace.



- 3) After an item has been scanned, it appears in a list in the CertoTrace scan menu. The object and the barcode are recorded in the protocol of the sterilization process.
- 4) After all items have been scanned and placed in the sterilization chamber, press the "Next"- button.
- 5) To cancel the CertoTrace wizard, press the "Back"- button in the upper left corner of the screen.
- 6) If no barcode exists for an item, use the label printer designer to create and print a barcode for the item. The label printer designer can be found under Settings->Sterilization->Label Printer Designer.

10.3.6 Step-by-step assistant

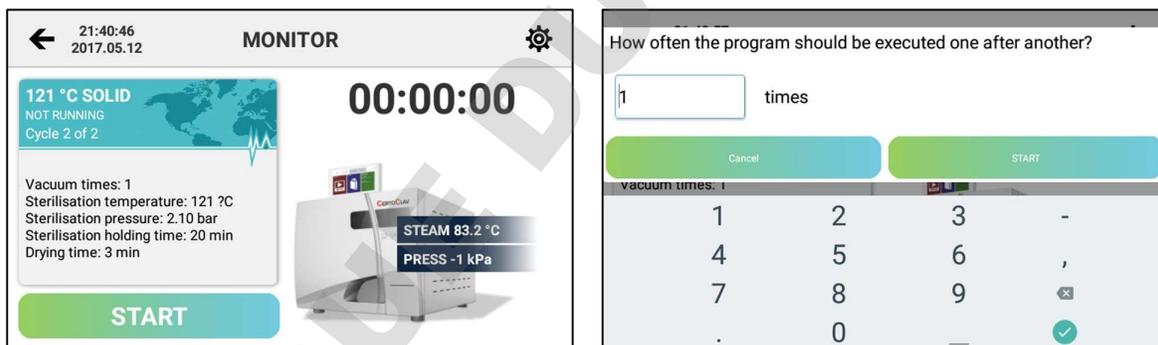
To activate the step-by-step assistant, navigate to the settings menu by clicking on the  icon in the upper right corner of the screen. Select the Sterilization option on the left side of the settings window. Press Step-by-Step Assistant to enable or disable it.

The step-by-step assistant guides the user through all necessary steps to operate the autoclave correctly by means of video instructions.



10.3.7 Material test mode and automatically repeated start

The material test mode can be activated via the checkbox in Settings->Sterilization->Material test. If the material test mode has been activated, the autoclave asks, before the program starts, how often the program should automatically repeat cycles.



A number between 1 and 1000 can be entered. The program will execute the set number of cycles fully automatically, one after the other. The status of the currently running program can be called up at any time, either browser-based at www.certocloud.com or offline via the CertoServer at <http://certocloud>. If you have activated e-mail and SMS notifications, you can retrieve data on the current status of the material test via SMS or e-mail. The e-mail and SMS notifications can be configured in Settings->Notifications. However, SMS notifications are only possible with the CertoCloud Premium account.

It is necessary to fill the freshwater tank regularly and empty the waste water tank regularly.

10.4 Unloading the autoclave

Once the sterilization cycle is complete, the screen will display "Program Complete" and you will hear three beeps. Now you can open the door and take out the sterilized load.

| | |
|---|---|
|  | Please use the supplied accessories to remove the load from the sterilization chamber. Do not open the door until the pressure inside the sterilization chamber is in the range of -5kPa to 5kPa. |
|  | To independently check the effectiveness of the sterilization cycles, place indicators together with the load in the sterilization chamber. |

10.5 Emptying the service water tank

If the screen displays "Empty the hot water tank", the wastewater tank is full. Please empty the process water with the QuickConnect hose supplied.

| | |
|---|--|
|  | Caution, the process water may be hot. |
|---|--|



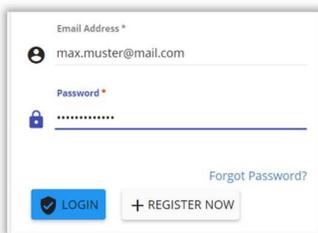
10.6 PC software

10.6.1 CertoCloud software features

The CertoCloud is a browser-based management software for your autoclave. It is available for PC, smartphone and tablet at www.certocloud.com. The CertoCloud is also available as an in-lab private cloud. For this purpose, a CertoServer must be connected to your laboratory network. The CertoServer does not require an Internet connection.



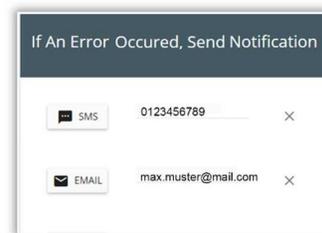
Create a user account, directly at the autoclave or web-based.



Tracking of real-time data from the autoclave.



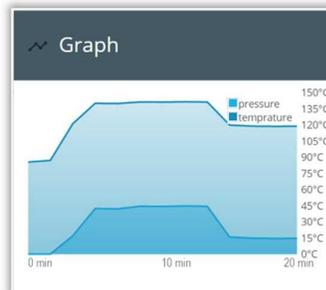
Management of SMS and e-mail notifications. For example, when maintenance is due. *



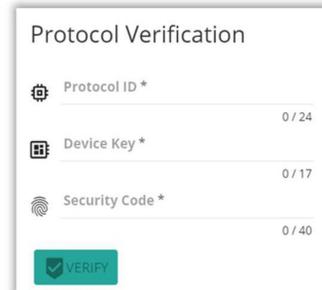
Download all sterilization protocols as signed PDF, Excel and ZIP files.

| cycle | Program Name | Start |
|-------|-----------------|----------|
| 76 | cloud generated | 7/22/ PM |
| 75 | 121°C SOLID | 7/22/ PM |
| 74 | Neues Programm | 7/22/ PM |
| 74 | 121°C SOLID | 7/22/ PM |

View all logs in the graphical view, as a list or in detailed view.



Prove the validity of your exported protocols.



*) SMS notifications are only possible with the CertoCloud Premium account!

10.6.2 Display of sterilization protocols via web browser

If your autoclave is connected to the Internet or to the local CertoServer, you can view and manage your protocols. A sample protocol is shown below.

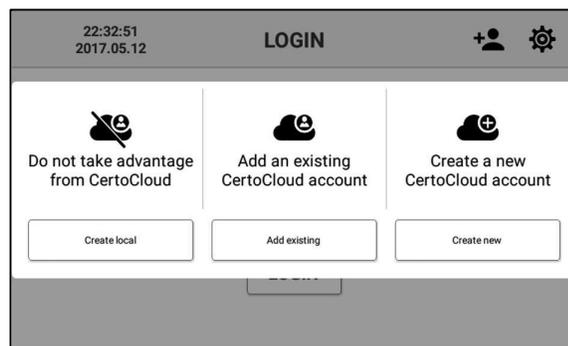


11 Control panel overview

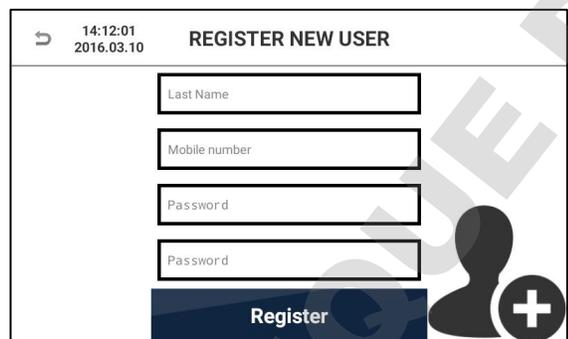
11.1 User registration and login



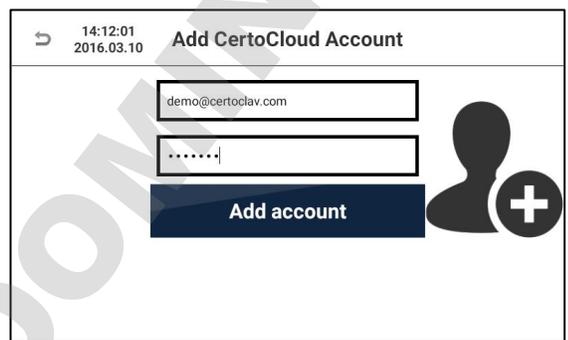
When the touch screen is switched on, the login window appears. To create a new user, press the “plus”-icon in the top right corner of the screen.



To create a local account without server connection, press the "Create local" button on the left side of the selection window. To add an existing CertoCloud user account with server connection press the middle “Add existing”-button. If you want to create a new CertoCloud account with server connection, press the “Create new”-button on the right side of the selection window.



To create an account, enter your user data. Text fields can be selected and edited by touch. Enter your telephone number, including country code. This is required, if you want to receive status notifications from the autoclave via SMS. Enter a password of your choice with at least 4 characters twice. To cancel the registration, press the “Back”-button in the upper left corner of the screen. To complete the registration, press the “Register”-button.



To add an existing CertoCloud account, enter your e-mail address and password. Then press “Add Account”. To cancel the registration, press the “Back”-button in the upper left corner of the screen.

To create a CertoCloud account, enter your user data in the text fields provided.

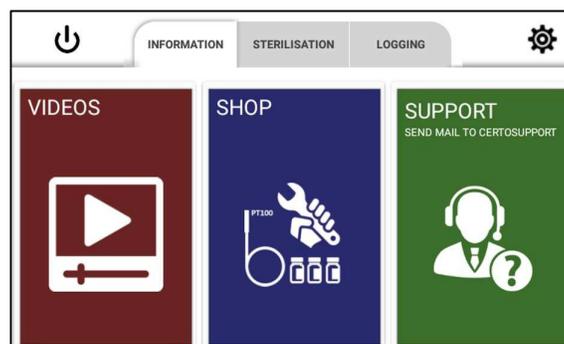
Please enter your mobile phone number including country code. To confirm your e-mail address and phone number, you will receive an email and an SMS. Enter the password of your choice twice and then press the “Register”-button.

To sign in to a recently created account, first select your e-mail address from the list and then enter your password. If you want to work with a user account with a server connection, make sure that online mode is activated. To activate the online mode, navigate to Settings->Device->Online Mode.

When you login to your CertoCloud account for the first time, you will be asked for an activation key. You will have received the activation key via SMS and e-mail after you created your CertoCloud account. Enter this key in the text box and press “Activate Account”. Now your CertoCloud account is activated and you can login with your CertoCloud account.

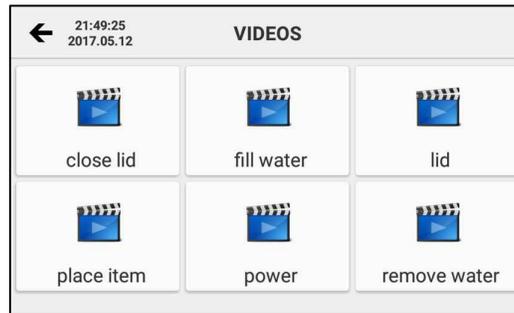
11.2 Support menu

Navigate to the “Information”-tab to display the Information menu. Here, it is possible to watch training videos, contact CertoSupport directly from the touch screen, or order spare parts, accessories or services for the autoclave.



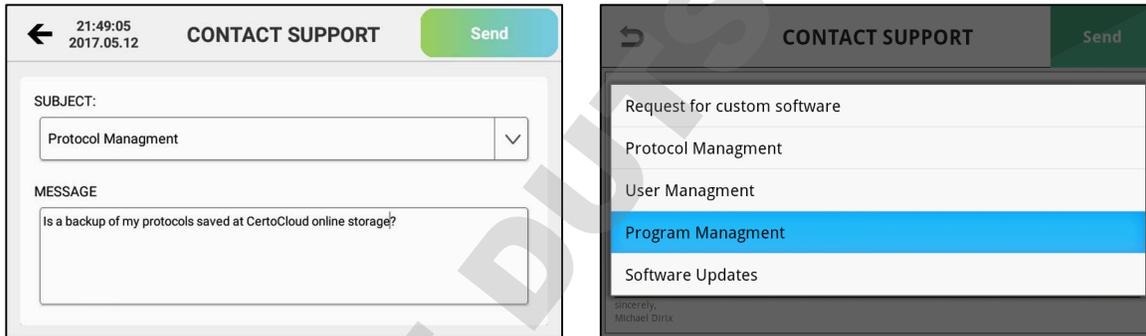
11.2.1 Tutorial videos

To scroll through the list of all available videos, press the “Video” section of the “Information”-tab. Select the desired video, to view it in full screen mode.



11.2.2 Send e-mail to CertoSupport

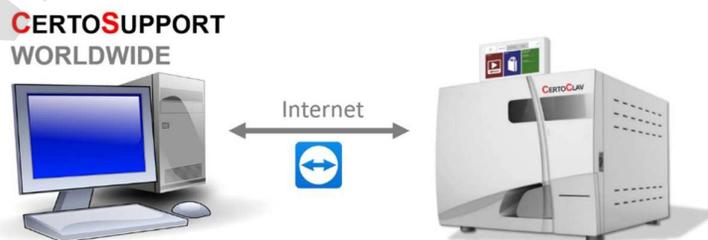
To send an e-mail to CertoSupport directly from the device, the device must be connected to the Internet. To connect the device to the Internet, you can plug a network cable into the Ethernet port or establish a wireless connection to your wireless router. Press the “SUPPORT”-button to open the e-mail window.



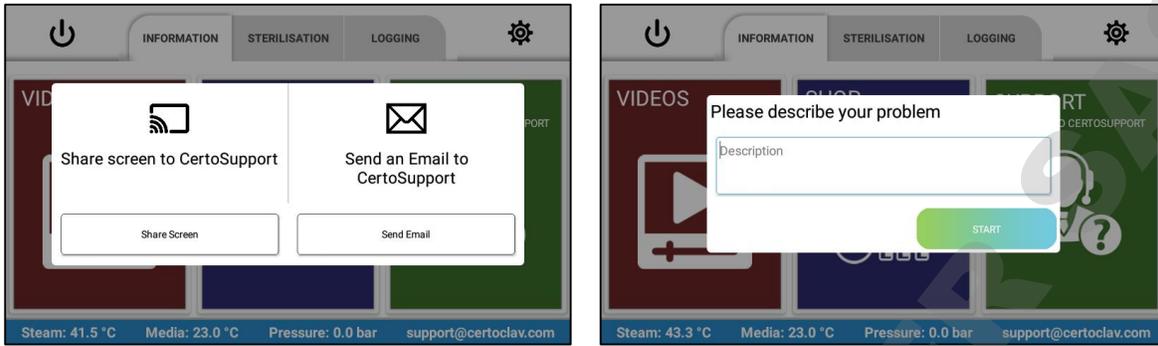
Select the subject of your message to CertoSupport from the drop-down menu. Then enter your message to CertoSupport in the message text field. To send the e-mail, press the “Send”-button.

11.2.3 TeamViewer remote support and screen sharing

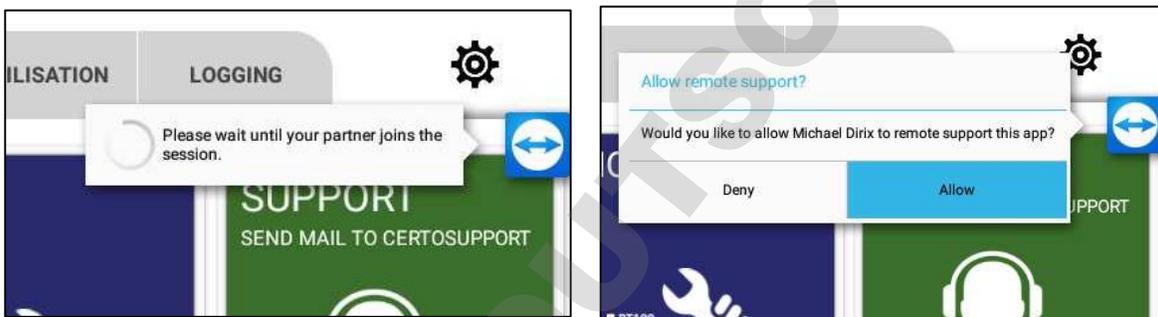
To split the screen with CertoSupport using TeamViewer, navigate to the “Information”-tab and press the “Support”-button. Remote support is only possible by making an appointment by e-mail or telephone beforehand.



As soon as you start a TeamViewer session, a window appears which gives you the opportunity to roughly describe the problem once more. Then press "Start".



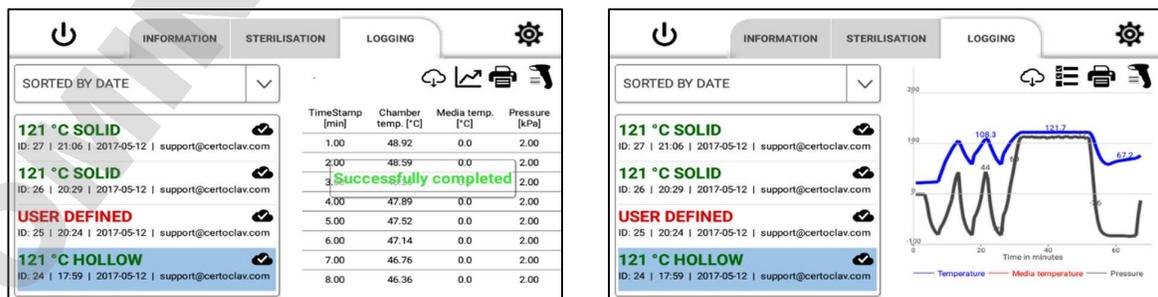
After you have pressed "Start", wait until CertoSupport has joined the TeamViewer Session. Once CertoSupport has joined the session, they will ask for your permission to share the screen. Press "Allow". Now the technician can access the menu of your device. To cancel the screen share, drag the "TeamViewer" icon to the "X" icon at the bottom of the screen.



11.3 Logging menu

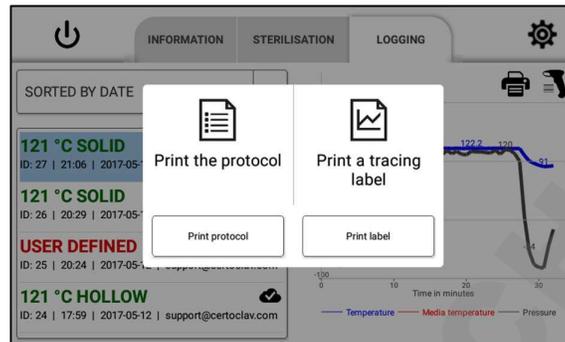
11.3.1 View logs

To view sterilization protocols, navigate to the "Logging"-tab. A list of all recorded protocols is displayed on the left side of the screen. The "Cloud" icon in the protocol list shows whether the protocols have been backed up to the CertoCloud or to your local CertoServer. Press the drop-down menu above the protocol list to sort the protocols by specific criteria. To view the details and a graphical view of a protocol, select it by touching the respective list entry. On the right side of the window, the graphical history of the protocol is now displayed. To display the protocol as a list, press the "List" icon above the graph.



11.3.2 Print out protocols

- 1) Make sure that a log printer is connected to the device.
- 2) Navigate to the “Logging”-tab.
- 3) On the left side of the screen, select the protocol you want to print.
- 4) Press the „Printer” icon in the upper right corner of the screen.
- 5) Select the “Print protocol” option.



11.3.3 Example print out

```

Header line 1
Header line 2
Header line 3

Protocol          CertoClav Vacuum Pro
Series
Model:           VAC-PRO-22L
S/N:             22ABCDEFGHJ
Program:         134 °C HOLLOW
Program description:
  3 x venting
  134 °C   2.1bar   30min
  Hollow instruments
  wrapped or unwrapped
Media:           NO
Cycle no:        971
Start time:      12.01.15 17:42:00
End time:        12.01.15 18:16:00
Result:          PASSED
hh:mm:ss        Temp °C   Press [bar]
17:42:00        27.5     1.00
17:42:20        27.5     0.50
17:42:40        27.6     0.18
17:43:00        80.4     0.80
[...]
18:15:00        65.9     0.18
18:15:20        65.4     0.18
18:15:40        68.0     0.50
18:16:00        70.2     1.00
Program finished successfully
END

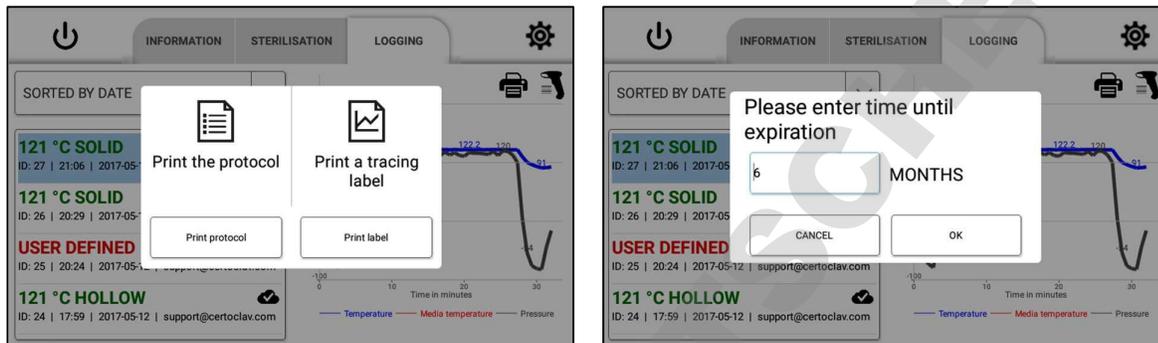
Signed by _____
Confirmed by _____

```

Optional

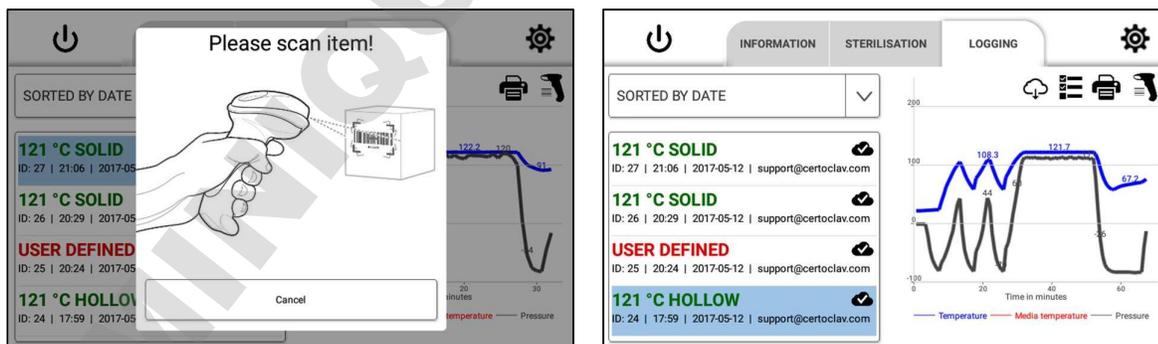
11.3.4 Tracing label printing

- 1) Make sure a label printer is connected to the machine.
- 2) Navigate to the “Logging”-tab.
- 3) Select the desired protocol on the left side of the screen.
- 4) Press the „Printer” icon in the upper right corner of the screen.
- 5) Select the "Print a tracing label" option.
- 6) Enter the shelf life of the sterilized products.
- 7) Press “OK” to print the self-adhesive label with expiry date and tracing barcode.



11.3.5 Tracing of marked products

- 1) Navigate to the Logging tab.
- 2) Press the “Scanner” icon, next to the “Printer” icon.
- 3) A dialog box appears. Now scan the barcode of the sterilized product using the barcode scanner.
- 4) The protocol of the sterilized product now appears on the screen. On the right side of the screen a graphical and list view of the protocol can be viewed.



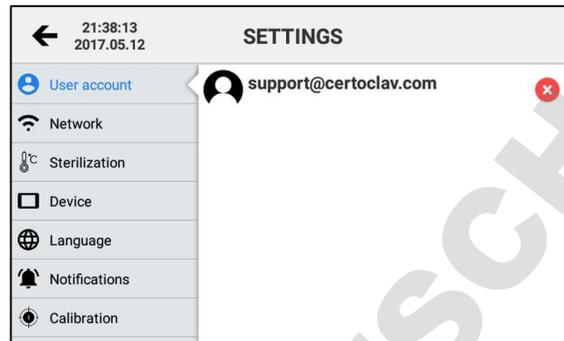
12 Settings

Press the  icon at the top right of the screen to enter the “Settings” menu.

The following settings can be adjusted here:

12.1 User administration

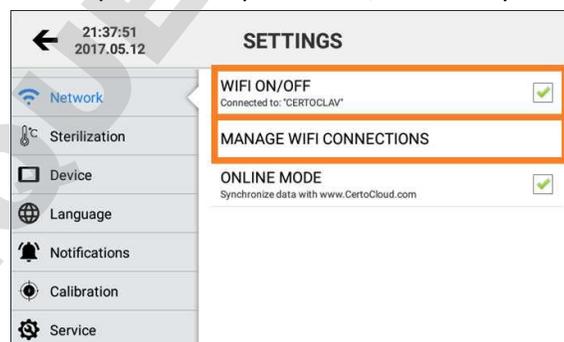
All registered users are now displayed on the right side of the window. Here you can change the user data and passwords via the “Edit”-button and remove a user account from the touch PC by pressing the “Delete”-button.



12.2 Network settings

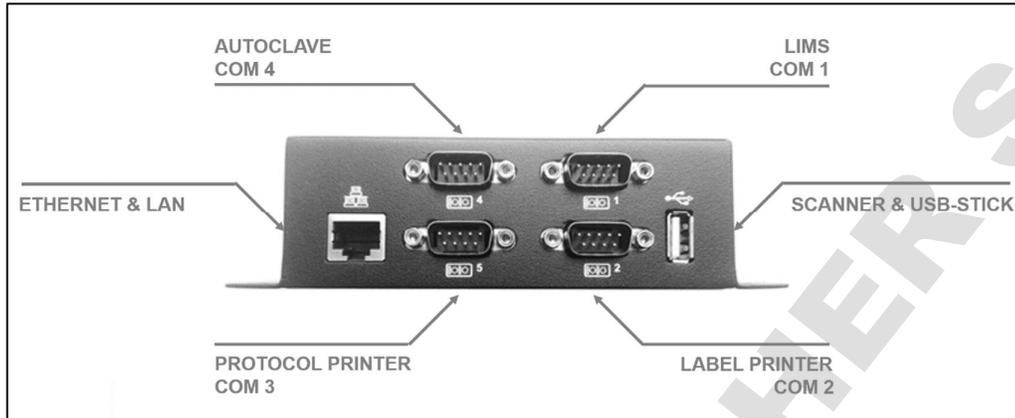
12.2.1 Connection to a Wi-Fi network

1. Click on the “Network”-button.
2. If the Wi-Fi checkbox is blank, select the empty checkbox to enable Wi-Fi.
3. Then press “Manage WLAN connections” to display a list of available WLAN networks. Select the relevant WLAN network and enter access keys and other parameters, if necessary.



12.2.2 Connection to a LAN network

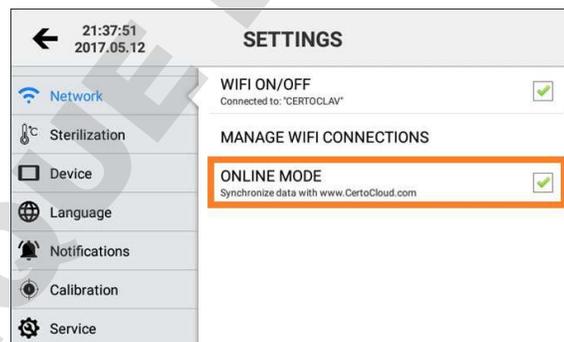
The autoclave can also be connected to a LAN network via ethernet cable. Connect the network cable to the ethernet port of the interface box.



12.2.3 Network communication

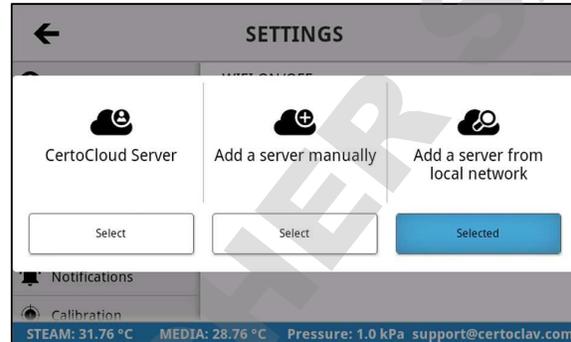
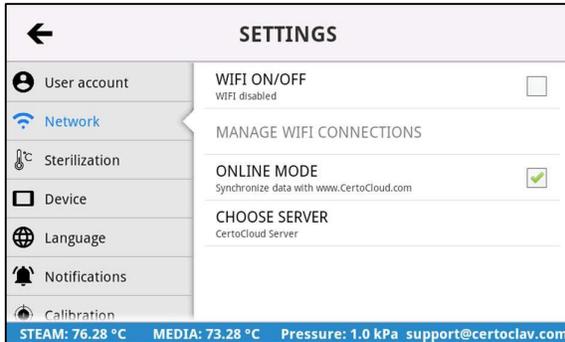
If the autoclave data is to be synchronized with the CertoCloud (www.certocloud.com) or the local CertoServer (<http://certocloud>), the online mode must be activated.

1. Select the “Network”-button on the left side of the settings window.
2. Click the “Online Mode” option to enable or disable data synchronization with CertoCloud. **Note:** If the online mode is deactivated, your protocols are only stored locally on the autoclave. As soon as you reactivate online mode, all protocols stored locally up to that point, are uploaded to CertoCloud and are available online in your backup storage.

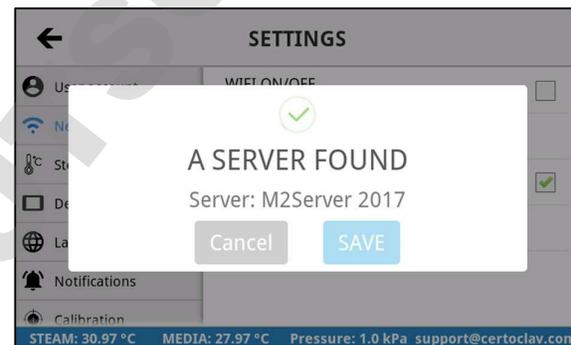
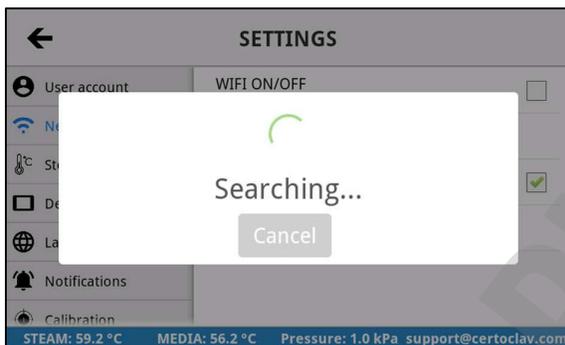


12.2.4 Connection of the autoclave with the local CertoServer

1. Connect the CertoServer to the interface box or the in-house network.
2. Connect the interface box to the same network as the CertoServer.
3. Navigate to: Settings->Network->Select server.
4. Select the option "Add server from local network".



5. The autoclave searches for the CertoServer in the local network.



6. After the CertoServer has been found, confirm with the "Save"-button.

12.3 Sterilization settings

12.3.1 Real-time logging on USB thumb drive

You can use a USB thumb drive to save the sterilization protocols in real time during sterilization. Please connect a USB thumb drive to the front USB port of the autoclave.



12.3.2 Step-by-step assistant

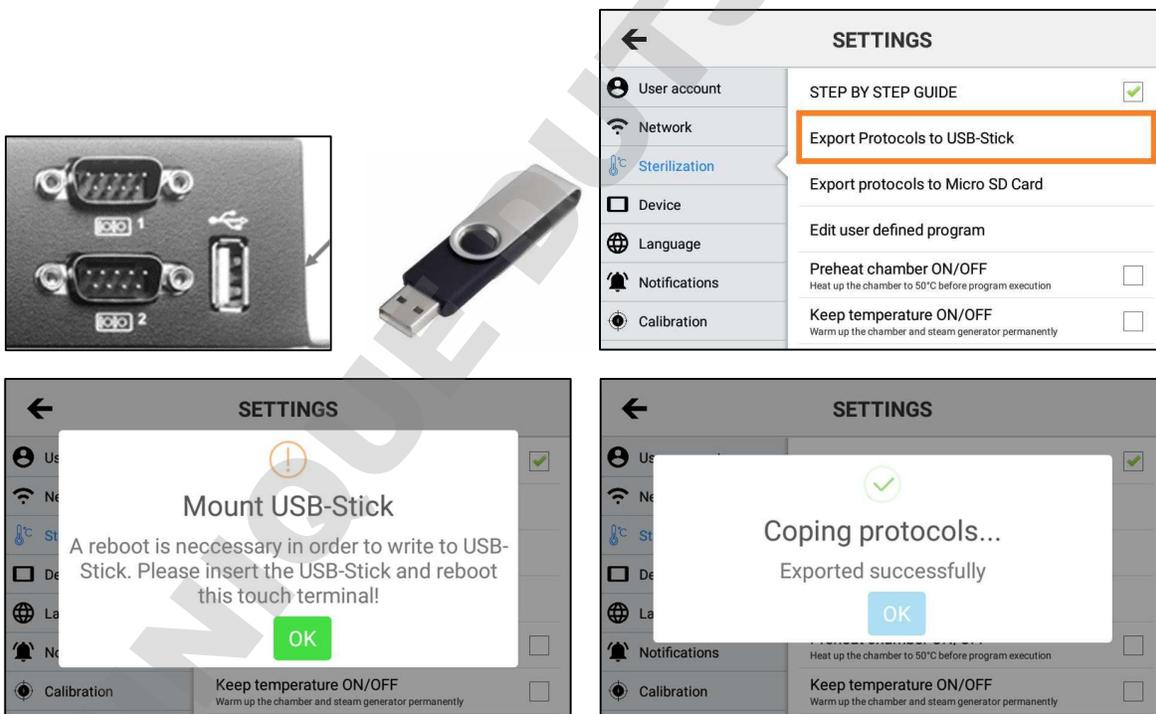
1. Enable or disable the step-by-step assistant by clicking the checkbox



12.3.3 Export all protocols to USB thumb drive

The touch PC can store around 1000 protocols in its internal memory. To export all protocols to a USB thumb drive, insert a USB thumb drive into the interface box.

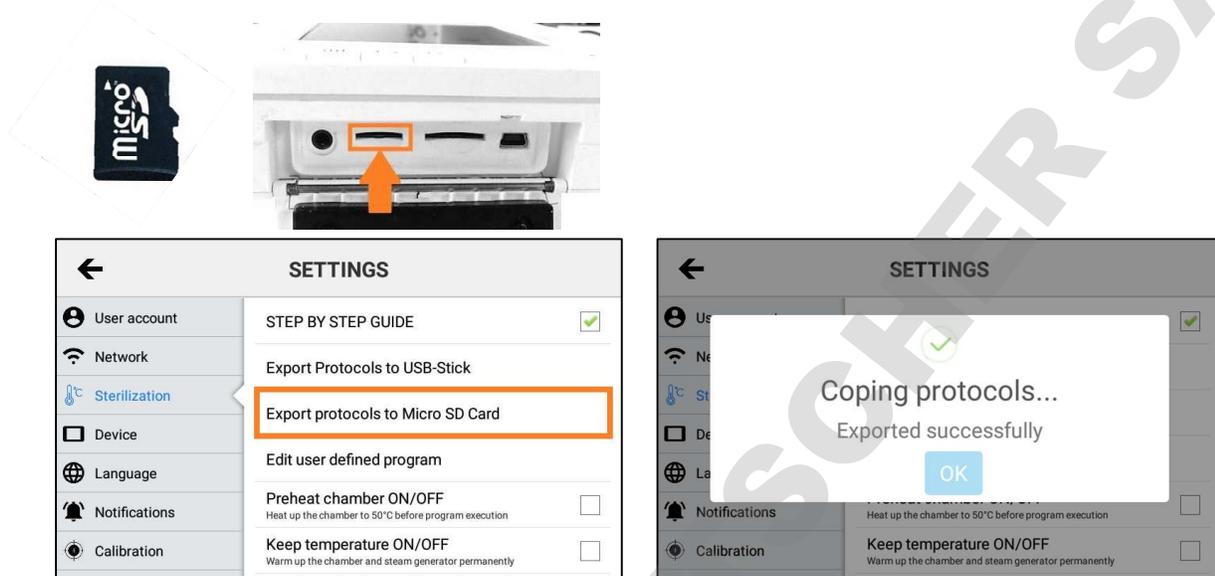
Navigate to Settings->Sterilization->Export protocols to USB thumb drive.



If the protocol export fails, your USB thumb drive is not being recognized immediately. In this case, leave the USB thumb drive plugged into the device and restart the touch screen. Now try to export the protocols again.

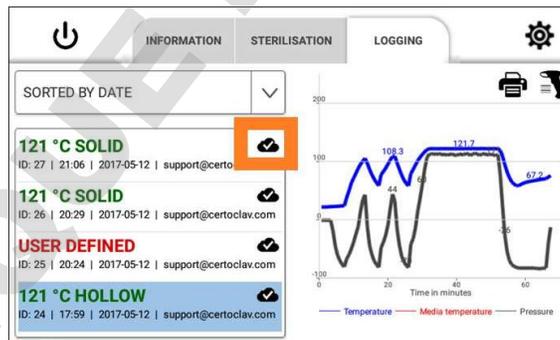
12.3.4 Export all protocols to SD card

1. Insert a micro-SD card into the hinged slot on the right side of the touch screen.
2. Click "Export all protocols to micro-SD card".
3. If the export of the protocols fails, restart the touch screen with the SD card inserted. Now try to export the protocols again.



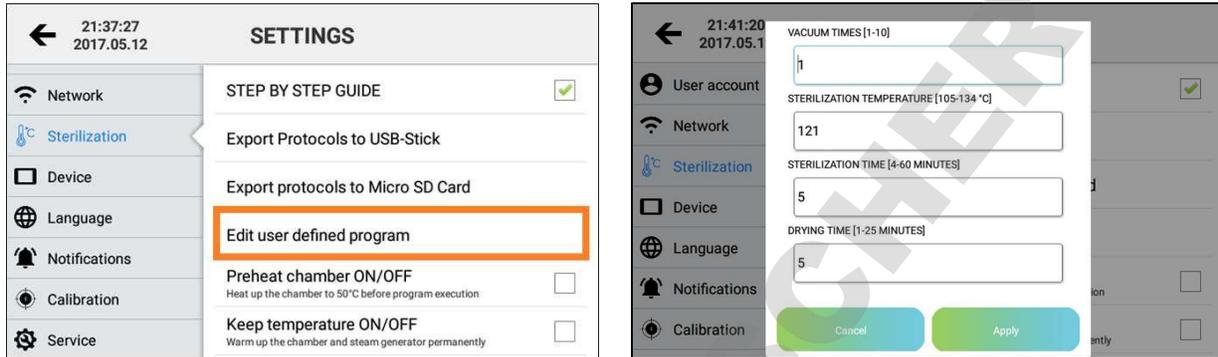
12.3.5 Export all protocols via network

2. Log into the autoclave with your CertoCloud or CertoServer account. Make sure that the online mode is activated. If the login is successful, all logs are uploaded to CertoCloud. The export was successful, if the cloud icon is displayed with a check mark.



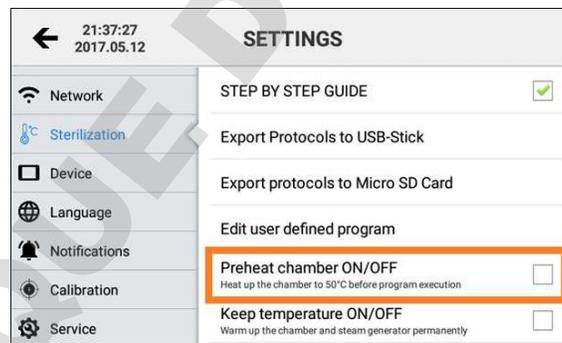
12.3.6 Changing a custom program

1. A window opens for editing the program parameters of the customizable program.
2. Specify the number of pre-vacuum phases between 1 and 10.
3. Specify a sterilization temperature between 105 °C and 134 °C.
4. Specify a sterilization time between 4 and 60 minutes.
5. Specify a drying time between 1 and 25 minutes.
6. Click “Apply” to save the program parameters or “Cancel” to return to the settings menu and cancel the operation.



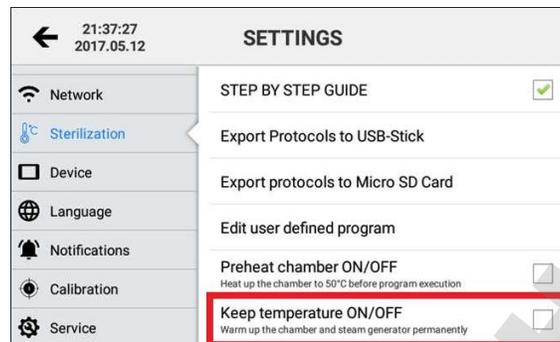
12.3.7 Switch preheating on or off

It is recommended to heat the chamber to 50 °C prior to the vacuum phase of the sterilization program. To activate this function, navigate to Settings->Sterilization->Chamber “Preheat ON/OFF” and activate the check box.



12.3.8 Permanently switch preheating on or off

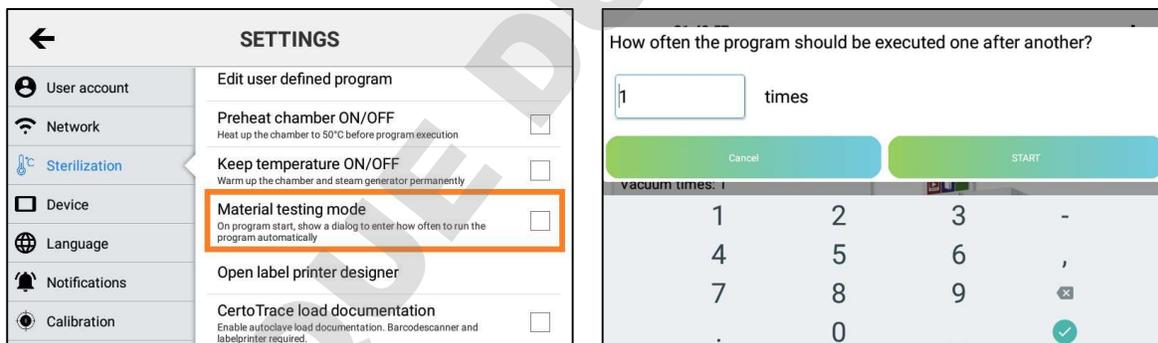
You can also keep the sterilization chamber in stand-by mode at 50 °C operating temperature for a maximum of 6 hours, to optimize the batch time. To enable this function, navigate to Settings->Sterilization->Hold temperature ON/OFF and select the checkbox. After the maximum time has expired, the heating switches off automatically. To reactivate the function, you must restart the device. The setting remains stored in the menu.



12.3.9 Material test mode – Automatically repeated start

To enable or disable the material test mode, navigate to the checkbox under Settings->Sterilization->Material Test Mode.

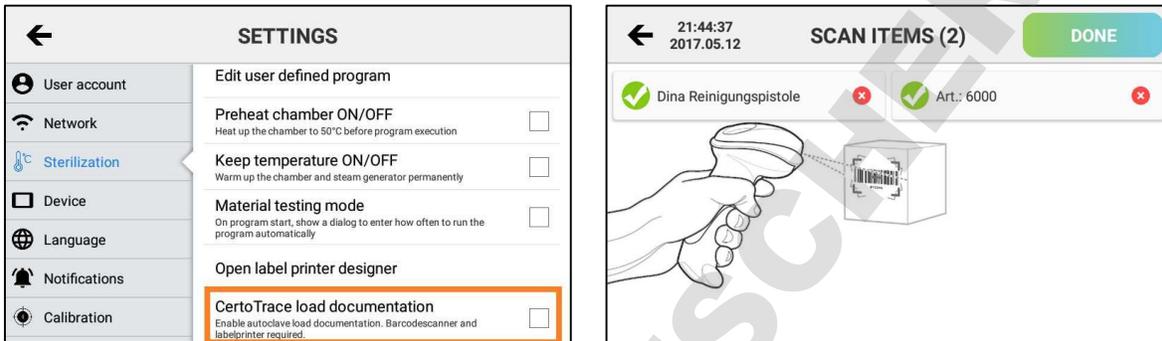
If the material test mode is activated, before starting a program for the first time, you will be asked how often it should be executed. This has the advantage that longer material tests can be performed fully automatically.



12.3.10 CertoTrace documentation solution

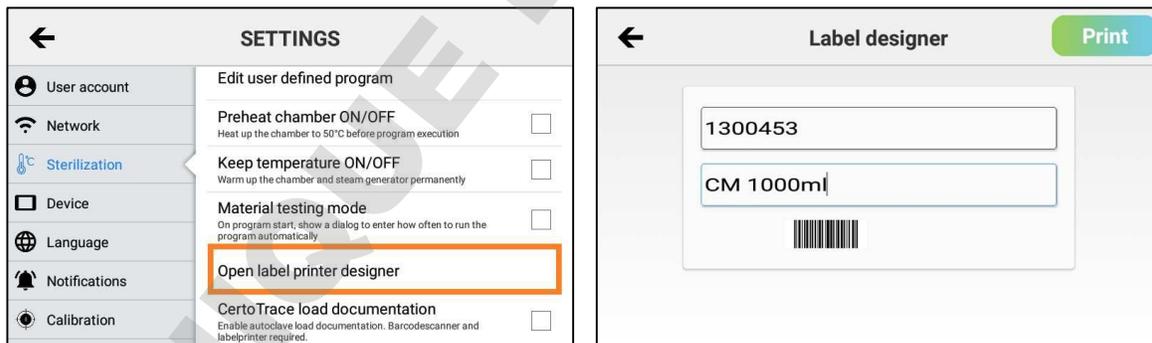
CertoTrace is the software for simple and professional documentation of the entire sterilization process. CertoTrace records which products were sterilized, by whom and when. Traceability of sterilized products and management of expiry dates is already integrated into the workflow. The CertoClav label printer prints expiry dates and a barcode for product traceability on self-adhesive labels.

To activate CertoTrace, navigate to Settings->Sterilization->CertoTrace load documentation. Check the box to activate CertoTrace. After activation, CertoTrace is automatically integrated into the workflow when a program is started.



12.3.11 Label designer

To mark items with barcodes, you can use the integrated label designer. The label designer can be opened under Settings->Sterilization->Label Designer.



12.4 System settings

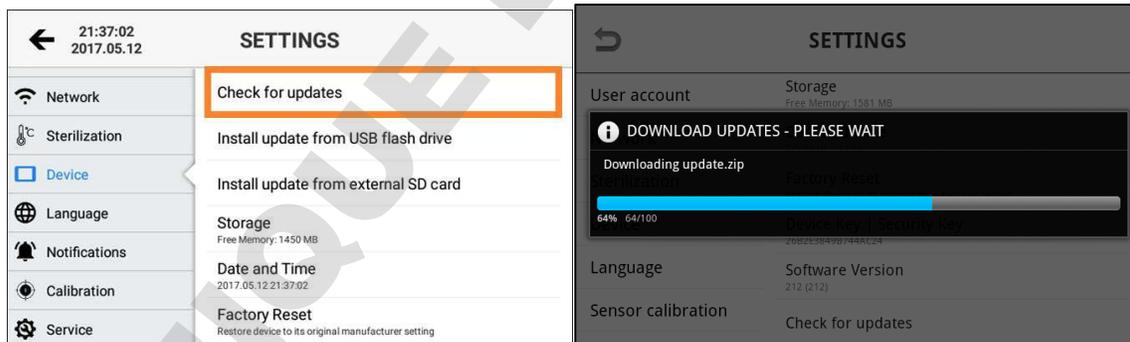
12.4.1 Change date and time

To change the autoclave's date and time, use the autoclave's built-in blue front LCD screen. Under ADV->DATE/TIME the real-time clock of the autoclave can be changed. For navigation use the "OK", "UP" and "DOWN" buttons.



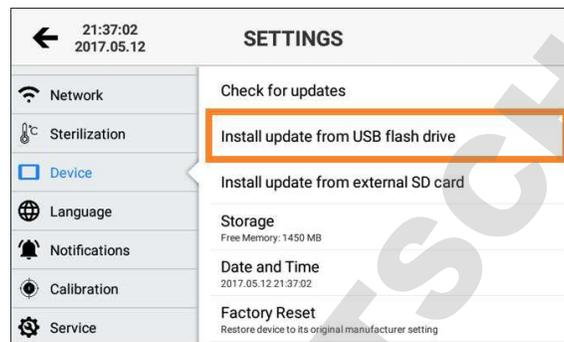
12.4.2 Install updates via the internet

1. Make sure the autoclave is connected to the Internet.
2. Click on the "Device" button.
3. In the details view on the right side, select "Check for updates".
4. A progress bar appears with the available download. Once all updates have been downloaded, they are installed automatically. If a new software version is available, an installation wizard will guide you through the installation process.



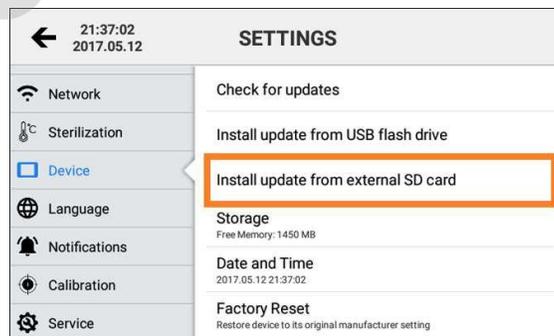
12.4.3 Install updates via USB thumb drive

1. Download the latest update from www.certoclav.com or ask for the latest update for your device by sending an e-mail to support@certoclav.com. Please inform the support team of the serial number of the autoclave. The serial number can be found on the type plate of the autoclave or under Settings->Device->Serial number. Copy the "update.zip" to the root directory of a USB thumb drive and insert this USB thumb drive into the interface box.
2. Click on the "Device" button.
3. In the detailed view on the right-hand side, scroll down and select the option "Installation of updates via USB thumb drive".
4. If the USB thumb drive is not recognized, restart the touch screen and try again.
5. Follow the instructions on the screen to install the respective updates.



12.4.4 Install updates via SD card

1. Download the latest update from www.certoclav.com or ask for the latest update for your device by sending an e-mail to support@certoclav.com. Please inform the support team of the serial number of the autoclave. The serial number can be found on the type plate of the autoclave or under Settings->Device->Serial number. Copy the "update.zip" to the root directory of a micro-SD card and insert this SD card into the slot on the right side of the touch screen.
2. Click on the "Device" button.
3. In the detailed view on the right-hand side, scroll down and select "Install updates via SD card".
4. If the SD card is not recognized, restart the touchscreen and try again.
5. Follow the instructions on the screen to install the respective updates.



12.4.5 Restore factory settings

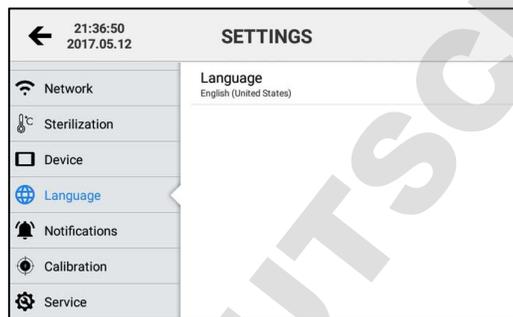


When you reset the touch screen to factory defaults, all protocols and user accounts not previously exported and/ or synchronized with CertoCloud are permanently deleted.

1. Click on the “Device” button.
2. In the detailed view on the right side, scroll to the “Restore Factory Defaults option” and select it.
3. The touch PC has been reset. All saved user accounts and protocols have been deleted.

12.4.6 Change language

1. In the settings menu, open the language menu by clicking on the “Language” button.
2. Select “Language” in the detailed view on the right side of the screen.
3. You will see a scrollable list of supported languages. Select a language by clicking on the desired language.



12.5 Configuration of SMS and e-mail notifications

If you do not have a CertoCloud account, you can create a new CertoCloud account via the login window. Note: To create a CertoCloud account, the autoclave must be connected to the Internet. Log in with your CertoCloud account.

Navigate to  Settings->Notifications to configure SMS and e-mail notifications.

If you would like to receive an e-mail when a program has been terminated, maintenance is required, or a program has been successfully completed, then activate the corresponding e-mail checkbox. Enter the e-mail address of your choice, which should receive the notification. If you have a CertoCloud Premium account, you can also enter a mobile phone number to receive an SMS notification. Notifications via SMS are only possible with the CertoCloud Premium account. Contact your dealer, if you are interested in an upgrade.

Finally, click “Save” to save the changes.

12.6 GLP and GMP data

Navigate to  Settings->GLP and GMP Data to view the GLP and GMP settings.

12.6.1 Header

If this setting is activated, the header is displayed and printed at the head of each sterilization protocol. Up to four lines of text are available.

12.6.2 Autoclave designation

Set a name for the device in this setting. An alphanumeric text can be entered. The default name is empty.

12.6.3 Project name

Click the “Project Name” button to enter a project name. An alphanumeric text of up to 25 characters can be entered. The default name is empty.

12.6.4 Advanced GLP and GMP settings

Select the following checkboxes in the advanced GLP and GMP settings to configurate the printout and digital copy of the sterilization protocols.

| Setting | Option (default value is marked bold) |
|-------------------------------|---------------------------------------|
| Print Autoclave Designation | YES , NO |
| Print User Identification | YES , NO |
| Print Project Name | YES , NO |
| Print Application Name | YES , NO |
| Print Signature Fields | YES , NO |
| Print Header | YES , NO |
| Print Date | YES , NO |
| Print Autoclave Serial Number | YES , NO |

12.7 Lock settings

To prevent unauthorized changes to the sensor parameters, programs and settings on the device, settings can only be changed when logged into the administrator account, which is password-protected.

13 Error messages

If an error occurs during a program cycle, the autoclave sounds an acoustic alarm and displays an error code on the screen. In addition, the autoclave automatically releases the pressure from the chamber and automatically switches off the heating. This security system ensures the safety of the users. If an alarm occurs, please write down the error code. Do not open the door until the autoclave has cooled down and is depressurized. Only then can the chamber be opened.

| | |
|---|---|
|  | We recommend starting the program again, to see if the error occurs repeatedly. |
|---|---|

Each of the following error messages is accompanied by a long, recurrent beep.

| Code | Status | Possible cause | Troubleshooting |
|------|---|---|--|
| E -1 | The program was terminated manually by the user. | User pressed the "STOP" button during sterilization. | - |
| E -2 | The communication between external touch screen and mainboard is interrupted. | The serial cable (COM 4) between touch screen and autoclave has loosened. | Check the cable connection between autoclave and touch PC. Otherwise restart the device and the touch PC. If the problem persists, navigate to Settings->Device-> Factory Reset to reset the touch PC to the factory settings. |
| E +2 | The sterilization pressure was exceeded by more than 40kPa. | The vacuum pump is defective. | Check the vacuum pump and then perform a vacuum test. |
| E31 | The temperature of the chamber is higher than 150 °C. | The steam generator sensor is defective. | Check, whether the temperature sensor (PT1000) in the chamber is properly inserted. If necessary, replace the temperature sensor. |
| E32 | The temperature of the chamber heating is higher than 280 °C. | The steam generator sensor is defective. | Check, whether the temperature sensor (PT1000) of the chamber heater is properly inserted. If necessary, replace the temperature sensor. |
| E51 | The temperature in the chamber is less than 0 °C. | The steam generator sensor is defective or the temperature in the chamber is too low. | Check, whether the chamber temperature is above 0 °C. Check that the temperature sensor (PT1000) in the chamber is properly inserted. If necessary, replace the temperature sensor. |

| Code | Status | Possible cause | Troubleshooting |
|------|---|--|---|
| E52 | The temperature of the chamber heating is less than 0 °C. | The steam generator sensor is defective or the temperature in the chamber is too low. | Check, whether the chamber temperature is above 0 °C. Check that the temperature sensor (PT1000) in the chamber is properly inserted. If necessary, replace the temperature sensor. |
| E63 | The temperature of the steam generator is less than 0 °C. The temperature of the steam generator is higher than 230 °C. | The steam generator temperature sensor is defective. Steam generator temperature is higher than 230 °C. Steam temperature control is unstable, causing steam generator temperature to become hotter than 230 °C. | Check, whether the steam generator temperature sensor is properly installed. Check steam generator temperature sensor (PT1000). If necessary, replace the temperature sensor. |
| E61 | The temperature control is unstable. The control temperature inside the chamber was exceeded by 6 °C. | The chamber temperature sensor is defective. | Check, whether the temperature sensor (PT1000) is properly installed. If necessary, replace the temperature sensor. |
| E62 | The temperature of the chamber heating is higher than 155 °C. The temperature control is unstable. | The chamber temperature sensor is damaged. The mainboard is damaged. | Check, whether the chamber temperature sensor is properly inserted. Check the temperature sensor (PT1000). Check the mainboard. |
| E41 | During the preheating period, a chamber temperature of 100 °C was not reached after 8 minutes. | Chamber heating is damaged. | Check the chamber heating. Check the resistance of the heating element. Check the heating rod wiring. |
| E42 | During the preheating period, a chamber temperature of 110 °C was not reached after 8 minutes. | Chamber heating is damaged. | Check the chamber heating. Check the resistance of the heating element. Check the heating rod wiring. |
| E5 | During the venting phase, the pressure in the chamber is still greater than 0.5 bar after 10 minutes. | Solenoid valve is blocked. | Check the water drain valve. Clean or replace if necessary. |

| Code | Status | Possible cause | Troubleshooting |
|------|--|--|--|
| E6 | The door was opened during operation or the door sensor is damaged. | Door sensor is damaged. | Check the door sensor and micro-switch. |
| E7 | The measured absolute atmospheric pressure is less than 70kPa. | Incorrect air pressure. The measured absolute atmospheric air pressure is too low for this location and must be corrected. | Pressure sensor calibration. See chapter 7.5. |
| E8 | In the pre-vacuum phase, the temperature in the chamber rises by less than 3 °C within 5 minutes. | No water in the tank or air escapes from the chamber. | Check the water level in the fish water tank. Check the chamber heater and the mainboard. |
| E9 | During the holding phase during sterilization, the measured pressure deviates by 0.3 bar from the intended pressure. | No water in the tank. Steam generator heating defective or water pump defective. | Check the steam generator heating, water pump and water level. |
| E10 | The electronic interlock has the wrong end position. | Electronic interlock defective. Mainboard defective. | Check the electronic interlock and the mainboard. |
| E11 | The electronic interlock has the wrong end position. | Electronic interlock defective. Mainboard defective. | Check the electronic interlock and the mainboard. |
| E12 | The vacuum in the sterilization chamber dose not reaches less than -70kPa twice in a row with a program that has at least 3 vacuum phases. | Vacuum pump defective, fan defective. | Check the vacuum pump and fan. |
| E99 | The communication between front display and mainboard is interrupted. | Ribbon cable not connected. CPU IC has loosened. | Check the flat ribbon cable and the connection plugs between front board and main board. Check whether the microcontroller IC on the mainboard is still firmly in the socket. |

14 Maintenance

| | |
|---|--|
|  | Make sure the autoclave is disconnected from the power supply during maintenance and repair. Make sure the autoclave is at room temperature. |
|---|--|

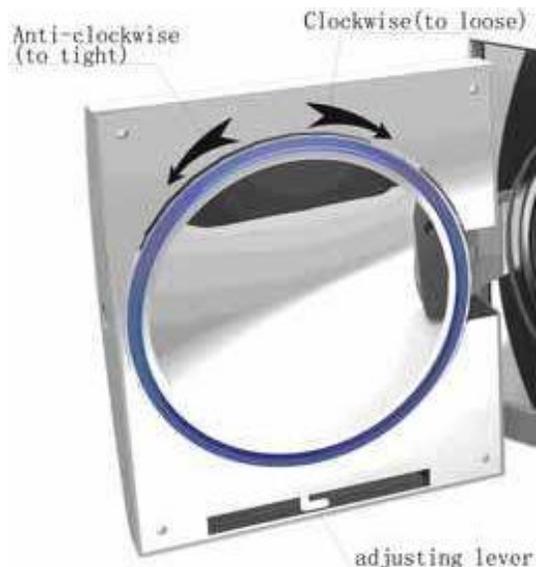
The following parts must be checked or replaced regularly:

- Bacteria filter
- Sealing ring
- Safety valve

| Component | Verification by | Cycle | Maintenance |
|---------------|-----------------|-------------|--|
| Door | Trained staff | 2 years | See service instructions or chapter <i>Adjusting door contact pressure</i> (14.1.) |
| Sealing ring | User | 1 year | See service instructions or chapters <i>Cleaning/Replacing the door seal</i> (14.2. & 14.3.) |
| Printer paper | User | As required | See the operating instructions of the printer. |
| Safety valve | Trained staff | 1 year | See service instructions or chapter <i>Replacing the safety valve</i> (14.4.) |

14.1 Adjusting door closing pressure

1. Pull the rotation lock lever down and hold the lever in this position (see figure).
2. Turn the round door counterclockwise to reduce the distance between the sterilization chamber and the door. As a result, the door is closer to the chamber and the contact pressure of the door is increased.
3. Turn the round door clockwise to reduce the tightness between the door and the sterilization chamber. Consequently, the door can be closed with less force.
4. Activate the rotation lock by continuing to rotate the door until it locks by itself.



| | |
|---|--|
|  | Start a vacuum test after each door adjustment. If the test is negative, the door should be readjusted. |
|  | If the door is too loose, it is possible that the door seal will be pushed out of its socket with a loud bang. Please make sure that the door is not too loose by performing a test run with the SOLID 134 °C program. |

14.2 Cleaning the door seal

The door seal should be cleaned regularly. Please use distilled water to clean the sealing ring. If water leaks still occur after cleaning, the door contact pressure must be adjusted, or the door seal must be replaced.

14.3 Replacing the door seal

1. Hold the ring seal with one hand and use your other hand to carefully lever the ring seal out of its duct with a screwdriver. Then slowly pull on the seal to remove it completely.
2. After removing the ring seal, clean the door with distilled water.
3. Before installation, also clean the new seal with distilled water and reattach it to the door.



14.4 Replacing the safety valve



The safety valve must only be replaced by trained personnel.

1. Check the safety valve regularly for visual defects. If a flaw or defect is found, the safety valve must be replaced.
2. Remove the pipe clamp (part 1 in the illustration). Then remove the hose to which the safety valve is connected.
3. Remove the nut on the hose attachment (part 2 in the illustration).
4. Remove the safety valve and replace it with a new one.



Please use only original spare parts from the manufacturer. Please contact your dealer if you have questions regarding maintenance and repair.

15 Transport and storage

15.1 Preparations

Allow the autoclave to cool down and remove the power plug from the socket.

15.2 Emptying the water tanks

Please empty all internal water tanks by connecting the QuickConnect hose to the fresh water drain and to the wastewater drain and drain the water.



15.3 Storage conditions

The autoclave should be stored at a room temperature between 5 °C and 40 °C maximum. The relative humidity must not be higher than 80%. Make sure that the storage area is well ventilated and does not contain any corrosive gases.



Do not drop the autoclave during transport.

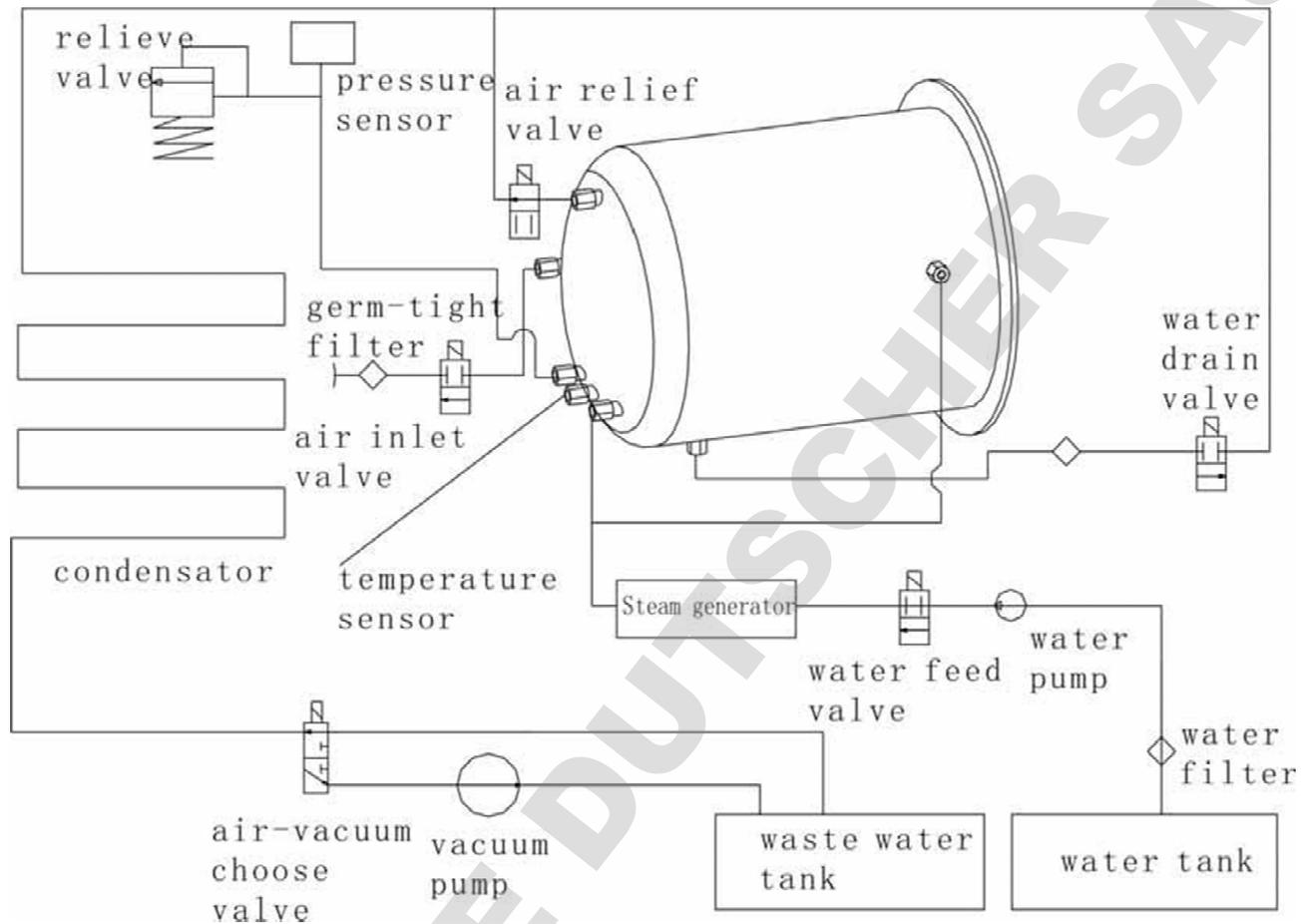
16 Warranty

Guarantee: **2 years**. The entitlement to free service is forfeited if any of the following situations arise:

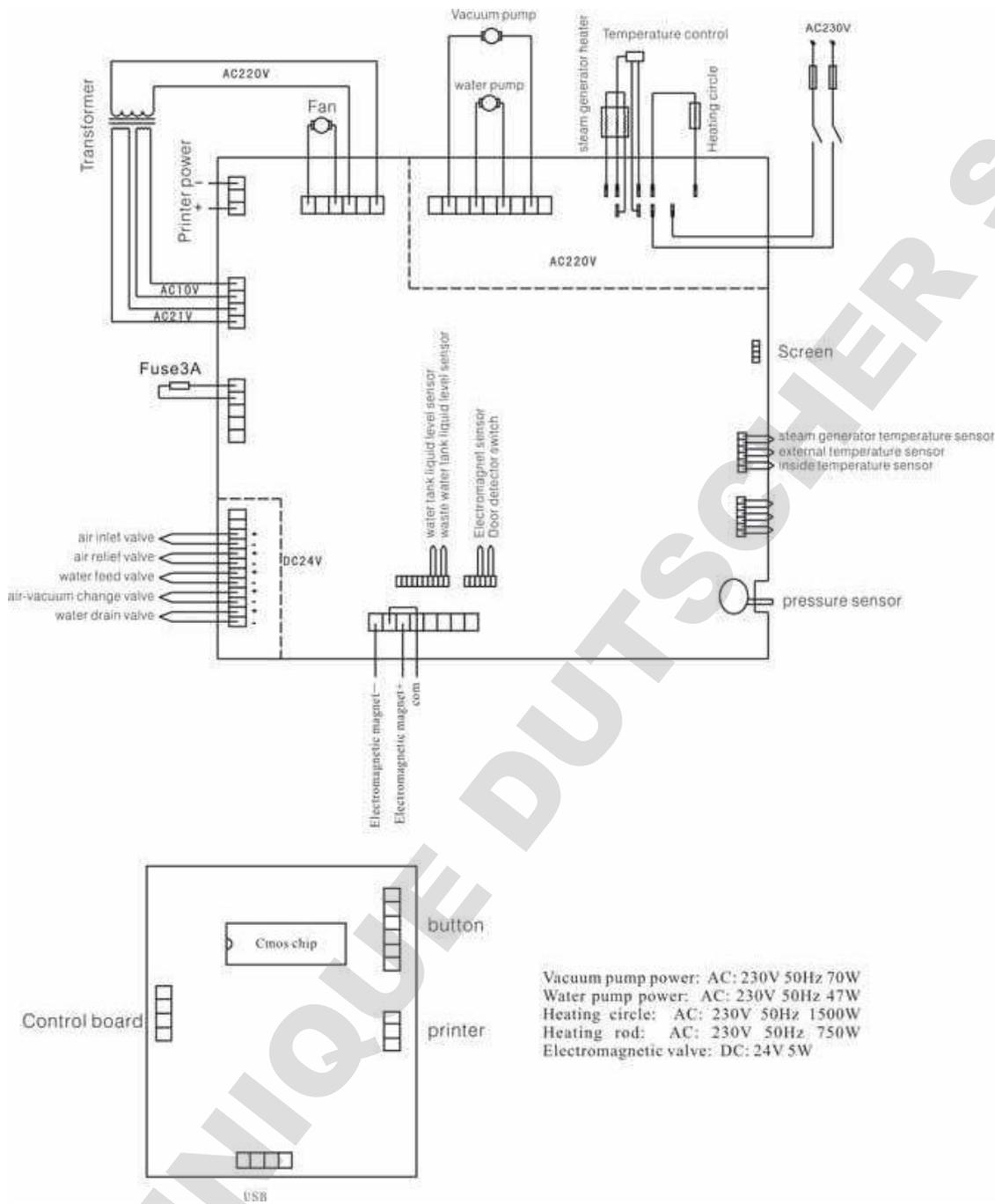
- The damage was caused by incorrect installation and/or operation.
- The damage was caused by negligent behavior.
- The damage was caused by force majeure such as inadmissible supply voltage or fire.

17 Appendix

17.1 Appendix 1: Structure diagram



17.2 Appendix 2: Electronic schematic



17.3 Appendix 3: EMV

Electromagnetische Emissionen

The Steam sterilizer is intended for use in the electromagnetic environment specified below. The customer or the user of the Steam sterilizer should assure that it is used in such an environment

| Emissions test | Compliance | Electromagnetic environment – guidance |
|---|------------|--|
| RF emissions CISPR 11 | Group 1 | The Steam sterilizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Vacuum | The Steam sterilizer is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

Electromagnetic immunity

The Steam sterilizer is intended for use in the electromagnetic environment specified below. The customer or the user of the Steam sterilizer should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|--|--|--|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | 6 kV contact 8 kV air | 6 kV contact 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | 2 kV for power supply lines 1 kV for input/output lines | 2 kV for power supply lines 1 kV for input/output lines | |
| Surge IEC 61000-4-5 | 1 kV line(s) to line(s) 2 kV line(s) to earth | 1 kV line(s) to line(s) 2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Interruptions and voltage variations in power supply input lines | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Steam sterilizer requires continued operation during power |

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|--|--|--|---|
| IEC 61000-4-11 | (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec | (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec | mains interruptions, it is recommended that the Steam sterilizer be powered by an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

Electromagnetic immunity

The Steam sterilizer is intended for use in the electromagnetic environment specified below. The customer or the user of the Steam sterilizer should ensure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|-----------------------------------|---------------------------------|--|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms 150 kHz to 80 MHz 3 Vrms 3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Steam sterilizer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2,5 GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level for each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 80 MHz to 2.5 GHz 3 V/m | |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Steam sterilizer is used exceeds the applicable RF compliance level above, the Steam sterilizer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Steam sterilizer. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

Portable and mobile RF communications equipment and the Steam sterilizer

The Steam sterilizer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Steam sterilizer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Steam sterilizer as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter | Separation distance according to frequency of transmitter | | |
|---|---|-------------------|--------------------|
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.5 GHz |
| W | $d = 1.2$ | $d = 1.2$ | $d = 2.3$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

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