

Instruction Manual CertoClav Vacuum Pro 45

Steam Steriliser Model STE-45-T



Dear customer,

Thank you for the trust you have placed in us by purchasing this autoclave.

CertoClav, a medium-sized family company, has specialised in the manufacture of tabletop autoclaves for more than 60 years.

This autoclave has been manufactured and tested according to strict requirements. However, please read through this instruction manual carefully.

The long-lasting functionality and value retention of your autoclave depend primarily on the maintenance of the device.

Instruction Manual CertoClav Vacuum Pro 45

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| 1 | Ge | neral Information | 6 |
|---|------|--|----|
| | 1.1 | Intended use | 6 |
| | 1.2 | Environmental protection | 6 |
| | 1.3 | Customer Service | 6 |
| | 1.4 | Ordering spare parts and special accessories | 7 |
| | 1.5 | Guarantee | 7 |
| 2 | Me | eaning of the Symbols on the Autoclave | 8 |
| 3 | Sa | fety Information | 9 |
| 4 | No | n-autoclavable Substances | 10 |
| 5 | Init | tial Start-up | 11 |
| | 5.1 | Device description | 11 |
| | 5.2 | Device dimensions | 11 |
| | 5.3 | Scope of supply | 12 |
| | 5.4 | Before initial start-up | 12 |
| 6 | Ins | tallation | 13 |
| | 6.1 | Setting up the autoclave | 13 |
| | 6.2 | Unlocking the autoclave door | 14 |
| | 6.3 | Touchscreen assembly | 14 |
| | 6.4 | Installing accessories | 16 |
| | 6.4 | 1.1 Connecting the protocol printer | 16 |
| | 6.4 | 2. Connecting the barcode reader | 16 |
| | 6.4 | I.3 Connecting the label printer | 16 |
| | 6.4 | 1.4 Connecting the CertoServer | 17 |
| | 6.5 | Pressure sensor calibration | 17 |
| | 6.6 | Validation and calibration | 18 |
| 7 | Ste | erilisation Programs | 19 |
| | 7.1 | Default settings | 19 |
| | 7.2 | Editing program parameters | 20 |
| 8 | Ba | sic Operation | 21 |
| | 8.1 | Switching on the touchscreen | 21 |
| | 8.2 | Switching off the touchscreen | 21 |
| | 8.3 | Standby Mode for the touchscreen | 21 |
| 9 | Ins | tructions for Daily Use | 22 |
| | 9.1 | Preparations before use | 22 |
| | 9.2 | Replenishing with distilled water | 22 |
| | 9.3 | Opening the autoclave door | 23 |

| 9.4 Step | os to start a sterilisation process | 24 |
|-----------|--|----|
| 9.4.1 | Selecting the sterilisation program on the screen | 24 |
| 9.4.2 | CertoTrace – Documentation and load management | 25 |
| 9.4.3 | Step-by-step video assistant | 26 |
| 9.4.4 | Loading the autoclave | 26 |
| 9.4.5 | Closing the autoclave door | 26 |
| 9.4.6 | Material tests and automatic repetitions | 27 |
| 9.4.7 | Status screen | 27 |
| 9.5 Unio | bading the autoclave | 28 |
| 9.6 Emp | otying the used water tank | 29 |
| 9.7 PC | software | 29 |
| 9.7.1 | Functions of the CertoCloud | 30 |
| 9.7.2 | Display of sterilisation protocols via web browser | 31 |
| 10 Contro | ol Panel of the Autoclave | 32 |
| 10.1 Lo | ogin Menu | 32 |
| 10.2 S | upport Menu | 34 |
| 10.2.1 | Tutorial videos | 34 |
| 10.2.2 | Send email to CertoSupport | 35 |
| 10.2.3 | TeamViewer, remote support and share screen | 36 |
| 10.3 Pi | rotocols Menu | 38 |
| 10.3.1 | Viewing protocols | 38 |
| 10.3.2 | Printing protocols | 38 |
| 10.3.3 | Example of a protocol printout | 39 |
| 10.3.4 | Print barcode | 39 |
| 10.3.5 | Tracing marked products | 40 |
| 11 Settin | gs | 41 |
| 11.1 U | ser administration | 41 |
| 11.2 N | etwork settings | 41 |
| 11.2.1 | Connecting to a WLAN network | 41 |
| 11.2.2 | Connecting to a LAN network | 42 |
| 11.2.3 | Network communication | 42 |
| 11.2.4 | Connecting to the CertoServer | 43 |
| 11.2.5 | Connecting to the CertoCloud server | 44 |
| 11.3 St | erilisation settings | 45 |
| 11.3.1 | Customising sterilisation programs | 45 |
| 11.3.2 | Material tests and automatic repetitions | 45 |

| 11.3.3 | 3 CertoTrace — Your support during material tests | 47 |
|---------|---|----|
| 11.3.4 | Label designer | 47 |
| 11.3.5 | 5 Real-time protocolling to USB | 48 |
| 11.3.6 | Exporting all protocols to a USB | 48 |
| 11.3.7 | Z Exporting all protocols to an SD card | 49 |
| 11.3.8 | B Exporting all protocols via a network | 50 |
| 11.4 | System settings | 51 |
| 11.4.′ | Changing the date and time | 51 |
| 11.4.2 | 2 Installing updates via the Internet | 51 |
| 11.4.3 | 3 Installing updates via USB | 52 |
| 11.4.4 | Installing updates via SD card | 53 |
| 11.4.5 | 5 Restoring the default settings | 53 |
| 11.4.6 | 6 Changing the language | 54 |
| 11.5 | Configuration of SMS and email notifications | 54 |
| 11.6 | Sensor calibration | 55 |
| 11.7 | GLP and GMP data | 55 |
| 11.7.′ | Header | 55 |
| 11.7.2 | 2 Autoclave designation | 55 |
| 11.7.3 | 3 Project designation | 55 |
| 11.7.4 | Advanced GLP and GMP settings | 56 |
| 11.8 | Locking settings | 56 |
| 12 Erro | r Messages | 57 |
| 13 Mai | ntenance | 59 |
| 14 Trar | nsport and Storage | 60 |
| 14.1 | Preparations | 60 |
| 14.2 | Emptying the water containers | 60 |
| 14.3 | Transport conditions | 60 |
| 14.4 | Storage conditions | 60 |
| 15 Tec | hnical Data | 61 |
| 16 Арр | endix | 62 |
| 16.1 | Appendix 1: Structural diagram | 62 |
| 16.2 | Appendix 2: Circuit diagram | 63 |
| 16.3 | Appendix 3: CE Declaration of Conformity for Autoclave | 63 |
| 16.4 | Appendix 4: CE Declaration of Conformity for Safety Valve | 65 |

1 General Information

Dear customer,

Before putting your autoclave into operation for the first time, please read through this instruction manual and follow its information and instructions. Do not use another instruction manual.

This instruction manual applies only to the CertoClav Vacuum Pro Series autoclaves with model designation STE-45-T.

Keep this instruction manual within easy reach for later use or for subsequent owners.

1.1 Intended use

This autoclave is intended for laboratory use. For example for the sterilisation of liquids, solids, waste and textiles as well as swabs, glasses, petri dishes, porous materials, powder, hollow bodies and instruments. Containers sealed with compressed air must not be sterilised. This autoclave has not been developed for private use.

Operation and maintenance of the autoclave may only be performed by trained personnel.

Comply consistently with all safety regulations in this instruction manual.

1.2 Environmental protection

The packaging materials are recyclable. Please do not dispose of the packaging in domestic waste but instead hand it over for recycling.

Old devices contain valuable recyclable materials, which should undergo recycling. Please therefore dispose of old devices via suitable collection systems.

1.3 Customer Service

If you have any questions or problems regarding the autoclave, please contact your dealer or the manufacturer by email to support@certoclav.com.

1.4 Ordering spare parts and special accessories

Use original accessories only and original spare parts for maintenance, which are approved by the manufacturer, so as not to impair the safety of the device.

You can obtain spare parts and accessories from your dealer or from the manufacturer.

1.5 Guarantee

The guarantee is valid for 2 years. The claim to free service shall be nullified if one of the following conditions is not met:

- The damage has been caused by incorrect installation.
- The damage has been caused by negligent conduct.
- The damage has been caused by improper operation.
- The damage has been caused by force majeure such as fire.

2 Meaning of the Symbols on the Autoclave

3 Safety Information

Besides the information in this instruction manual, the general safety and accident prevention regulations of the legislation must be observed.

Please read carefully! To avoid personal injury, fire or damage to the autoclave, please pay attention to the following safety rules:

- ▲ Do not install the autoclave anywhere where the power supply cannot be disconnected quickly.
- \triangle Operate the autoclave with the supply voltage indicated on the type plate of the autoclave only.
- ▲ **DANGER** Use a socket with protective conductor and make sure that the protective conductor is well earthed.
- \triangle Do not touch the mains plug or socket with wet hands.
- \triangle Do not strain, bend or twist the cables. Do not place any heavy objects on the cables.
- \triangle Do not block the door of the autoclave.
- \triangle Do not cover the ventilation openings on the rear of the autoclave.
- ▲ If you notice any unusual odours or noises during operation, disconnect the autoclave immediately from the power supply and contact your dealer or the manufacturer by email to <u>support@certoclav.com</u>.
- ▲ **WARNING** If you do not operate the autoclave for a longer period, please disconnect it from the power supply and empty the internal water tank.
- \triangle Do not modify the device.
- \triangle The autoclave must not be installed anywhere where there is a risk of explosion.
- ▲ Do not autoclave containers sealed with compressed air, as these containers could implode or explode.
- \triangle Fill the water tank with distilled or demineralised water only.
- A Please fill the bottles and other containers with liquid to maximum half only.
- ▲ Only remove containers with liquids from the chamber as soon as a liquid temperature of less than 80 °C is measured. There is a risk of boiling retardation of the liquid.
- \triangle The autoclave must not be transported full.
- \triangle The autoclave must not be opened with force.

4 Non-autoclavable Substances

Never use the autoclave to sterilise the following materials or alkaline solutions. The sterilisation of such substances can cause an explosion, corrosion of the sterilisation chamber, pipes or wear to the seals.

Explosive substances

- Nitroglycol, nitroglycerin, 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

Combustible substances

- Metallic lithium, potassium, sodium, yellow phosphorous, phosphorous sulphide, red phosphorous
- Celluloids, calcium carbide (carbide), calcium phosphide, magnesium powder
- Aluminium powder, magnesium powder, metal powders apart from aluminium powder
- Sodium dithionite (or sodium hydrosulphite)

Oxidising agents

- 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

Flammable substances

- Ethyl ether, benzine, acetaldehyde, propylene oxide, carbon disulphide and other substances whose flashpoint is in the range from -30 to 0 °C
- Methanol, ethanol, xylene, benzyl acetate (or amyl acetate) and other substances whose flashpoint is between 0 and 30 °C
- Kerosene, gas oil, turpentine oil, isopentyl alcohol (or isoamyl alcohol), acetic acid and other substances whose flashpoint is between 30 and 65 °C
- Flammable gas (hydrogen, acetylene, ethylene, methane, ethane, propane, butane and other substances, which work at a temperature of 60 °C at an absolute pressure of 0.2 bar)

If a salty solution is spilled inside the chamber, remove all liquid from the chamber and wipe up the liquid around the door seal. Clean the door seal with distilled or demineralised water.

5 Initial Start-up

Check whether all parts are provided when unpacking. If any parts or missing or you discern transport damage during unpacking, please contact your dealer or the manufacturer immediately by email to support@certoclav.com.

5.1 Device description

This autoclave is an automatic steam steriliser with vacuum pump and steam generator. Depending on the program and setting, the sterilisation temperature is between 105 °C and 134 °C. Solid materials and liquids can be sterilised. The autoclave has a flexible media sensor in order to measure and control the temperature directly in the medium. The program parameters and sterilisation programs are displayed on the front LCD screen as well as the mobile touchscreen. If a problem is discerned during the sterilisation process, the autoclave automatically issues an error message. If the boiler pressure or boiler temperature are too high, the autoclave will automatically disconnect the power supply and thus guarantee the safety of the operator. The autoclave is equipped with an internal water tank for fresh and used water.

5.2 Device dimensions

5.3 Scope of supply

Standard scope of supply

- CertoClav Vacuum Pro 45
- Declaration of Conformity
- Instruction Manual
- 1 power cable for the autoclave
- 1 waste water hose
- 1 mobile touchscreen
- 1 power cable for the touchscreen
- 1 base for the touchscreen with four fastening screws
- 1 interface box for the touchscreen
- 1 data cable (2 m length)
- 1 tray set with 3 screws

Recommended accessories

| Product | Order number |
|--|--------------|
| CertoServer for automatic backups with browser-based interface | 8500508 |
| CertoCloud Premium licence for the online autoclave management platform www.certocloud.com | 8500212 |
| Baseplate for bottles | 8500404A |
| Wire basket including drip pan | 8500406 |
| Distillation device for water | 8500482 |
| Log printer | 1300187 |
| Thermal paper | 8500496 |
| Label printer | 8500502 |
| Barcode reader | 8500503 |
| Direct thermal labels | 8500507 |
| | |

5.4 Before initial start-up

| Unpacking the autoclave | This autoclave is delivered in a wooden crate. The metal tabs on the bottom of the crate can be opened with a large slotted screwdriver. After this the wooden crate can be raised and removed. | | | |
|----------------------------|---|--|--|--|
| Location | Install the autoclave in a dry location free of dust. The air humidity should be between $30 - 60$ % and the ambient temperature $5 - 26$ °C. Make sure that the table is suitable for the weight of the autoclave. | | | |
| Scope of supply | The touchscreen and remaining accessories are in the autoclave chamber when delivered. | | | |

6 Installation

6.1 Setting up the autoclave

If you wish to place the autoclave on a laboratory table, check whether the table is suitable for the weight of the autoclave.

For problem-free operation, the autoclave must be aligned by adjusting the device feet using spirit level in direction inclined backwards so that condensation can drain off in the drainage port at the rear end of the autoclave. The autoclave should be installed horizontally in a vertical direction.

Please leave at least 10 cm free space around the autoclave. Leave at least 20 cm free space at the ventilation slits on the right of the autoclave. Make sure that the room is well ventilated

Keep the specified distance to the surrounding areas. Failure to comply can lead to heat accumulation. This could impair the function of the autoclave and shorten the service life of the pressure pump and result in prolonged program times.

Connect the power cable to the device socket on the rear of the autoclave.

Note: Check whether the data on the type plate of the autoclave correspond to the data for the power source. Check whether the safety switch of the autoclave is in the upper position. Switch on the autoclave at the rocker switch.

6.2 Unlocking the autoclave door

The touchscreen and remaining accessories are in the autoclave chamber when delivered.

To open the autoclave door, please hold the UP arrow for about 3 seconds until you hear the electronic interlock humming. The door now opens the you ca remove the content and continue installation.

6.3 Touchscreen assembly

Mount the base with the four screws supplied on the touchscreen.

After assembling the base, the touchscreen should appear as shown in the figure opposite.

Connecting the touchscreen to the interface box.

Connecting the power cable of the touchscreen to the interface box.

Place the touchscreen on an even stable surface only. You can also place the watertight touchscreen on the autoclave or next to it.

Connect the autoclave to the RS232 cable at the COM4-port of the extension box to the RS232-port on the rear of the autoclave.

Switch on the touchscreen.

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

If a notification indicating a connection failure with the autoclave appears on the screen, the touchscreen and autoclave are not connected correctly. Check whether the autoclave is switched on and connected to the COM4-port of the interface box.

6.4 Installing accessories

Optionally available accessories.

6.4.1 Connecting the protocol printer

Connect the protocol printer (thermal or dot-matrix printer) to the COM1-port of the interface box. You can find the connecting cable in the box for the protocol printer. Follow the instructions in the protocol printer manual.

6.4.2 Connecting the barcode reader

Connect the barcode reader to the USB port of the interface box. You can find the connecting cable in the box for the barcode reader. Follow the instructions in the barcode reader manual.

6.4.3 Connecting the label printer

Connect the label printer to the COM2-port of the interface box. You can find the connecting cable in the box for the label printer. Follow the instructions in the label printer manual.

6.4.4 Connecting the CertoServer

If you do not have an Internet connection but wish to use the CertoCloud, we recommend connecting the local CertoServer to the autoclave.

6.5 Pressure sensor calibration

As the atmospheric pressure depends on the installation site, you should recalibrate the pressure sensor after changing the installation site.

Calibration method:

The autoclave is calibrated via the Service screen on the front of the autoclave. The Calibration Menu should only be operated by trained personnel. To access the Calibration Menu, hold down the UP and DOWN arrow keys simultaneously for 10 seconds while switching on the autoclave. To calibrate the pressure sensor to atmospheric pressure, open the door of the autoclave and confirm P-ZERO with the M button.

If the pressure sensor has not been calibrated properly after installing the autoclave, a situation may occur where the autoclave fails to start a program.

6.6 Validation and calibration

All sensors of the autoclave have been validated and calibrated at the factory. The autoclave has a G ¼ access on the side panel of the chamber for calibration purposes. We recommend using battery powered sensors such as those made by EBRO. If a calibration on site is necessary after installation, ask your dealer or contact the manufacturer directly by email. To obtain instructions for calibrating the autoclave, please ask your dealer for IQ/OQ documentation or send an email to support@certoclav.com.

The temperature sensors should be calibrated by trained technical personnel only.

To access the calibration menu, hold down the UP and DOWN arrow keys simultaneously for 10 seconds while switching on the autoclave. This menu lets you display and edit the current offset values of the chamber temperature probe, heating temperature probe, steam generator temperature probe or media temperature probe.

7 Sterilisation Programs

7.1 Default settings

| Program | Vacuu m phases | Sterilisation time [min] | Sterilisation temperature [°C] | Sterilisation pressure [kPa] | Vacuum retention time [min] | Drying time [min] |
|---------------|----------------------|--------------------------|--------------------------------------|------------------------------------|-----------------------------------|----------------------|
| 134°C SOLID | 1 | 4 | 134 | 210 | - | 5 |
| VACUUM TEST | 1 | - | - | -75 | 10 | 15 |
| 121°C WRAPPED | 3 | 20 | 121 | 110 | - | 5 |
| 134°C WRAPPED | 3 | 4 | 134 | 210 | - | 5 |
| B&D TEST | 3 | 3.5 | 134 | 210 | - | - |
| HELIX TEST | 3 | 3.5 | 134 | 210 | - | - |
| 134°C PRION | 3 | - | 134 | -75 | 15 | - |
| 121°C LIQUID | - | 30 | 121 | 110 | - | - |

The SOLID program should only be used for unwrapped solids. Hollow bodies of type A and B or porous materials cannot be sterilised with this program.

The VACUUM TEST program performs a pressure leak test.

The WRAPPED programs are suitable for the sterilisation of porous material, hollow bodies of type A and B, packaged waste and instruments. Both programs do not differ in end result. If the load is temperature sensitive and cannot therefore be sterilised at 134°C, please select the 121°C program.

The B&D TEST or HELIX TEST program tests hollow bodies of type A. The programs are almost identical. The only difference involves the fact that the B&D TEST program is a B&D test package, while the HELIX TEST is used as a test device. (PCD: Process Challenge Device).

The 134°C PRION program is specially designed for the sterilisation of prions on all kinds of surface.

The 121°C LIQUID program is used for the sterilisation of liquids in bottles and other open vessels. We recommend using the integrated flexible media sensor for this program. The media sensor is immersed in the liquid medium or in a reference glass with distilled water during the sterilisation. The autoclave now adjusts the retention time during sterilisation so that the medium retains the required sterilisation temperature for at least 30 minutes. If you do not use the media sensor the media temperature cannot be recorded during sterilisation.

Never place pressure-sealed bottles, bags or containers without pressure equalisation mechanism into the autoclave. These could explode due to overpressure during cooling.

Only fill the glasses to maximum half their capacity.

Please perform a vacuum test each month. If the program is not completed successfully, please contact your dealer or the manufacturer by email (<u>support@certoclav.com</u>).

All programs can be customised by the user.

7.2 Editing program parameters

To edit the program parameters, press and hold the M key for 5 seconds while switching on the autoclave at the rocker switch.

Use the arrow keys to toggle between the menu entries.

Use the M key to confirm and save an entry.

Use the Enter key to cancel the process. A menu for editing the program parameters opens. Select the desired program to change the retention time and drying time after the sterilisation phase.

Retention time: 1-59 minutes.

Drying time: 1-19 minutes. Setting parameter N to 0 deactivates the drying.

8 Basic Operation

8.1 Switching on the touchscreen

Press and hold the \Box button on the front (to the right of the screen) for at least 3 seconds.

Switch on the autoclave at the rocker switch below the front cover.

8.2 Switching off the touchscreen

Press the \Box button on the front (to the right of the screen) for at least 3 seconds. A message will then appear on the screen. Select "Shutdown" to switch off the screen.

8.3 Standby Mode for the touchscreen

Briefly press the \Box button next to the screen. The background light of the screen then switches off. Press the \Box button again to reactivate the touchscreen.

Please make sure that the autoclave is earthed.

9.1 Preparations before use

Switch on the autoclave at the green mains switch. Switch on the touchscreen directly via the screen. To do so, press the \Box button on the front of the screen (to the right of

the screen) for at least 3 seconds. After this the autoclave touchscreen switches on and displays the login window. The autoclave is ready for operation.

Before the first use, the touchscreen displays the notification "Please fill the water tank with distilled water". As soon as the water is filled, the notification disappears and the autoclave is ready for operation.

9.2 Replenishing with distilled water

The inlet to the freshwater tank is located on the cover of the autoclave. Open the tank cover and full the tank with distilled water.

Only distilled or demineralised water is suitable for operating the autoclave.

Make sure that you do not overfill the tank. Do not fill with more than 4 litres of water maximum. If the tank has been overfilled, the surplus water can be drained via the wastewater hose on the front of the autoclave. If the notification "Please fill the water tank with distilled water" appears on the screen during sterilisation, the sterilisation process must not be terminated. Before the next sterilisation process is started, however, the tank must be replenished with distilled water.

Before filling the water tank with distilled water, please switch on the autoclave and make sure that the autoclave is horizontal with 1° inclination to the rear.

Only fill the fresh water tank with demineralised or distilled water. A water quality sensor continuously monitors the quality of the filled water. If the water used to full the tank is too impure, a warning message will appear on the integrated LCD screen of the autoclave and touchscreen.

Neither the manufacturer nor dealers are liable for damage resulting from the use of contaminated water.

9.3 Opening the autoclave door

To open the door, click on the lock icon at the top right of the Main Menu. The door then opens automatically.

9.4 Steps to start a sterilisation process

First check if the autoclave is ready for operation before starting the program. If no warning or error message is displayed on the touchscreen, the autoclave is ready for operation.

9.4.1 Selecting the sterilisation program on the screen

After logging in, navigate to the Sterilisation tab. You will see 4 programs in the centre. Scroll down in the list to view all available programs.

Press on a program to select it. Confirm that you wish to start the program.

If activated in the settings, step-by-step videos will be displayed before starting the program.

9.4.2 CertoTrace - Documentation and load management

CertoTrace is a software package enabling simple and professional documentation of the entire sterilisation process and tracing of all sterilised products.

If CertoTrace is activated, the CertoTrace Assistant will be executed directly after selecting a program.

Scan the barcode of bottles, instruments or other objects that have been placed in the autoclave, in order to be able to trace their sterilisation with CertoTrace.

Once an object has been scanned in, it will appear in a list of the CertoTrace Scan Menu. The object and the barcode are noted in the protocol of the sterilisation process.

After all objects have been read in and placed in the sterilisation chamber, press on the Next button.

To terminate the CertoTrace Assistant, press the Back button at the top left of the screen.

If a barcode does not exist for an object, use the label designer to generate and print out a barcode for the object.

To open the label designer, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Sterilization" and then "Open label printer designer".

9.4.3 Step-by-step video assistant

To activate the step-by-step video assistant, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Select the Sterilisation entry on the left of the Settings window. Press on the Step-by-step video assistant to activate or deactivate the step-by-step video assistant.

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

9.4.4 Loading the autoclave

Please make sure that the total volume of the loads is less than 70 % of the volume of the autoclave chamber.

Please leave at least 10 mm free space between the load and sterilisation chamber wall.

To check the effectiveness of the sterilisation processes independently, place the indicators or bags together with the load into the sterilisation chamber. If you execute the B&D or Helix program, place the indicator in the centre of the sterilisation chamber. A reliable test result is attained in this way.

9.4.5 Closing the autoclave door

To close the autoclave door, press the door gently against the boiler. The vacuum pumps then suctions the door the it is automatically locked electrically.

If the temperature in the sterilisation chamber is too high, the door of the autoclave can only be closed with difficulty. Wait 2 minutes before closing the door.

9.4.6 Material tests and automatic repetitions

Material tests can be activated wit checkboxes in the settings. To activate or deactivate Material Test Mode, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Sterilization" and then "Material testing mode".

If Material Test Mode has been activated, the autoclave asks how often the program is to be executed automatically in succession before the program start.

| ← 21:40:46 2017.05.12 M | ONITOR Ö | ¥ | How often the progra | am should be e | xecuted one afte | er another? | |
|---|--------------------------|---|----------------------|----------------|------------------|-------------|--|
| 121 °C SOLID NOT RUNNING Cycle 2 of 2 | 00:00:00 | | 1 | imes | | | |
| Vacuum times: 1 | | | Cancel | | | START | |
| Sterilisation temperature: 121 ?C Sterilisation pressure: 2.10 bar | CHENCLW STEAM 83 2 °C | | 1 | 2 | 3 | - | |
| Drying time: 3 min | PRESS -1 kPa | | 4 | 5 | 6 | , | |
| STADT | | | 7 | 8 | 9 | | |
| START | | | • | 0 | | | |

You can enter a number between 1 and 1000. The program will execute the desired number of cycles fully automatically in succession. The status of the program cycle can be called up at any time via a browser at <u>www.certocloud.com</u> or offline on the CertoClav server at <u>http://certocloud</u>. If you have activated email or SMS notifications, you can call up the current status of the material test by SMS or email. The email or SMS notifications can be configured in the settings. You can find the notifications in the Settings under the Notifications menu item.

9.4.7 Status screen

The Status screen becomes visible as soon as a program is running.

Information on the current cycle is listed on the left of the screen. The current steam temperature and data on the pressure are on the right of the screen. If the liquid program has been started, the temperature of the liquid will also be visible.

To show a graph of the temperature and pressure, hold and drag the autoclave symbol to the left. The graphic recording will then become visible.

9.5 Unloading the autoclave

As soon as the sterilisation cycle has finished, "Program finished" is displayed on the screen and you will hear three beep sounds. Return to the Main Menu and press the lock icon to open the door. You can then open the door and remove the sterile load.

Risk of scalding! Hot steam or hot water can escape from the chamber when opening the door.

Do not open the door until the pressure in the sterilisation chamber is in the range from -5kPa to 5kPa.

9.6 Emptying the used water tank

If "Empty the used water tank" is displayed on the screen, the used water tank is full. Please empty the used water via the wastewater hose supplied. The left port is for used water, the right port is the drain for distilled fresh water.

Used water may be hot.

9.7 PC software

CertoCloud is a browser-based management software package for your autoclave. The software is available at <u>www.certocloud.com</u> for PC, smartphone and tablets.

CertoCloud is also available as a laboratory-internal private cloud. The CertoServer must be connected to your laboratory network for this. The CertoServer does not require an Internet connection.

| Welcome to Certocloud On CertoCloud you can easily access, control and manage your laboratory devices from everywhere. | CERTO CLOUD |
|--|--------------------------------------|
| Certocloud Features | Email Address * emo@certoclav.com |
| Create and Manage Programs | Password * |
| Store all Protocol information in the cloud | <u></u> |
| Review the history and status of Protocol | |
| () LEARN MORE ABOUT CERTOCLAV | Forgot Password? |

9.7.1 Functions of the CertoCloud

| Email Address * max.muster@mail.com Password * Forgot Password? Forgot Password? + REGISTER NOW | Creation of user accounts directly at the autoclave or web-based. |
|--|---|
| Autoclave Lab 2 Serial 220002576 Model Certoclav 22 Vac Pro Firmware DEFAULT | Tracing real-time data. |
| If An Error Occured, Send Notification SMS 0123456789 × EMAIL max.muster@mail.com × | Administration of SMS and email notifications. For instance, if maintenance is due. |
| Isst of Protocols Cycle ↑ Program Name Start 76 cloud generated 7/22/ 75 121°C SOLID 7/22/ 74 Neues Programm 7/22/ 74 121°C SOLID 7/22/ 74 121°C SOLID 7/22/ 74 121°C SOLID 7/22/ 74 121°C SOLID 7/22/ | Downloading of all sterilisation protocols as signed PDF, Excel or ZIP file. |

Viewing of all protocols as graphic view, list or detailed view.

| Protocol Verification | |
|------------------------|--|
| Protocol ID * | Validity verification of exported protocols. |
| 0/24 Device Key* | |
| 0/17 🔞 Security Code * | |
| 0 / 40 | |
| VERIFY | |

9.7.2 Display of sterilisation protocols via web browser

To manage the autoclave and view protocols, please use a browser to visit <u>www.certocloud.com</u> or <u>http://certocloud</u>. A typical protocol is shown below.

| CLOUD | | | | | PORT@CERTOCLAV.CO |
|---|----------------------|---------------------|----------------------------|---|--|
| DEVICES > NEW CERTOCLAV | > PROTOCO | DLS > PRO |)TOCOL-63FBE298 | | |
| | | | CSV | PDF PDF | zip |
| Cycle Number Device Name 3 New Certoclav | Program Na LIQUID | me Tir 8/ | ne Started 2/17 6:41 PM | Date Finished 8/2/17 8:11 | Status PM PASSED |
| ~ Graph | | | | | |
| 9 | | | | s s s s s s s s s s s s s s s s s s s | ressure emperature 135°C nedia temperature 135°C |
| 7 | | | | | 105°C |
| 6 | | | | | 90°C |
| 2 | | | | | 75°C |
| 3 | | | | | 45°C |
| 2 | | | | | 30°C |
| 1 | | | | | 15°C |
| 0 0 Mins 10 Mins 20 Mins | 30 Mins 40 Mins | s 50 Mins | 60 Mins | 70 Mins 8 | 0°C 80 Mins |
| Program | | Data P TimeStamp | Points | Pressure | , Media Temperature |
| Liquid sterilization 121 °C 1.1bar 20min | | 0 | 62.8 | 1.03 | 30.2 |
| With media sensor | | 0.35 | 65.3 | 0.69 | 30.3 |
| Vacuum times: 1 Sterilisation temperature: 121°C Sterilisation pressure: 2.10 bar | | 0.68 | 67.3 | 0.49 | 30.5 |
| Sterilisation holding time: 20 min | | 1.02 | 68.7 | 0.36 | 30.6 |
| | | 1.35 | 69.9 | 0.26 | 30.9 |
| | | 1.68 | 71 | 0.2 | 31.1 |
| | | 2.02 | 71.8 | 0.21 | 31.3 |
| | | 2.35 | 74.9 | 0.63 | 31.8 |

10 Control Panel of the Autoclave

Icons, tabs and text fields can be edited by pressing with your finger.

10.1 Login Menu

| 2 | 22:32:31 017.05.12 | LOGIN | ∲ |
|---|-----------------------|--------------|------------|
| | | | |
| | support@c | ertoclav.com | 4 8 |
| | ••••• | | |
| | | LOGIN | |
| | | | |

The Login window appears after switching on the touchscreen. To create a new user, press on the plus symbol at the top right of the screen.

To create a local account without server connection, press on "Do not take advantage from CertoCloud".

Ro add an existing CertoCloud user account with server connection, press on "Add an existing CertoCloud account".

If you wish to create a new CertoCloud user account with server connection, press on "Create a new CertoCloud account".

Enter your user data to create a new CertoCloud user account. Enter your phone number including country code. This is needed if you wish to receive status notifications from the autoclave by phone. Enter a password of your choice with at least 4 characters and repeat entry. To cancel the registration, press on the Back button in the top left corner of the screen. Press on "Register" to complete the registration.

| Ú | 14:12:01 2016.03.10 | Add CertoCloud Account | |
|---|------------------------|------------------------|--|
| | | demo@certoclav.com | |
| | | •••••• | |
| | | Add account | |
| | | | |
| | | | |

To add an existing CertoCloud user account, enter your email address and password. Then press on "Add account". To cancel the registration, press on the Back button in the top left corner of the screen.

| 22:32:31 2017.05.12 | LOGIN | | + | ø |
|------------------------|---------------|---|--------|---|
| | | | | |
| support@ | certoclav.com | æ | \sim | |
| ••••• | | | | |
| | LOGIN | | | |
| | | | | |

To enable you to log into a CertoCloud user account recently created, first select your email address from the list and then enter your password. Make sure that Online Mode is activated if you wish to use a user account with server connection.

When you log into your CertoCloud user account for the first time, you will be prompted for an activation code. You should have received the activation code by SMS or email after you created your CertoCloud solution. Enter this code in the text field and press on "Activate account". Your CertoCloud user account is now activated and you can now log into the autoclave with this.

10.2 Support Menu

Navigate to the Information tab to view the Information Menu. Here you can watch training videos, contact the CertoSupport directly from the touchscreen or order spare parts, accessories or service for your autoclave.

10.2.1 Tutorial videos

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

10.2.2 Send email to CertoSupport

An Internet connection must be available to send an email to CertoSupport from the touchscreen. To connect the touchscreen to the Internet, you can either connect a network cable to the Ethernet port or establish a WLAN connection to your WLAN router. Navigate to the Information tab and press Support. In the dialog window that follows select the option "Send an Email to CertoSupport".

Now select the desired subject from the dropdown list and then enter your message in the text field. Press on "Send" to send the email. We will respond to your question within 24 hours via the email address of your autoclave account.

| CONTACT SUPPORT | | ← ^{21:4} / ₂₀₁₇ . | 9:05 05.12 | CONTACT SUPPORT | Send |
|-----------------------------|----------|---------------------------------------|---------------|--|--------|
| Request for custom software | SUBJECT: | | | | |
| Protocol Managment | | Protocol | Managm | ent | \sim |
| User Managment | MESSAGE | | | | |
| Program Managment | | Is a backup | of my pro | otocols saved at CertoCloud online storage | |
| Software Updates | | | | | |
| sincerely, Michael Dirix | | | | | |

10.2.3 TeamViewer, remote support and share screen

To share the screen via TeamViewer, navigate to the Information tab and press Support. In the dialog window that follows select the option "Share screen to CertoSupport". The TeamViewer request is now accepted if a schedule with the CertoSupport has been agreed beforehand via email or phone.

To arrange a time window for the remote support, navigate to the Information tab and press Support. In the dialog window that follows select the option "Send an Email to CertoSupport".

Request a schedule for the remote support. We will usually respond to your request within 12 hours.

As soon as you start a TeamViewer session, a window appears, giving the opportunity to describe the problem roughly once again. Then press on "Start".

After pressing on Start, wait until CertoSupport has joined the TeamViewer session.

As soon as CertoSupport has joined the session, we will ask your permission to split the screen. Press on "Allow".

| | | | ġ. |
|------|---------------------------------|-------|--------|
| | Allow remote support? | | |
| C | Would you like to allow Michael | | |
| | Deny | Allow | JPPORT |
| - 07 | | | |

The CertoSupport service technician is now able to service your autoclave. Please wait until the technician has made the required settings to your device. To cancel the screen transmission, drag the TeamViewer icon to the X symbol at the bottom of the screen.

10.3 Protocols Menu

10.3.1 Viewing protocols

To view sterilisation protocols, navigate to the Logging tab. A list of all recorded protocols is displayed on the left half of the screen. The cloud symbol in the protocol list indicates whether the protocols have been backed up in the CertoCloud or on your local CertoServer. Press on the dropdown menu above the protocol list to sort the protocols according to define criteria. To display the details and graphic view, select the protocol by pressing with your finger on the list element. A graph of the protocol will now be shown on the right of the window. To display the protocol as a list, press on the list symbol above the graph.

| | ATION LOGGING | 墩 | |
|---|--|------------------------------------|---|
| SORTED BY DATE | · 4 | > └~ ╋ 飞 | SORTED BY DATE 🗸 🖓 🔁 🖥 |
| | TimeStamp Chamber [min] temp. [°C] | Media temp. Pressure [°C] [kPa] | 121 °C SOLID |
| ID: 27 21:06 2017-05-12 support@certoclav.com | 1.00 48.92 | 0.0 2.00 | ID: 27 21:06 2017-05-12 support@certoclav.com |
| 121 °C SOLID | 200 48.59 3 Successfully 400 47.89 | 0.0 2.00 2.00 2.00 | 121 °C SOLID ID: 26 20:29 2017-05-12 support@certoclav.com |
| USER DEFINED | 5.00 47.52 | 0.0 2.00 | USER DEFINED 🚳 \/\/\/ |
| ID: 25 20:24 2017-05-12 support@certoclav.com | 6.00 47.14 | 0.0 2.00 | ID: 25 20:24 2017-05-12 support@certoclav.com |
| 121 °C HOLLOW | 7.00 46.76 | 0.0 2.00 | 121 °C HOLLOW |
| ID: 24 17:59 2017-05-12 support@certoclav.com | 8.00 46.36 | 0.0 2.00 | D: 24 17:59 2017-05-12 support@certoclav.com Temperature Media temperature Pressure |

10.3.2 Printing protocols

Navigate to the Logging tab. Select the protocol you wish to print out on the left of the screen. Press on the pressure symbol at the top right of the screen. Now select the option "Print the protocol".

10.3.3 Example of a protocol printout

10.3.4 Print barcode

Navigate to the Logging tab and select the protocol last recorded on the left of the screen. Press on the pressure symbol at the top right of the screen. Now select the option "Print a tracing label".

| ር በ | INFORMATION STERIL | ISATION | LOGGING | \$ |
|--|--------------------|----------------------|---|--|
| SORTED BY DATE 121 °C SOLID ID: 27 21:06 2017-05 121 °C SOLID | Print the protocol | Print a lat | tracing bel | 1222 120 |
| ID: 26 20:29 201745 USER DEFINED ID: 25 20:24 201745 121 °C HOLLOV ID: 24 17:59 201745 | Print protocol | -100 0 — Tempe | label ¹⁰ Time in erature — Media | 20 30 minutes a temperature — Pressure |

Now enter the shelf-life of the sterilised products.

| ር | INFORMATION | STERILISATION | LOGGING | | ø |
|---|---|---------------|--|--------------------------------------|------------------|
| SORTED BY DATE | Please en expiratior | iter time unt | til | 122.2 12 | a 3 |
| 121 C SOLID ID: 27 21:06 2017-05 121 °C SOLID ID: 26 20:20 2017.05 | 6 | MONT | HS | | |
| USER DEFINED | CANCEL |] [| ок | | |
| ID: 25 20:24 2017-05- 121 °C HOLLOV ID: 24 17:59 2017-05- | 12 support@certoc V 12 support@certoc | slav.com | ¹⁰ Time i Temperature —— Mec | 20 n minutes dia temperature — | 30 — Pressure |

Then press on OK to print the self-adhesive label with shelf-life date and barcode.

10.3.5 Tracing marked products

Navigate to the Logging tab and press on the Scan icon.

A dialog window appears. Scan the barcode of the sterilised product with the barcode reader. The protocol for the sterilised product now appears on the screen. A graphic view and list view of the protocol can now be seen on the right of the screen.

| ባ | INFORMATION | STERILISATION | LOGGING | 竛 |
|--|------------------------------|---------------|---|---------------------------|
| SORTED BY DAT | Ξ | 200 | Ģ | = 🖶 🗐 |
| 121 °C SOLID ID: 27 21:06 2017-0 | 05-12 support@certoo | Clav.com | | 67.2 |
| 121 °C SOLID ID: 26 20:29 2017-0 | 05-12 support@certoo | clav.com | Λ̈́, Ϊ | |
| USER DEFINE | D)5-12 support@certod | clav.com | JVV | U |
| 121 °C HOLLO ID: 24 17:59 2017-1 |)W 05-12 support@certod | clav.com | ²⁰ Time in minutes Temperature — Media tempe | s 60 rature — Pressure |

11 Settings

11.1 User administration

Press on the symbol on the right of the screen to navigate to the settings. Select the User Administration list entry in the left window. The User Administration will now be shown on the right of the window. Press on Edit to change your user data and password or on Delete to delete your user account.

| • | 21:38:13 2017.05.12 | SETTINGS | |
|-----|------------------------|-----------------------|---|
| 0 | User account | support@certoclav.com | 8 |
| ŝ | Network | | |
| Ĵ.c | Sterilization | | |
| | Device | | |
| | Language | | |
| Ť | Notifications | | |
| ۲ | Calibration | | |

11.2 Network settings

11.2.1 Connecting to a WLAN network

Navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Then press on "Network". If no checkmark is set at "WiFi On/Off", press on the empty checkbox to activate WiFi.

After this press on "Manage WiFi connections" to display a list of available WLAN networks. Select the relevant WLAN network and enter any required access code and further parameters.

11.2.2 Connecting to a LAN network

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

11.2.3 Network communication

Online Mode needs to be activated if the autoclave data is to be synchronised with the CertoCloud or the local CertoServer. If the CertoCloud is sued for synchronisation, email and SMS notifications will also be available.

Navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Then press on "Network". Now select Online Mode to activate or deactivate the data synchronisation.

Note: If Online Mode is deactivated, your protocols will only be saved locally on the autoclave. As soon as you reactivate Online Mode, all protocols saved locally up until then are synchronised with the CertoCloud and are thus also available online in your backup memory.

11.2.4 Connecting to the CertoServer

If you do not have an Internet connection but wish to use the CertoCloud, we recommend connecting the local CertoServer to the autoclave.

Connect the CertoServer to the LAN and switch in the server. Connect the autoclave to the same network via Ethernet cable or WLAN.

Navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Network" and then on "choose server".

| ← SETTINGS | | | | | |
|-----------------------------|--|--|--|--|--|
| e User account | WIFI ON/OFF WIFI disabled | | | | |
| Network | MANAGE WIFI CONNECTIONS | | | | |
| C Sterilization | ONLINE MODE | | | | |
| Device | CHOOSE SERVER | | | | |
| Hanguage | CertoCloud Server | | | | |
| (Institution) Notifications | | | | | |
| Calibration | | | | | |
| STEAM: 76.28 °C | /IEDIA: 73.28 °C Pressure: 1.0 kPa_support@certoclav.com | | | | |

Select the "Add a server from local network" option.

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

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

11.2.5 Connecting to the CertoCloud server

If the autoclave is connected to the Internet, you can alternatively use the free CertoCloud for documentation and configuration of the autoclave.

To activate communication with the CertoCloud, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Network" and then on "choose server".

Select the "CertoCloud Server" option.

11.3 Sterilisation settings

11.3.1 Customising sterilisation programs

To customise a sterilisation program, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Sterilization" and then "Edit user defined program".

| ← 21:37:27 2017.05.12 | SETTINGS | |
|------------------------------|--|----------|
| Network | STEP BY STEP GUIDE | ~ |
| & ^C Sterilization | Export Protocols to USB-Stick | |
| Device | Export protocols to Micro SD Card | |
| Language | Edit user defined program | |
| Notifications | | |
| Calibration | Preheat chamber ON/OFF Heat up the chamber to 50°C before program execution | |
| Service | Keep temperature ON/OFF Warm up the chamber and steam generator permanently | |

Now define the program parameters individually corresponds to your requirements:

- Number of prevacuum pumps between 1 and 10
- Sterilisation temperature between 105 °C and 134 °C
- Sterilisation time between 4 and 60 minutes
- Drying time between 1 and 25 minutes

Then press on "Apply" to save the program parameters or on "Cancel" to return to the Settings Menu and cancel the process.

| (21:41:20) | VACUUM TIMES [1-10] |
|--------------------|-----------------------------------|
| B User account | |
| Network | |
| Sterilization | STERILIZATION TIME [4-60 MINUTES] |
| Device | 5 |
| Hanguage | DRYING TIME [1-25 MINUTES] |
| 1 Notifications | ion |
| Calibration | Cancel Apply antly |

11.3.2 Material tests and automatic repetitions

If Material Test Mode is activated, you will be asked how often a program is to be executed before starting it for the first time.

| How often the program | n should be e | xecuted one afte | er another? |
|-----------------------|---------------|------------------|-------------|
| | | | |
| 1 time | | | |
| un un | les | | |
| | | | |
| Cancel | | | |
| Vacium times: I | | | |
| vacuum times. T | | | |
| 1 | 2 | 3 | - |
| | _ | | |
| 4 | 5 | 6 | , |
| 7 | 0 | 0 | _ |
| / | 8 | 9 | X |
| | 0 | | |
| • | 0 | | |

This has the advantage that longer material tests an be performed fully automatically without user interaction.

To activate or deactivate Material Test Mode, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Sterilization" and then "Material testing mode".

| ← SETTINGS | | | | |
|------------------------------|--|--|--|--|
| e User account | Edit user defined program | | | |
| | Preheat chamber ON/OFF Heat up the chamber to 50°C before program execution | | | |
| § [℃] Sterilization | Keep temperature ON/OFF Warm up the chamber and steam generator permanently | | | |
| Device | Material testing mode On program start, show a dialog to enter how often to run the | | | |
| 🕀 Language | program automatically | | | |
| Notifications | Open label printer designer | | | |
| Calibration | CertoTrace load documentation Enable autoclave load documentation. Barcodescanner and labelprinter required. | | | |

11.3.3 CertoTrace — Your support during material tests

CertoTrace is a professional documentation software package for the entire sterilisation process. CertoTrace records which products have been sterilised, when and by whom. The tracing of sterilised products and management of shelf-lives is thus integrated in the work process.

To activate CertoTrace, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Sterilization" and then "CertoTrace load documentation". After activation, CertoTrace is automatically integrated in the workflow when starting a program.

| ← SETTINGS | | | | |
|-----------------------|--|--|--|--|
| O User account | Edit user defined program | | | |
| Network | Preheat chamber ON/OFF Heat up the chamber to 50°C before program execution | | | |
| Sterilization | Keep temperature ON/OFF Warm up the chamber and steam generator permanently | | | |
| Device | Material testing mode | | | |
| Hanguage | On program start, show a dialog to enter now often to run the program automatically | | | |
| 1 Notifications | Open label printer designer | | | |
| Calibration | CertoTrace load documentation Enable autoclave load documentation. Barcodescanner and labelprinter required. | | | |

11.3.4 Label designer

The CertoClav label printer prints shelf-life data and a barcode for tracing the product on self-adhesive labels.

You can use the integrated label designer to identify articles with barcodes. To open the label designer, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Sterilization" and then "Open label printer designer".

| ÷ | SETTINGS | ← Label designer | Print |
|-----------------------|--|------------------|-------|
| e User account | Edit user defined program | | |
| Network | Preheat chamber ON/OFF Heat up the chamber to 50°C before program execution | 1300453 | |
| Sterilization | Keep temperature ON/OFF Warm up the chamber and steam generator permanently | CM 1000ml | |
| Device | Material testing mode | | |
| Language | On program start, show a dialog to enter now often to run the program automatically | | |
| 1 Notifications | Open label printer designer | | |
| Calibration | CertoTrace load documentation Enable autoclave load documentation. Barcodescanner and labelprinter required. | | |

11.3.5 Real-time protocolling to USB

You can use a USB stick to save the sterilisation protocols in real-time during the sterilisation process. For this, please connect a USB stick to the front USB port of the autoclave.

11.3.6 Exporting all protocols to a USB

The autoclave can save any number protocols internally. To export all protocols to a USB stick, plug a USB stick into the interface box.

Navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Sterilization" and then "Export protocols to USB-Stick".

If the protocol export fails, your USB stick and not been recognised. In this case plug the USB stick into the device and restart the touchscreen. Now attempt to the export the protocols again.

11.3.7 Exporting all protocols to an SD card

The autoclave can save any number protocols internally. To export all protocols to an SD card, plug a Micro SD card into the opened push-in compartment on the right of the touchscreen.

Navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Sterilization" and then "Export protocols to Micro SD Card".

| 9 User account | STEP BY STEP GUIDE | ✓ | | \bigcirc | |
|-----------------------|--|---|---------------------------------------|--|--|
| • Network | Export Protocols to USB-Stick | | rrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrr | Coping protocols | |
| C Sterilization | Export protocols to Micro SD Card | | De | Exported successfully | |
| | Edit user defined program | | 🕀 La | ОК | |
| Notifications | Preheat chamber ON/OFF Heat up the chamber to 50°C before program execution | | Notifications | Heat up the chamber to 50°C before program execution | |
| Calibration | Keep temperature ON/OFF Warm up the chamber and steam generator permanently | | Calibration | Keep temperature ON/OFF Warm up the chamber and steam generator permanently | |

If the protocol export fails, restart the touchscreen with the SD card inserted. Now attempt to the export the protocols again.

11.3.8 Exporting all protocols via a network

Log into the autoclave with your CertoCloud or CertoServer user account. Make sure that Online Mode is activated. If the login is successful, all protocols will be synchronised with the CertoCloud. The export has been successful if checkmark icons are displayed in the protocol list.

11.4 System settings

11.4.1 Changing the date and time

Use the buttons of the LCB screen to change the date and time of the autoclave. Use the M button to navigate to "Basic Set" and then to "Date" for this. To adapt the required parameters, use the arrow buttons and confirm the correct value with M button.

| Program Basic Set Report | DATE:12-04-03 TIME:09:10:08 LANGUAGE:ENG Counter: 12 |
|--------------------------------|---|
| | 000000000 |

11.4.2 Installing updates via the Internet

Make sure that autoclave is connected to the Internet. Go to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Device" and then on "Check for updates".

| 4 21:37:02 2017.05.12 | SETTINGS |
|------------------------------|--|
| Network | Check for updates |
| | Install update from USB flash drive |
| Device | Install update from external SD card |
| Language | Storage |
| Notifications | Free Memory: 1450 MB |
| Calibration | 2017.05.12 21:37:02 |
| Service | Factory Reset Restore device to its original manufacturer setting |

A progress display appears with the download. All updates are automatically installed as soon as they are downloaded. If a new software version is available, an installation assistant will guide you through the installation process.

| Ĵ | SETTINGS |
|---|--|
| User account | Storage Free Memory: 1581 MB |
| DOWNLOAD UPDATE | S - PLEASE WAIT |
| Downloading update.zip Sterilization | Factory Reset |
| 64% 64/100 | Device Key Security Key 20828384987444624 |
| Language | Software Version |
| Sensor calibration | Check for updates |

11.4.3 Installing updates via USB

Download the latest update from <u>www.certoclav.com</u> or ask for the latest update for your device by email to <u>support@certoclav.com</u>. Please indicate the serial number of your autoclave for the Support Team. You can find the serial number on the type plate of the autoclave or in the settings. For this, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Device".

Copy the "update.zip" to the main directory of a USB stick and plug this USB stick into the extensive cable of the touchscreen.

Navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Device" and then on "Install update from USB flash drive".

If the USB stick is not recognised, restart the touchscreen and try again. Follow the instructions on the screen to install corresponding updates.

11.4.4 Installing updates via SD card

Download the latest update from <u>www.certoclav.com</u> or ask for the latest update for your device by email to <u>support@certoclav.com</u>. Please indicate the serial number of your autoclave for the Support Team. You can find the serial number on the type plate of the autoclave or in the settings. For this, navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Device".

Copy the "update.zip" to the main directory of Micro SD card and plug this into the push-in compartment on the right of the touchscreen.

Navigate to the Settings Menu by clicking on the symbol at the top right of the screen. Press on "Device" and then on "Install update from external SD card".

If the SD card is not recognised, restart the touchscreen and try again. Follow the instructions on the screen to install corresponding updates.

11.4.5 Restoring the default settings

Navigate to the Settings Menu by clicking on the symbol at the top right of the screen and pressing on "Device". In the detailed view on the right of the screen scroll to the Restore default settings entry and press on it.

Once you have reset the touchscreen in the default settings, all protocols and user accounts not previously exported and not synchronised with the CertoCloud will be deleted.

11.4.6 Changing the language

Navigate to the Settings Menu by clicking on the symbol at the top right of the screen and press on "Language". Pressing the current language setting in the detailed view on the right of the screen opens a dropdown list with the languages supported. Select a language by clicking on the desired language.

| ← ^{21:36:50} 2017.05.12 | SETTINGS |
|-------------------------------------|-------------------------------------|
| | Language English (United States) |
| | |
| Device | |
| 🕀 Language | |
| 1 Notifications | |
| Calibration | |
| Service | |

11.5 Configuration of SMS and email notifications

If you still do not have a CertoCloud account, you can create a new CertoCloud account in the Login window.

Note: The autoclave must be connected to the Internet to be able to cerate the CertoCloud account. Log in with your CertoCloud user account.

To configure SMS and email notifications, navigate to the Settings Menu by clicking on the symbol at the top right of the screen and pressing on "Notifications".

If you wish to receive an email if a program is terminated, when maintenance is necessary or once a program has successfully been executed, activate the relevant assigned checkbox.

Enter the email address of your choice, which is to be used for the notification. If you have a CertoCloud account, you can also save a mobile phone number to which notifications via SMS are to be sent. Then press on "Save" to save the changes.

| 4 21:36:24 2017.05.12 | SETTING | S | |
|-------------------------------|--|-----------------------|--|
| Network | | SAVE | |
| € ^{°C} Sterilization | If an error occured, send notification | | |
| Device | by SMS | phone number | |
| Language | | | |
| (1) Notifications | 🖌 by email | support@certoclav.com | |
| Calibration | If maintenance required, send notification | | |
| Service | by SMS | phone number | |

11.6 Sensor calibration

The sensor calibration should be calibrated by trained personnel only.

To calibrate the sensors, navigate to the Settings Menu by clicking on the symbol at the top right of the screen and pressing on "Calibration".

Press on the offset you wish to adjust. The offset parameters must be in the interval [-3°C; 3°C] and [-5 kPa; +5kPa]. Then press on "Apply".

11.7 GLP and GMP data

To view the GLP and GMP settings, navigate to the Settings Menu by clicking on the symbol at the top right of the screen and pressing on GLP and GMP data.

11.7.1 Header

The header setting activates the printout of the GLP header. Up to four text lines are available. If this setting is activated, the header will be displayed at the top of each sterilisation protocol and printed out.

11.7.2 Autoclave designation

Designate the autoclave in this setting. An alphanumeric text can be entered. The standard name is empty.

11.7.3 Project designation

Designate your project in this setting. An alphanumeric text of up to 25 characters can be entered. The standard designation is empty.

11.7.4 Advanced GLP and GMP settings

Activate the following checkboxes in the Advanced GLP and GMP settings to configure a printout and digital copy of the sterilisation products.

| Setting | Option (Default value is bold) |
|-------------------------------|---------------------------------------|
| Print autoclave designation | YES, NO |
| Print user identification | YES, NO |
| Print project designation | 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 |

11.8 Locking settings

To prevent unauthorised changes to the autoclave, sensor parameters, programs and settings, it is only possible to change settings in the password-protected Administrator user account.

12 Error Messages

If an error occurs during a program cycle, the autoclave will sound an acoustic alarm and display and error code on the screen. The autoclave will also automatically release pressure from inside the sterilisation chamber and switch off the heating. This safety system is designed to protect the user. If an alarm occurs, please write down the error coded and switch off the device. Do not open the door. Switch the device on again and wait until the pressure returns to -0.5 kPa ~0.5 kPa.

We recommend rebooting the program in order to see whether the error occurs again.

A repeated long beep sound is audible at each of the following error messages. The user must confirm the error message by pressing the M button for a longer period so that the error memory is deleted.

| Code | Error | Possible cause | Troubleshooting |
|------|--|--|---|
| E-1 | The program was terminated manually by the user. | User has pressed the STOP button during sterilisation. | - |
| E-2 | The communication between the external touchscreen and mainboard is interrupted. | The serial cable (COM 4) between the touchscreen and autoclave has become detached. | Screw the COM4 cable into the RS232 base on the rear of the autoclave again. If the problem is still not resolved, restart the autoclave and touchscreen. If the problem continues to persist, navigate to the Settings to reset the touchscreen. |
| E1 | Sensor error | The sensor of the steam generator is defective. | Contact your dealer. |
| E2 | Sensor error | The sensor of the chamber probe is defective | Contact your dealer. |
| E3 | Sensor error | The sensor of the heating probe is defective | Contact your dealer. |

| E5 | Pressure relief error | The pressure could not be released from the chamberContact your dealer. | | |
|-----|---|--|---|--|
| E6 | Door sensor error | The door is open during sterilisation | Contact your dealer. | |
| E9 | Temperature control | The temperature could not be retained | Contact your dealer. | |
| E11 | Steam generator heating | The steam generator could not be preheated | Contact your dealer. | |
| E12 | Chamber heating | The jacket heating could not be preheated | Contact your dealer. | |
| E13 | Vacuum pump or leak tightness | The generation of a vacuum during a cycle has failed | Clean the door seal and restart the process. Contact your dealer if the error persists. | |
| E20 | Program terminated manually | The user has terminated the program manually during a current cycle | | |
| E22 | Vacuum pump or leak tightness | Vacuum test has failed | Clean the door seal and restart the process. Contact your dealer if the error persists. | |
| E23 | Vacuum test was terminated unexpectedly | The temperature in the chamber has become too hot during the program cycle | Deactivate the "Keep warm" or "Retain temperature" function in the sterilisation settings and wait until the chamber has cooled down. | |
| E24 | The pressure is less than 30 kPa at an temperature of 120°C. | The temperature-pressure ratio does not correspond to that of saturated steam. | Contact your dealer. | |
| E25 | Door locking failed | The door could not be locked. The door is possibly set too narrow. | Contact your dealer. | |
| E26 | Door opening failed | | Contact your dealer. | |
| E27 | The vacuum test cannot be started | The temperature in the chamber is too hot to start the vacuum test | Deactivate the "Keep warm" or "Retain temperature" function in the sterilisation settings and wait until the chamber has cooled down. | |

13 Maintenance

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

Make sure that the autoclave is disconnected from the power supply during maintenance and repair.

Make sure that autoclave is at room temperature.

The following components need to be checked or replaced regularly:

- Sealing ring
- Safety valve

Inspection plan:

| Component | Inspection by | Cycle | Maintenance |
|--------------|-------------------|--------------------------|--|
| Door | Trained personnel | Every 2 years | See service instructions |
| Sealing ring | Trained personnel | Annually | See service instructions |
| Fuse | Trained personnel | If the fuse has tripped. | Operate the fuse lever on the rear of the autoclave. |
| Safety valve | Trained personnel | Annually | See service instructions |

14 Transport and Storage

Always keep the transport crate in which the autoclave was delivered.

14.1 Preparations

Allow the autoclave to cool down and pull the mains plug out of the socket.

14.2 Emptying the water containers

Please empty all internal water tanks: Connect the wastewater hose to the wastewater port for the fresh and used water. Activate the drain by pulling on the connection port. Press the connection port back towards the autoclave to stop the flow.

14.3 Transport conditions

Please contact your dealer.

Do not drop the autoclave during transport

14.4 Storage conditions

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

15 Technical Data

| Supply voltage | 230VAC, 50Hz, | 2300VA |
|-------------------------------|-----------------|--------|
| Maximum operating pressure | 0.21 🗆 0.23 | MPa |
| Maximum operating temperature | 135 🗆 137 | °C |
| Capacity of water tank | 4 | I |
| Device dimensions (W*H*D) | 640*560*840 | mm |
| Chamber dimensions | Ø 319, T 617 | mm |
| Chamber material | Stainless steel | |
| | 304L | |
| Net weight | 120 | kg |
| Ambient temperature | 5 - 40 | °C |
| Relative air humidity | ≤ 80 | % |
| Air pressure | > 70 | kPa |
| Noise level | < 70 | dB |
| | | |

16 Appendix

16.1 Appendix 1: Structural diagram

- V1: Vacuum pump valve
- V2: Air filter valve
- V3: Pump valve
- V4: Water release valve
- V5: Vacuum pump start valve

16.2 Appendix 2: Circuit diagram

16.3 Appendix 3: CE Declaration of Conformity for Autoclave

EU/EG Declaration of Conformity

| The | manufacturer | |
|-------|---------------|--|
| 1 IIE | Inanulaciulei | |

Ningbo Ican Machines Co., Ltd. No.77,Yunlin East Road, Gulin Town, Haishu District, Ningbo, China

hereby declares, under its sole responsibility, that the product described below is

| Designation: | Steam Sterilizer |
|--------------|---|
| Property: | vessel, piping, assembly, agitator, compressor, according to EN-2014/68/EU |
| Model/Type: | CB-45T |

All relevant harmonization regulations of the following product directives of the European Union fulfilled: (select all applicable product guidelines)

| | guideline | Description of the |
|---|------------|---|
| | 2014/68/EU | Directive on the availability of pressure equipment on the market |
| ~ | 2014/30/EU | Electromagnetic Compatibility Directive |
| • | 2014/35/EU | Directive on the making available on the market of electrical equipment for use within certain voltage limits |

Harmonised standards and technical specifications:

 EN 13480, AD2000, EN ISO 12100:2010, EN764-1:2015+A1L2016, EN 764-5:2014, EN 764-7:2002+AC:2006

Specific information concerning the Pressure Equipment Directive 2014/68/EU

| Max. permissible pressure PS: | 2.8 bai |
|----------------------------------|---------|
| Max. permissible temperature TS: | 141 °C |
| Volume: | 45 L |
| Fluid: | Steam |
| Fluid group: | Water |
| Test pressure PT: | 3.5 bai |
| | |

Conformity assessment procedure applied: Category: II Module: E1

EU Certificate of Conformity

No. 0B170816.NIMDW08

Notified body EU identification number 1282 Ente Certificazione Macchine Srl Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) – ITALY

Specific data according to EMC directive 2014/30/EU:

The product has been placed on the market according to article § 14 a), internal production control according to Annex II of the EMC Directive.

Spain, 29.05.2019 Place / Date (day/month/year)

I'm Hui

Management Representative

Page: 1 of 1

| Template: Declaration of Conformity DG MS NSP EMV | Template ID: | creator: customer | Rev.no.: 1 | Date: 19.05 2017 |
|---|--------------|-------------------|------------|------------------|
| ATEX | | | | |

16.4 Appendix 4: CE Declaration of Conformity for Safety Valve

| | VA GENERAL | N. from 018023901 to 018026900 | | |
|---|--|--|--|--|
| USE Tipo: D7/A OT LOC. CAMPASSO - 20010 PIANELLO VALTIDONE (PC) Italy - Tel +39 0523994629 - Fax +39 0523997219 Tipo: D7/A OT http:// www.movagenetalia - E-mait im/gonwagenetalia - E-mait im/gonwagenetalia - E-mait im/gonwagenetalia - EVAN di 137040393 - CF 01317650005 Tipo: D7/A OT LOC. CAMPASSO - 20010 PIANELLO VALTIDONE (PC) Italy - Tel +39 0523994629 - Fax +39 0523997219 Tipo: D7/A OT Intp:// www.movagenetalia - E-mait im/gonwagenetalia - E-mait im/gonwagenetalia - E-mait im/gonwagenetalia - EVAN di 137040393 - CF 01317650005 Tipo: D7/A OT Dis. N° 041-1 Rev. 20/05/08 Dis. N° 041-1 Rev. 20/05/08 Dis. N° 041-1 Rev. 20/05/08 | | | | |
| DICHIARAZIONE DI CONF DECLARATION OF CONFO KONFORMITATSERKLARU DECLARATION DE CONFORMI | DICHIARAZIONE DI CONFORMITÁ Allegato IV D. E. 2014/68/UE DECLARATION OF CONFORMITY Annex IV, E. D. 2014/68/EU KONFORMITATSERKLARUNG Anlage IV Richtlinie 2014/68/EU DECLARATION DE CONFORMITÉ Annexe IV D. E. 2014/68/UE | | | |
| PROGETTO, COSTRUZIONE DESIGN, MANUFACTU PROJEKT, KONSTRUKTION UN PROJET, FABRICATION ET VE | E COLLAUDO CONFORME ALLA DIRETTIVA 20 RE AND TEST ACCORDING TO 2014/68/EU DIRE D ABNAHMEPRUFUNG GEMAB EG-RICHTLINIE 2 RIFICATION CONFORME A LA DIRECTIVE 2014 | 014/68/UE - 15/05/14 CATEGORIA IV Modulo H1 CTIVE - 15/05/14 CLASS IV Module H1 2014/68/EU - 15/05/14 KATEGORIE IV Formblatt H1 /68/UE-15/05/14 CATEGORIE IV Module H1 | | |
| Garanzia qualità totale Nr. : Garantie gesamte Qualität Nr. : | Full quality assurance system Nr. : Garantie qualité totale Nr. : | Module H1: DGR-0036-Q8-1180-15 | | |
| Norme e spec. utilizzate : (Codes of AD-Merkblatt A2 - VdTUV-Me | spec.ref.) : (Angewandte normen und spezifikatio srkblatt Sicherheitsventil 100 / Racc. "E" ed.1979 | nen): (Regulements et spec. utilise): / ISO 4126 - 1 / AS1271-2003 / EN-378 / EN13136 | | |
| Organismo notificato : TÜV (Notified body) : Wes (Meldestelle): D 8 (Organisme agree) : | / SÜD Industrie Service GmbH stendstraße 199 0686 Munich | ⁰⁰³⁶ CE | | |
| - Marchio del costruttore: (Manifacturer's Mark): | - P.N.: 60 - D.N.: (Nenndruck): (Nominal Diameter): (I | Entrata: - Uscita: n): (Out): Entratin): G 1/4" ISO 228 (Austria): | | |
| (Herstellerzeichen): (Marquae du constructeur) | (Anschlusgewinde): ((- h / do: 0,28571 (D.N): | Entre): (Sortie): | | |
| - Materiali: (Material): (Material): (Matériaux): | - Diametro orifizio: do (Opening diameter): do 7 mm | (Area): 0,385 cm ² (Offnung): (Surface): | | |
| 1- UNI EN12164 CW614N R360 3- UNI EN12164 CW614N R360 5- UNI EN12164 CW614N R360 5- UNI EN12164 CW614N R360 | - Alzata: h (Valve Lift): h (Haussement): h - Coefficiente di efflusso: (Flow coefficient.): (Goefficient d'écoulement - Pressione di taratura: (Setting Pressure): (Coefficient d'écoulement - Pressione di taratura: (Setting Pressure): (AusfluBziffer.): (Coefficient d'écoulement - Pressione di taratura: (Setting Pressure): 2,6 bar (Abgleichungssdruck): (Pression de tarage): - Sovrappressione: % della pressione di taratura (Overpressure): (% of Setting Pressure) (Uber-Unterdruck): 10% (% Abgleichungsdruck) (Surpression): (% De la pression de taras TIPO FLUIDO: (FLUID TYPE): (MEDIUM): (Type - Scarico in atmosfera: (Discharge en atmosphere): TIPO FLUIDO: (FLUID TYPE): (MEDIUM): (Type - Scarico in atmosfera: (Discharge in Atmosphere): - Scarico in atmosfera: (Discharge in Atmosphere): - Scarico in atmosphere): | <pre>amosferic: (Operating temperature limits for materials used at atmospheric pressure): -20 / +200 °C (Betriebstemperaturgrenze der unter Luftdruck verwendeten Materialen): (Limites de température de fonctionnement des matériaux utiliés sous pression atmosphérique): - Coefficiente di efflusso ridotto : (Reduced flow coefficient): Kdr = 0,9xKd = 0,81 (Reduzente Ausflußziffer): (Coefficient d'écoulement réduit - Variabilità campo di taratura (Variabilità campo di taratura: (Variabilità campo di taratura): (Variabilità champ de tarage): - Scarto di chiusura: % della pressione di taratura (Closing variation): (% of Setting Pressure) (Unterdruck): 15% (% Abgleichungsdurck) (Unterdruck): 15% (% Abgleichungsdurck) en de fluide): ARIA-AIR-LUFT Temper.: 0 °C 81,9 Nm / h 1364,92 lt/min.</pre> | | |
| 9- UNI EN 10270-1 SM | (Abild gegen Athosphare). Child Co (Decharge en atmosphere): TIPO FLUIDO: (FLUID TYPE): (MEDIUM): (Type - Scarico in atmosfera: (Dichergie Atmosfera) | e de fluide): | | |
| 1º VITON (-20 / +200 °C) Anno costruzione: (Year of manufacture): (Baujahr): (Annee de fabrication): | (UIScharge in Atmosphere): kg/h (Abfluß gegen Atmosphere): kg/h (Decharge en atmosphere): Si dichiara che la valvola ha subito con buon esito il controllo finale compresa la prova We declare that this valve has passed successfully the test, and the hydraulic te Hiermit bestätigen wir, dass das Ventil die Abschlusskontrolle einschließlich der u | 3 Nm / h It/min. idraulica del corpo a 1,5 x P.N. st of the body to 1,5 x P.N. hydraulischen Gehäuseprüfung mit einem Druck von 1,5 x Nenndruck bestanden hat. | | |
| 2018 | On declare que la soupape a ete soumise avec resultat satisf EN 10204 3.1 Cod : | fiant a le control final y-compri l'epreuve hydraulique du corps a 1.5x NUOVA GENERAL | | |
| Nr.Ord. : E-MAIL | S.V. Code : | Date : 02/01/2018 | | |

Orders Dealer verification Instruction manuals Technical Support

Certoclav Sterilizer GmbH Peintner Straße 10 A-4060 Leonding

Tel: +43 732 674 278 E-Mail: <u>support@certoclav.com</u> Website: <u>www.certoclav.com</u>