Instruction Manual

CertoClav Vacuum Pro Series

CV-8-V-Pro
CV-12-V-Pro
CV-18-V-Pro
CV-22-V-Pro

CE

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CE Declaration of Conformity

PRODUCT: CERTOCLAV AUTOCLAV

This is to certify, that the CERTOCLAV Product Ranges CV-8-Vac-Pro, CV-12-Vac-Pro, CV-18-Vac-Pro and CV-22-Vac-Pro comply with the following regulations of the European Community:

2014/35/EU Low Voltage Directive
Associated Standards:
EN 61010-2-040:2005 Part 2: Particular requirements for sterilizers and washer-disinfectors used to treat medical material.
EN 61010-1:2001 Safety requirements for electrical equipment for measurements, control and laboratory use – Part 1: General requirements
The Certoclav pressure equipment is constructed according Low Voltage Directive.

2014/30/EU Electromagnetic compatibility

Associated Standards:
EN 61326-1:2013 Electrical Equipment for measurements, control and laboratory use - EMC Requirements- Part 1: General requirements
EN 61000-3-2:2006 + A1:2009 + A2:2009 Electromagnetic Compatibility (EMC) — Part 3- 2: Limits — Limits for harmonic current emissions (equipment input current equal to or less than 16 A per phase)
EN 61000-3-3:2013 Electromagnetic compatibility — Part 3- 3: Limits — Limits for voltage fluctuation and flicker on the public low-voltage system (equipment having an input current equal to or less 16 A per phase) and not subject to conditional connection.

2011/65/EU Restriction of the use of certain hazardous substances (RoHS) Directive
Associated Standards:
EN 50581:2012 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Base unit assembled from Ningbo Yinzhou Life Medical Technology Co., LTD in
No. 1, Jinghui Road, Hengjie Town, Yinzhou, Ningbo, Zhejiang, China

Manufacturer:
CERTOCLAV Sterilizer GmbH
Georg Grinninger-Str. 37
A-4050 Traun / Austria

Mag. Moritz Gruber
Geschäftsführer

Traun, 29.10.2016

1 Use range of this instruction manual

This instruction manual is for the following models:

- CV-8-V-Pro
- CV-12-V-Pro
- CV-18-V-Pro
- CV-22-V-Pro

	Please do not operate the device according to other instruction manuals.
	This manual is made for CertoClav Vacuum Pro Series autoclaves, which are controlled by CertoTouch User Interface.
	Please read the manual carefully before operating the autoclave.
	Please operate the autoclave strictly according to this manual.
	Please keep this manual in a reachable place near the autoclave.
	Please contact your local distributor or CertoClav Support (support@certoclav.com) if there's any problem with the autoclave.
	The person who operates and maintains the autoclave shall be specified and well-trained.
	Please appoint a specific person to operate and maintain the device. The person must be well-trained.

2 Explanation of symbols

	CAUTION!
	PROTECTIVE CONDUCTOR TERMINAL
	HOT SURFACE, KEEP AWAY
	ENVIRONMENTAL PROTECTION – Electrical waste should not be disposed together with household wastes. If possible, please contact local distributor or government to recycle it.
	MANUFACTURER
	COMMUNAUTE EUROPEENNE
	DATE OF PRODUCTION
	SERIAL NUMBER
	EUROPEAN REPRESENTATIVE
	THIS SIDE UP
	KEEP AWAY FROM RAIN
	DO NOT ROLL
	STACKING LIMITED TO 3
	ROOM TEMPERATURE: 5℃~40℃
	RELATIVE HUMIDITY：≤80%

3 Safety warnings - Read carefully

	Electric shock, fire or equipment damage might happen if you ignore the below warnings

- ⚠ Please use a 3-hole socket, and ensure the socket has been connected well with the ground. Do not put the autoclave in a place where the power is difficult to cut off.
- ⚠ Do not use power with a different voltage from that stated in this manual.
- ⚠ Do not touch the plug or socket with wet hands.
- ⚠ Do not pull, change, over-bend or twist the wires, and do not put heavy things on the wires.
- ⚠ Do not put the autoclave on an unstable table.
- ⚠ Do not block the door of the autoclave, or cover the ventilation holes and radiation holes.
- ⚠ Do not put anything on the top of the autoclave.
- ⚠ If you find any abnormal smell or sound during operation, please cut off the power immediately and contact us or your local distributor.
- ⚠ If you do not use the autoclave for a long time, please cut off the power and store the autoclave in a dry and cool place.
- ⚠ Only plug in the mobile touchscreen from CertoClav into the serial port on the back. No other devices.
- ⚠ Never manipulate the safety devices. Operate only the mobile touchscreen and autoclave of the same series.
- ⚠ Use only in accordance with this manual. Store the manual in a space accessible to all users.
- ⚠ Must not be installed in a space that is subject to the danger of explosions.
- ⚠ Use only with rated voltage.
- ⚠ Only for use in laboratories. Operate only by trained personnel. Do not use in domestic settings.
- ⚠ Do not autoclave tightly sealed containers (especially glass bottles) since there is no pressure compensation.
- ⚠ Fill the water tank with only distilled water.
- ⚠ Please always fill bottles at maximum half full with liquid.
- ⚠ If the pressure is released quickly when autoclaving liquids, there is a possibility that the liquid will boil.
- ⚠ Do not transport when filled. Do not open with force.
- ⚠ This autoclave must only be maintained by CertoClav or authorized retailers. Always use original spare parts.
- ⚠ Use original spare parts from the manufacturer only.

4 Forbidden substances for autoclaving

Never use the autoclave to sterilize any of the following hazardous materials or substances with alkali content. Sterilization of such objects can cause explosion, corrosion of the working chamber or chamber piping, and deterioration of gaskets.

Explosive substances

Nitroglycol, nitroglycerin, nitrocellulose, and other explosive nitric esters.

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

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

Ignitable substances

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

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

Aluminum powder, magnesium powder, and metallic powders other than aluminum powder.

Sodium dithionite (or sodium hydrosulfite).

Oxidizing 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, gasoline, acetaldehyde, propylene oxide, carbon disulfide, and other substances whose flash points range from -30 to 0 C.

Methanol, ethanol, xylene, benzyl acetate (or amyl acetate), and other substances whose flash points range from 0 to 30 C.

Kerosene, gas oil, turpenine oil, isopentyl alcohol (or isoamyl alcohol), acetic acid, and other substances whose flash points range from 30 to 65 C.

Flammable gas (hydrogen, acetylene, ethylene, methane, ethane, propane, butane, and other substances that become gases at a temperature of 60 C at 0.2 bar absolute pressure.)

If liquid with salt water and much salinity of salt agar etc. has been spilled in the chamber, remove all the water in the chamber and wipe up all the water around the lid gasket.

5 Introduction

This autoclave is an automatic vacuum steam sterilizer. The autoclave can perform all kinds of cycles known as class B, class S, and class N autoclaves. The autoclave sterilizes liquids in bottles, hollow bodies of type A and B, porous materials, textiles, double wrapped, single wrapped, and unpacked solid instruments. In material testing mode, the cycles can be performed fully automatically without user interaction. The autoclave has a 7" touch interface and a digital built-in front panel LCD screen; four independent temperature sensors, a flexible media temperature sensor, a high precision pressure sensor, a vacuum pump made-in-Germany, safety valves, an electrical locker, safety switches, and two independent microcontrollers ensure the safe operation and automatic monitoring of the autoclave. The autoclave detects errors automatically. If an error has occurred, the autoclave cuts off power automatically and ensures the safety of the operator.

5.1 Use range of the autoclave

Sterilization:

This autoclave can be used in laboratory practices for the sterilization of liquids, textiles, double wrapped instruments, solid instruments, hollow materials, porous materials, and liquids in bottles. The autoclave can perform class B, class S, and class N cycles.

Automated material testing:

The autoclave has also been designed to perform material tests for any materials and medical products (class B, class S, and class N cycles). With an RO System (order number 8500499), the autoclave can automatically perform up to 300 cycles without any need for user interaction. The status of the autoclave can be monitored via network. The autoclave alarm system sends notifications via sound, SMS, and email.

5.2 Technical data

- Environmental temperature: 5℃～40℃
- Relative humidity: ≤80%
- Atmospheric pressure: >70kPa;
- Voltage: 230VAC, 50Hz, 2500VA
- Maximum working pressure: 0.21～0.23MPa
- Maximum working temperature: 134～137℃
- Life span of the autoclave: +10 years

5.3 Requirements of transportation and storage

- Environmental temperature range: 5~40℃
- Relative humidity: ≤80%
- No corroding gases

5.4 Dimensions and weight

Net weight of the autoclave	
Model	Net weightt
CV-12-C-Pro	47,70 kg
CV-18-V-Pro	50,25 kg
CV-22-V-Pro	53,50 kg

6 Scope of delivery

Please check the product box for the following items

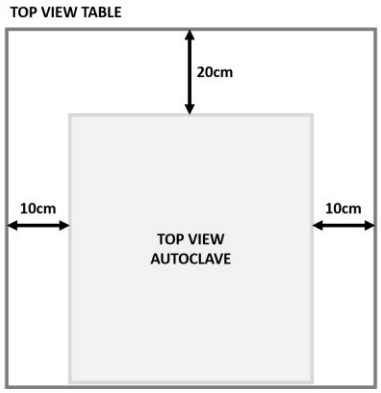
Position	Description	Quantity
1	Autoclave	1
2	Quick-connect drain water hose	1
3	Tray set: 1 x tray holder 3 x tray 1 x tray frame	1
4	Power cable for autoclave	1
5	RS232 cable for autoclave	
6	User manual	1
7	Interface box	1
8	Touchscreen	1
9	Power cable for touchscreen	1
10	Stand bracket for touchscreen including four screws for mounting	1
11	Guarantee card	1
12	Safety test report	1

7 Installation and commissioning

7.1 Unpacking the autoclave

1. The autoclave is packed in a wooden carton.
2. Use a flat screwdriver to open the cover.
3. Take out the user manual, guarantee card, touchscreen, and accessories.
4. The autoclave can be lifted out by two persons.

7.2 Installation of the autoclave



6. When installing the autoclave on top of a table, please keep the autoclave at least 10cm away from anything in the surrounding area. The table must be able to resist at least 65kg weight. Keep the rear side of the autoclave at least 20cm away from the surrounding wall. It is recommended to install the autoclave in a well-ventilated location. Don't block the radiator of the sterilizer. Keep the table stable, flat, and horizontal.

7. Open the autoclave, take out the tray set and the accessories out of the chamber to unwrap it.

8. Mount the stand bracket to the touchscreen with four screws. The screws are included with the stand bracket.

9. The assembled touchscreen must look like the screen in the following picture.

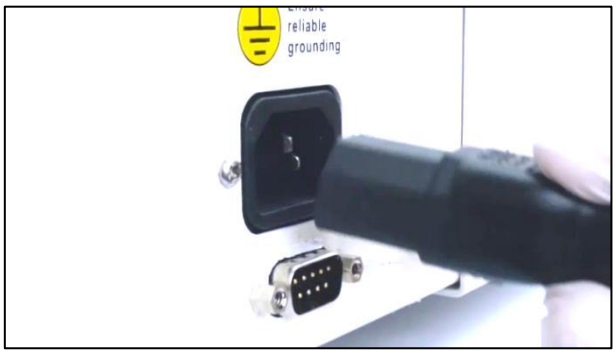
10. Connect the Touch PC universal connector with the interface box.

11. Connect the power supply of the touch PC with the interface-box.

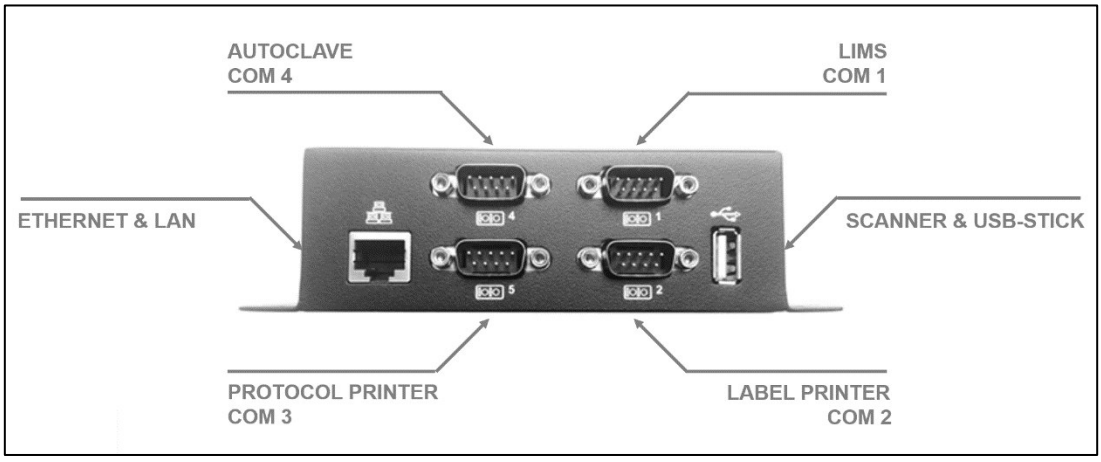
12. Place the touchscreen only on level, stable surfaces. The waterproof industrial touchscreen can be placed on top of the autoclave or next to it.

⚠	Please ensure that the table of installation is strong enough for an autoclave including water and load weight.

13. Plug in the power cable to the back of the autoclave. Note: Please check if the power input specification on the nameplate of the autoclave fits the power source specification. Ensure proper grounding. Check if the fuses on the rear of the autoclave are switched to the upper position. Turn on the autoclave base unit.



14. Connect the COM 4 RS232 cable with the RS232 port on the back of the autoclave.



15. Turn on the touch screen.

16. If the login screen appears after a few seconds, the touchscreen has been connected correctly.

17. If a connection error message appears on the touchscreen, the touchscreen is not able to connect to the autoclave. Please check to see if the touchscreen has been connected correctly with the COM 4”cable. If the problem still remains, please perform a factory reset on the touchscreen. Navigate to Settings -> Device->Factory Reset and confirm the warning dialog.

7.3 Installation of optional accessories

7.3.1 Connection of the protocol printer

Connect the protocol printer with the COM 1 port of the interface box.	

7.3.2 Connection of the barcode scanner

Connect the barcode scanner with the USB-host connector of the interface box.	

7.3.3 Connection of the label printer

Connect the label printer with the COM 2 port of the interface box.	

7.3.4 Connection of the R/O System

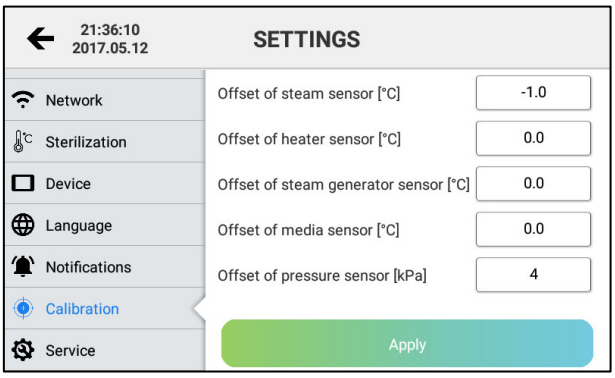
Follow the instructions of the user manual of the CertoClav R/O System.	

7.4 Atmospheric pressure adjustment

Because every place of installation has a bit different level of atmospheric pressure, the user shall adjust the atmospheric pressure before first use of the autoclave.

Adjustment method:

1. Power on the autoclave and touchscreen.
2. Open the door of the autoclave.
3. Navigate to Settings->Calibration.



Enter an offset for the pressure sensor in [kPa] so that the blue front panel LCD screen shows a pressure of 0 kPa. For example: If the blue front LCD screen shows a pressure of +5 kPa, then enter a value of -4 kPa into the offset field. Press the Apply button to save the parameters permanently.

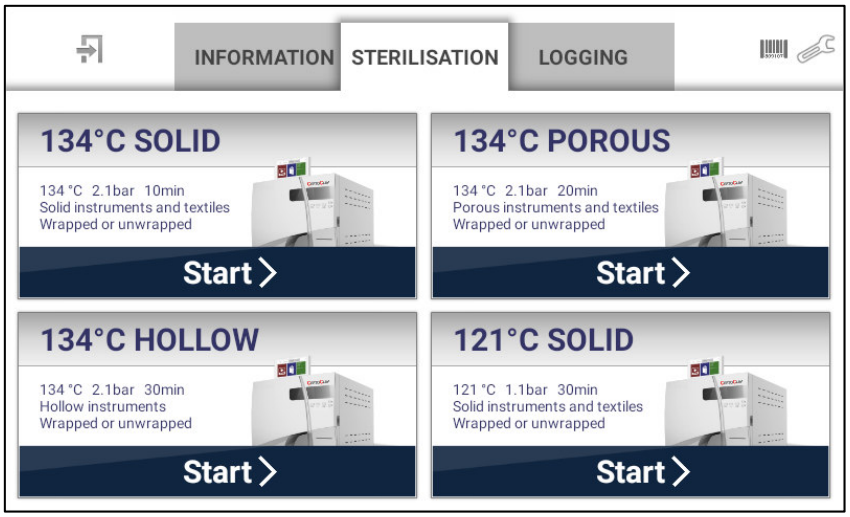
⚠	The autoclave might not run if the user does not adjust its atmospheric pressure before first use..

7.5 Validation and calibration

All the sensors of the autoclave were validated on the date of manufacture. For calibration purposes, the autoclave has a G1/4 calibration port on the chamber. If calibration in the place of installation is required, please contact your distributor, or directly support@certoclav.com to get a detailed service manual with instructions for the validation and calibration of the internal sensors.

8 List of available sterilization programs

Program name	Number of Pre-vacuum times	Sterilizing time [min]	Sterilizing temperature [°C]	Sterilizing pressure [kPa]	Vakuum persist time [min]	Drying time [min]
121°C SOLID	1	20	121	110	-	3
121℃ POROUS	3	20	121	110	-	7
121℃ HOLLOW	3	20	121	110	-	10
134℃ SOLID	1	4	134	210	-	3
134℃ POROUS	3	4	134	210	-	7
134℃ HOLLOW	3	4	134	210	-	10
USER DEFINED	1-10	1-60	105-134	20-210	-	0-40
B&D TEST	3	3.5	134	210	-	7
VACUUM TEST	-	-	-	-80	15	-
CLEAN	3	5	105	20	-	10
PRIONS	3	19	135	210	-	10
LIQUID	-	20	121	110	-	0



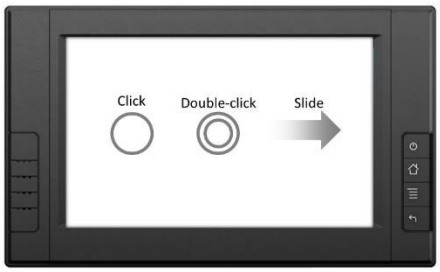
- The 121°C programs and 134°C programs have no difference in sterilization results. If the instruments cannot be sterilized in 134 °C, please choose the 121°C program. The program parameters: the number of pre-vacuum-times, sterilizing time, sterilizing temperature, sterilizing pressure, and drying time can be adjusted.
- The 121°C Solid and 134°C Solid programs can only sterilize solid instruments which are not wrapped. For example, cleaning pistols, bottles, peelings, pliers, and forceps. The program parameters: the number of pre-vacuum-times, sterilizing time, sterilizing temperature, sterilizing pressure, and drying time can be adjusted.
- The 121°C Porous and 134°C Porous programs can sterilize materials that are made of porous material. The program parameters: the number of pre-vacuum-times, sterilizing time, sterilizing temperature, sterilizing pressure, and drying time can be adjusted.
- The 121°C Hollow and 134°C Hollow programs can sterilize the hollow bodies of types A and B according to EN ISO 13060. The program parameters: the number of pre-vacuum-times, sterilizing time, sterilizing temperature, sterilizing pressure, and drying time can be adjusted.

- For the User-Defined program, the program parameters are: the number of pre-vacuum-times, sterilizing time, sterilizing temperature, sterilizing pressure, and drying time can be adjusted. The User Defined program can't be used for liquid sterilization with a media temperature sensor.
- The B&D Test (Bowie-Dick Test) is a test to measure the performance of the pre-vacuum of medical class b steam sterilizers. The test simulates a load of 7 kg tightly bundled textiles. Please check the color indicator of a B&D test indicator for B&D validation. The B&D test program must also be used for the Helix test. For the Helix test, a process challenge device (PCD) must be used for validation.
- The Vacuum Test is an air leakage test. The vacuum test must be started after installation and maintenance. Regularly performing the vacuum test is recommended.
- The Clean program is for cleaning the autoclave and loads. If the autoclave shows "Need Clean" on the front LCD panel, then run the Clean program. The Clean program can be used to clean loads.
- Prion program: This program is to sterilize prion contaminated materials, rubbish, and instruments.
- Liquid program: The sterilization of liquids, filled in open bottles. It's recommended to place the flexible media sensor into one reference bottle with liquid. Only in this case, can a proper sterilization of liquids be guaranteed and stored into the protocol. Please fill the bottles only half-full to avoid the risk of scalding during removal of the bottles after sterilization.

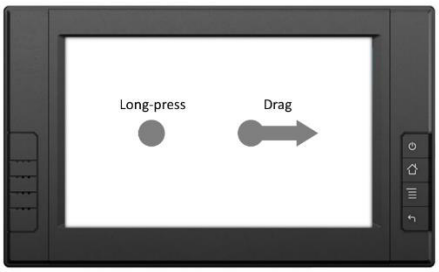
	The Bowie-Dick Test is not to be considered a biological performance test. It is intended only to forewarn the user that the air removal system has deteriorated during performance and should be corrected before sterilization problems occur as indicated by a biological indicator failure.
	Please don't put sealed bottles, bags or containers in the autoclave. They can explode because of too much pressure.
	It is recommended to do a vacuum test every month. If the result is FAIL, do not use the autoclave anymore and call your local distributor, or support@certoclav.com directly.

9 Basic operation

Click and slide

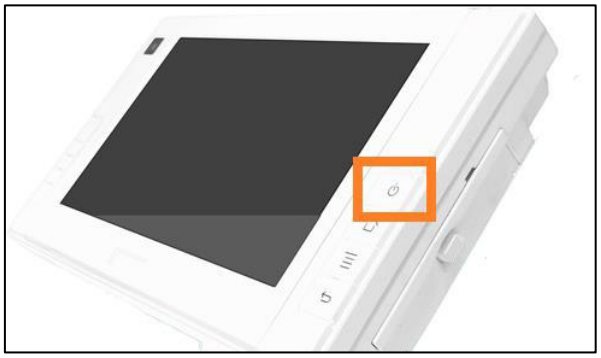


Long-press and drag



9.1 Turning on the autoclave

1. Press the ⏻-button at the front right of the touchscreen for at least three seconds.
2. Turn the green power switch of the autoclave on.



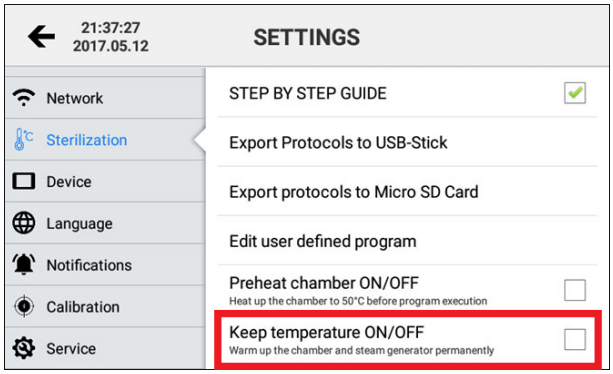
9.2 Turning off the autoclave

Please press the ⏻ button at the front right of the touchscreen for at least three seconds. A notification window will pop up. Please select the Turn Off option, in order to turn off the touchscreen.

9.3 Turning the autoclave into stand-by

Give a short press of the ⏻ button at the front right of the touchscreen. The background light will be switched off. Press the ⏻ button again to wake up the touchscreen.

You can keep the chamber of the autoclave at 50°C for at maximum six hours in stand-by to optimize the batch time. To activate or deactivate this function navigate to Settings->Sterilization->Keep Temperature ON/OFF, and activate the Checkbox.



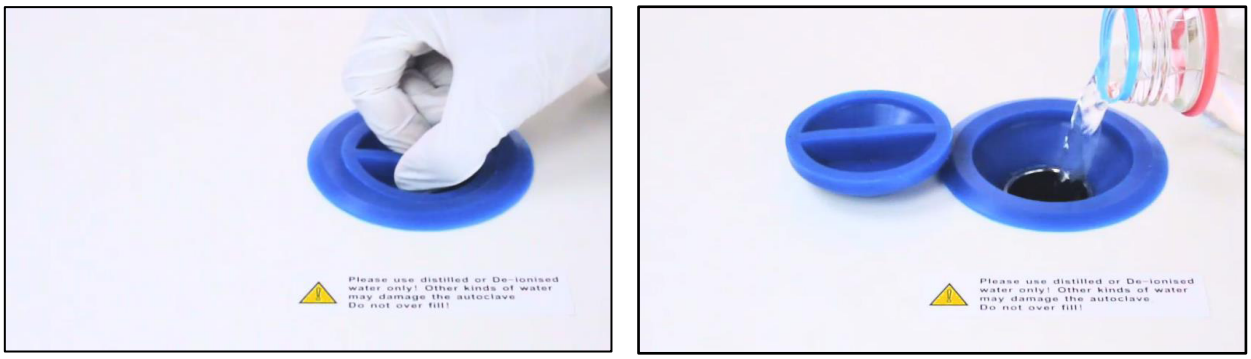
10 Instructions for daily use

10.1 Preparation

1. If the autoclave is turned off, turn on the autoclave (See Chapter 9.1)
2. If no error, warning or notification is visible on the screen, the autoclave is ready to use.

⚠	Please ensure the autoclave is well grounded.
⚠	Before the first usage, the touchscreen will display the notification “Please fill water in the autoclave”. As soon as the water is filled, the message will disappear and the autoclave is ready to use.

10.2 Refilling water (Stand-alone)



If the LCD shows “Please fill water”, the water inside of the autoclave is not enough to start a new sterilization cycle. It is required to fill it with water before starting a new sterilization cycle. If the LCD shows the message “Please fill water” during a sterilization cycle, it is not required to stop the current sterilization cycle because the water inside of the autoclave is still enough for the current cycle. But to start the next cycle, it’s required to firstly refill the water. To refill the water, open the water tank lid on top of the autoclave and fill with distilled or de-ionized water only. See picture above.

While refilling water, a peep sound notifies the user that the minimum amount of water to start the next cycle has been reached. The user can stop or continue filling the water. Please be careful not to overfill the clean water container. If the water tank has been overfilled, it is possible to drain the water from the quick-connect drain connector on the front of the autoclave.

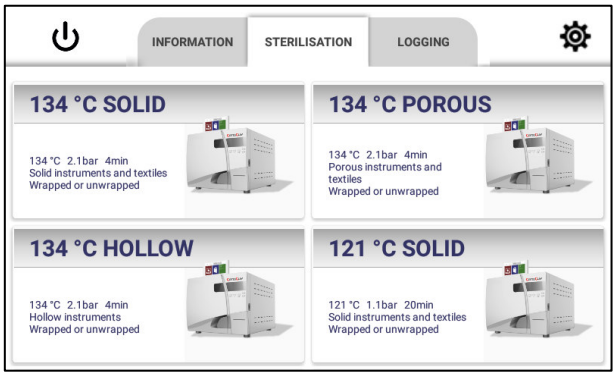
⚠	Only distilled water can be used for this autoclave. Otherwise, there will be a problem with the steam generator and solenoid valves. The user shall be responsible for the problem if he/she uses other kinds of water.
⚠	Before filling the water, please turn on the autoclave and ensure the autoclave is horizontal. After filling the water, if possible, please drain the waste water.
⚠	Only fill demineralized or distilled water in the fresh water tank. A water quality sensor continuously monitors the water quality of the filled water. A warning notification appears on the integrated LCD screen if the quality of the filled water isn’t good enough.

10.3 Steps to start a cycle

If the touchscreen doesn't show any errors or warnings, the autoclave is ready to work.

10.3.1 Selection of a program

1. After login, navigate to the sterilization tab.
2. In the middle four programs are visible. Please scroll the vertical scrollable list down to browse through all twelve available programs.
3. Click on the Start button to choose and start a program.
4. Please confirm the dialog to start the program.
5. If CertoTrace is enabled, the tracing assistant will be opened.
6. If the step-by-step guide is enabled, a video step-by-step guide will be shown.

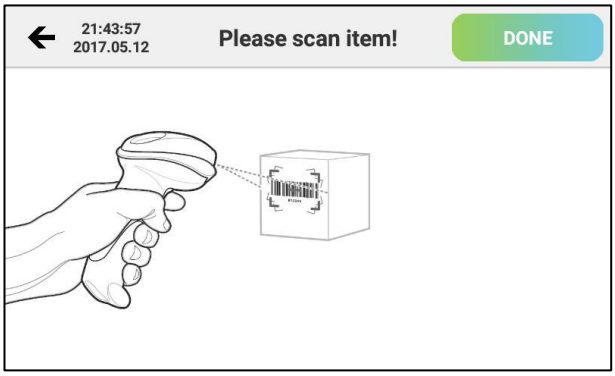


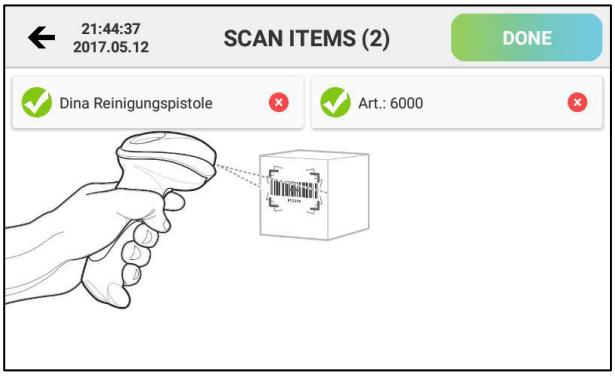
10.3.2 CertoTrace – Decontamination process documentation

CertoTrace is a feature, enabling simple and professional documentation across the whole instrument decontamination process.

7) If CertoTrace is enabled (Settings -> Sterilization -> CertoTrace Load Documentation), the CertoTrace assistant will be shown after starting a program. Please note: The CertoClav barcode scanner and label printer is necessary in order to take advantage of the CertoTrace load documentation system.

8) Please scan the barcode of the items, which are going to be placed into the autoclave chamber.





9) After scanning an item, it will appear on a scrollable list of items, shown in the CertoTrace assistant menu. The item name and article number will be stored into the forgery protocol record.

10) After scanning all items, press the Done button.

11) To cancel the CertoTrace Assistant, press the Back button on the top left corner of the screen.

12) Please note: If no barcode label for a specific item exists yet, the user can use the label printer designer tool to print custom labels. Label printer designer is located under Settings-> Sterilization-> Label printer designer.
13) If enabled, the step-by-step guide will be shown after pressing the Done button.

10.3.3 Step-by-step guide

If the step-by-step guide is enabled (Settings -> Sterilization -> Step-by-Step Guide), the step-by-step guide will be shown after choosing a program. The step-by-step video assistant will guide the user through all the necessary steps to prepare and load the autoclave correctly.

Press the Next Step button to navigate through the open monitoring menu.

10.3.4 Load the autoclave

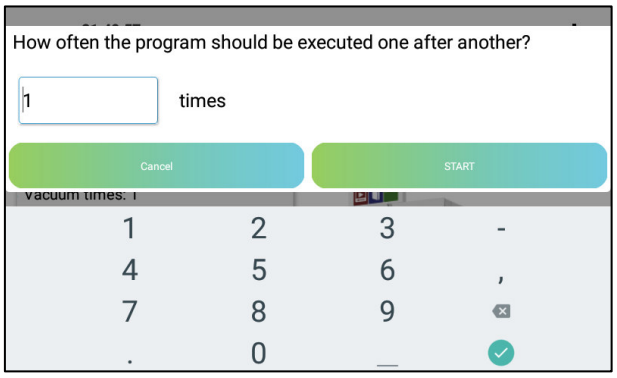
⚠	Make sure that the volume of the load is smaller than 70% of the volume of the chamber.
⚠	Use the supplied tool to take out the load. This is necessary to protect hands from burns.
⚠	There must be at least 10mm space between the wall and the load.
⚠	If you do a B&D test, you need to put the test paper at the center of the sterilization package to ensure a reliable test result.

10.3.5 Close the autoclave's door

⚠	If the temperature and pressure inside the chamber are high, the door will be difficult to close. We suggest closing the door quickly, or, you can wait thirty seconds, then close the door.

10.3.6 Material testing mode – Automatic repeating start

If material testing mode is enabled (Settings -> Sterilization -> Material-Testing Mode), the autoclave will ask how often the chosen program should be executed after another fully automatically.



It is possible to enter any desired number from 1 to 1000. If a warning or error occurs during execution, the autoclave is able to report to service staff of your choice via E-Mail and SMS.

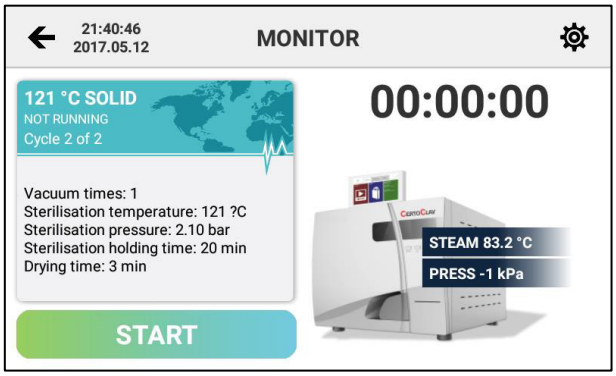
If the user is registered at CertoCloud, which is a free autoclave management software for this autoclave, the live-status and protocol information about each recorded cycle will be automatically uploaded to the CertoCloud. The user can access the CertoCloud via www.certocloud.com from a PC, tablet PC, and smartphone to check the current status of the material test.

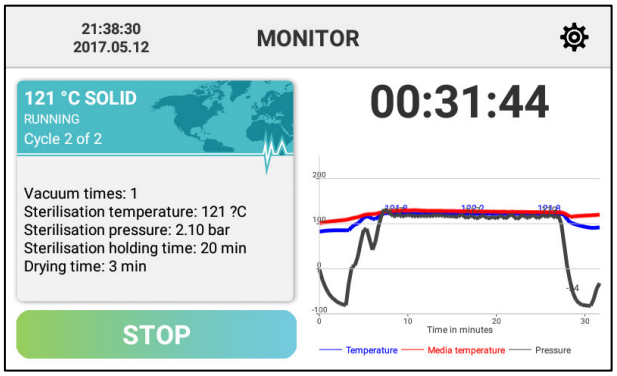
We recommend ordering the CertoClav R/O-System (Order number: 8500499) together with the autoclave in order to take maximum advantage of the material testing mode. The R/O System refills the autoclave fully automatically with distilled water, so that no staff are necessary to operate the autoclave during the test.

10.3.7 Autoclave status screen

During program execution, 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 level are visible. If the liquid program has been started, the liquid temperature is also visible.

To show a graphical view of the temperature and pressure profile of the current cycle, please hold your finger on the autoclave and swipe it to the left. Then, a graph of the logging history becomes visible.





10.4 Unload the autoclave

When the sterilization cycle is finished, a message on the screen will show “Program finished – Please open door”. A notification alarm sounds three long beeps. The user can then open the door and take out loads inside the chamber.

⚠	You shall use a tray-holder tool when taking out loads to prevent scalding your hands. Don’t open the door until the pressure is within a range from -05 kPa to +05 kPa.
⚠	To ensure the effectiveness of sterilization, during daily use, we suggest putting test paper or pouches with indicators together with the loads into the sterilization chamber.

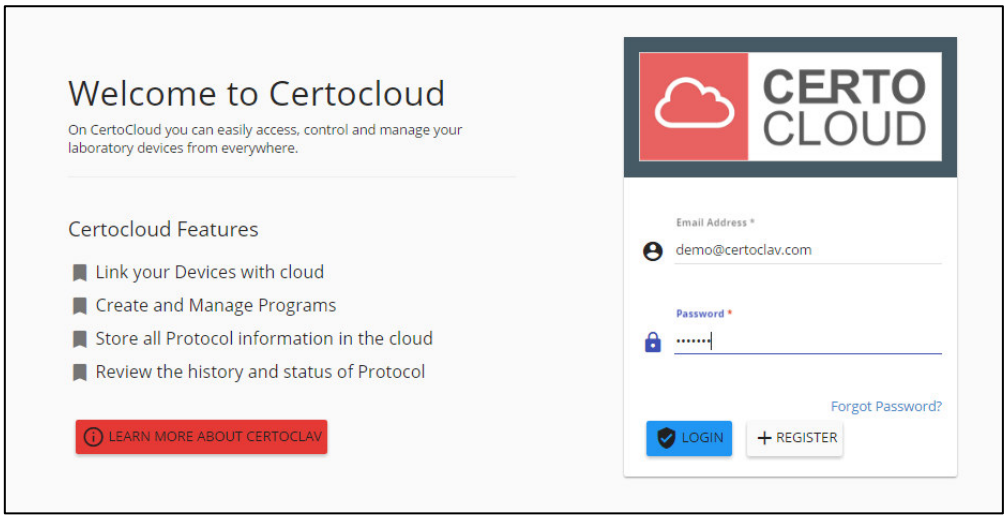
10.5 Drain water from the waste water tank

If the LCD shows “Please drain water from the waste water tank!”, the waste water tank is full, the user must drain the waste water.

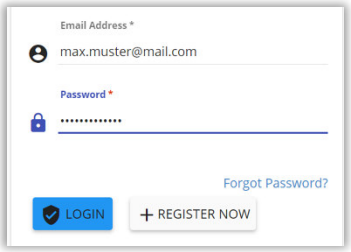
⚠	The waste water might be very hot, so please be careful when draining.

10.6 CertoCloud software

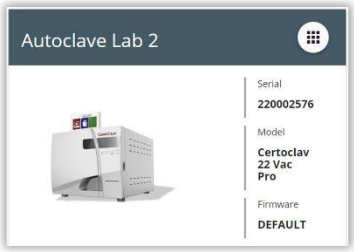
CertoCloud is a web-based management software for your autoclaves. CertoCloud can be reached at on any browser at www.certocloud.com via PCs, Smartphones, and Tablets.



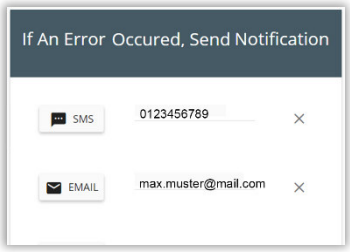
Register a user account, direct at the autoclave, or via web-interface www.certocloud.com.



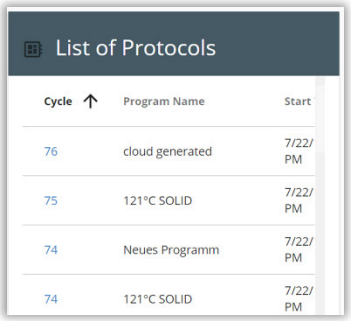
View real-time data of the autoclave via web-interface



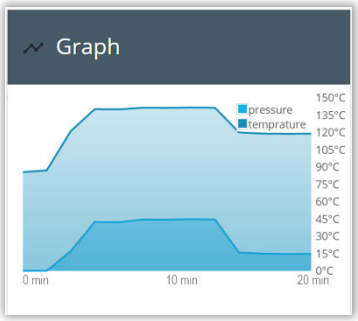
Management of SMS and e-mail notifications.



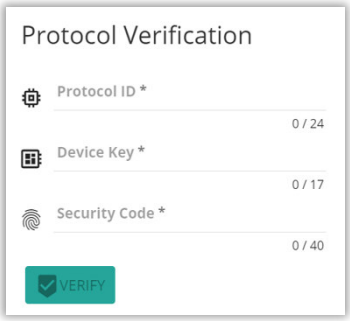
Download all sterilization protocols as signed PDF, Excel, or ZIP file.



Graphical view of all sterilization records

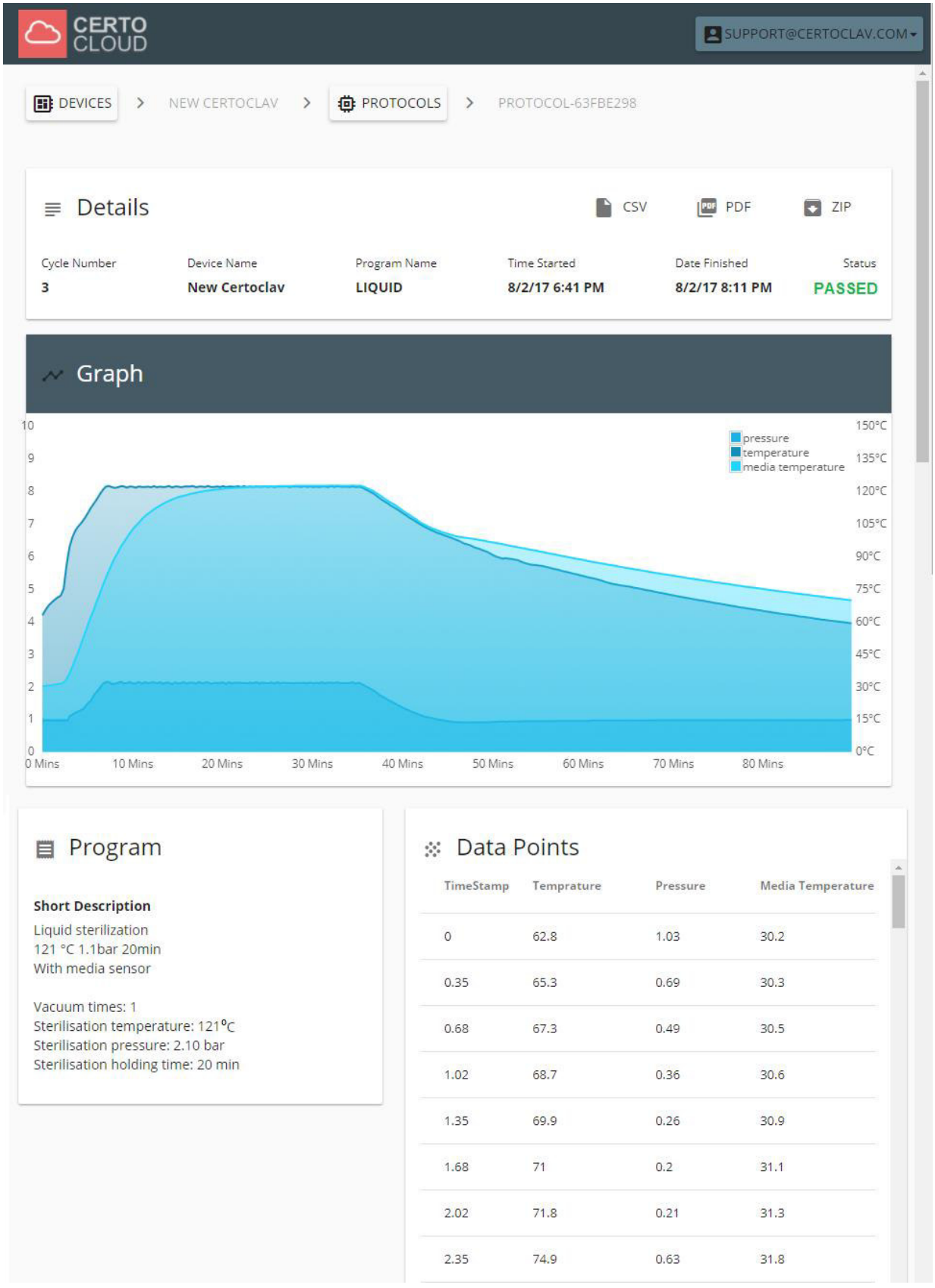


Verify authenticity of downloaded protocols



10.6.1 View protocol from web-browser

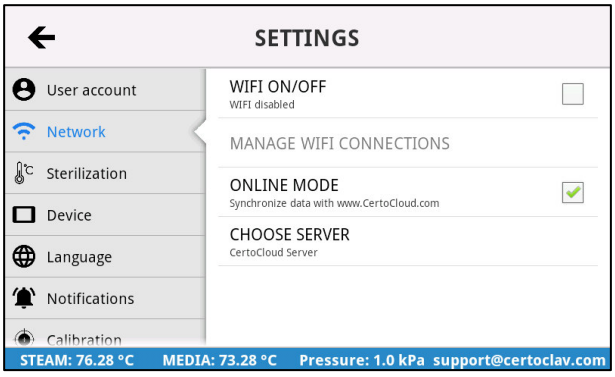
Example protocol from web-based CertoClav software.

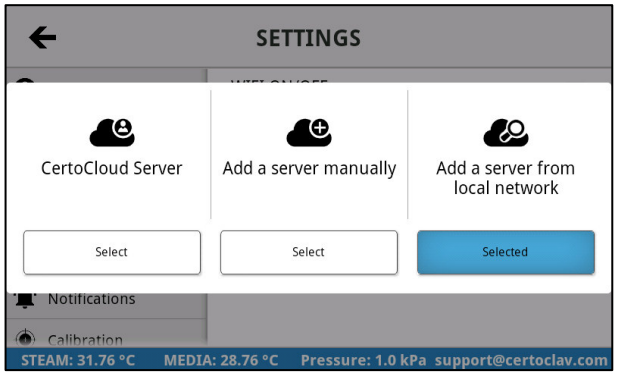


10.7 Connect to the CertoClav local server

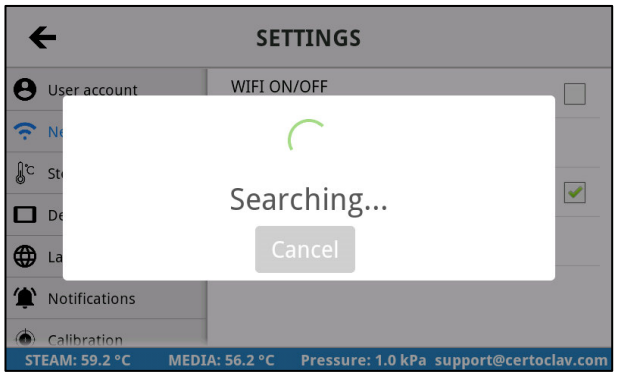
To connect with the CertoClav local server, a CertoClav server is required.

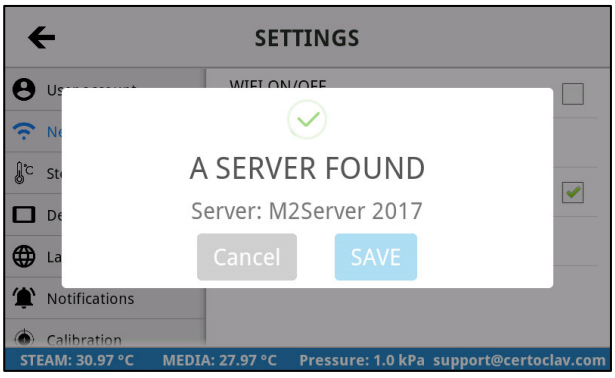
7. Plug the ethernet cable into the CertoClav interface box to connect the autoclave with the local area network. Make sure that the CertoClav server is connected with the same network via a switch or router.
8. Navigate to Settings->Network->Choose Server.
9. Choose the option: “Add a server from local network.”





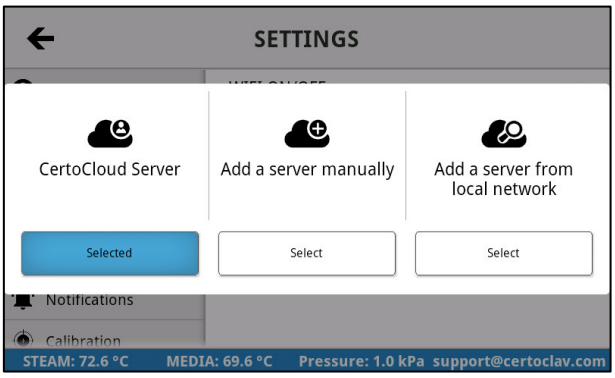
1. The autoclave searches the CertoClav server in the local area network.





1. After the CertoClav local server was found, press the Save button.

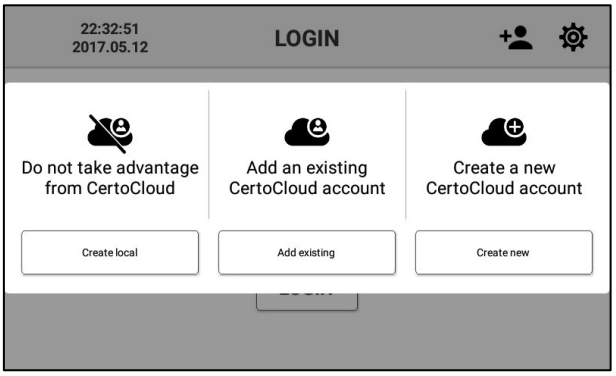
If the internet connection is available, the CertoCloud online server is available. To enable communication with the CertoCloud server navigate to Settings->Network->Choose Server and select the CertoCloud Server option.



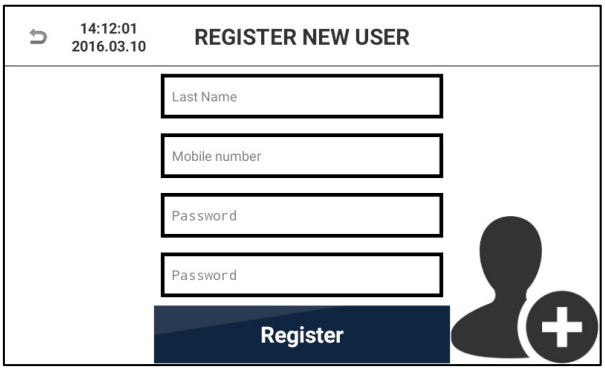
11 Autoclave menu overview

11.1 Login menu

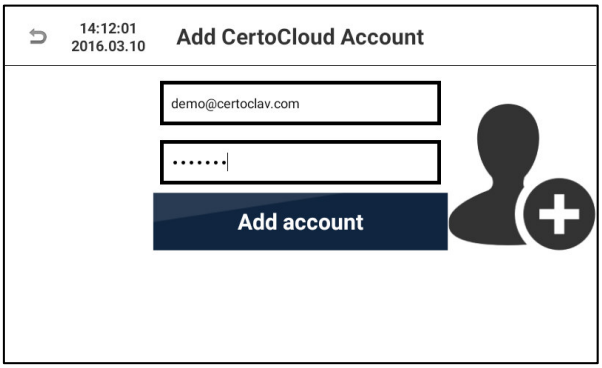
After switching the Certotouch on, the login window will appear. In order to log in with the administrator account, enter the standard password “admin”. This password can afterwards be changed in the user settings. To log in with your personal account, click on the user name and choose your email address from the list.



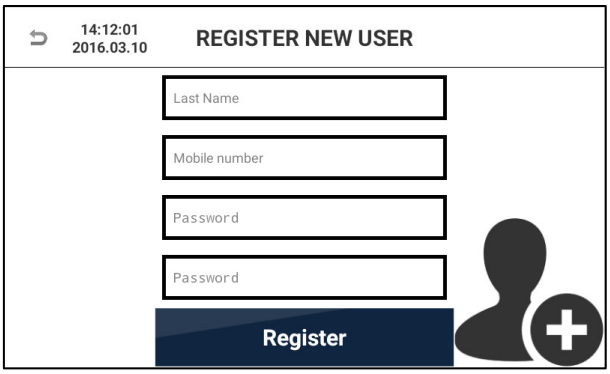
To add an existing CertoCloud account or to create a new user account click on the button at the top right of the screen. A dialog appears. To create an account without a CertoCloud connection, press the Local button. To add an existing CertoCloud account to the device, press the Existing button. If you don’t have a CertoCloud account yet, press the Create New button. To create a new CertoCloud account, an internet connection via ethernet or Wifi is required.



To create a local account, enter your user date. The text fields can be selected and edited by clicking on the text field. Enter the complete mobile phone number including the international prefix. This number is necessary if the status messages per SMS are enabled. Please choose a password with at least four characters and retype it. Confirm the user registration by clicking the Register User button. To abort the registration, press the Back button. To complete the registration, press the Register button



To add an existing CertoCloud account, enter your e-mail address and password. Afterwards press Add Account to confirm the account. To abort the registration, press the Back button on the left-top of the screen.



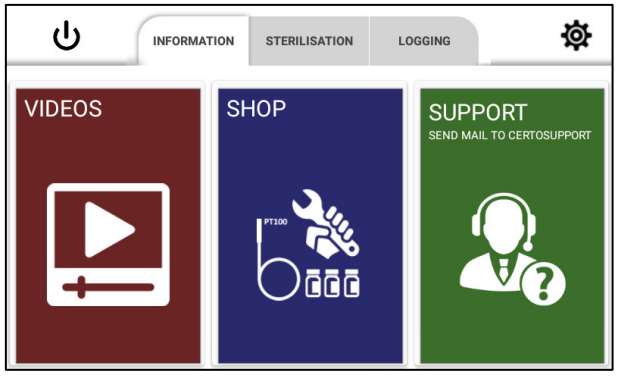
To create a new CertoCloud account, enter your user data into the appropriate text fields. Please enter your phone number with the international prefix. To validate your phone number and e-mail address, an e-mail and an SMS will be sent to your e-mail and your phone. Please enter your password twice and press the Register button.

To login with the created user account, choose your email address from the list and enter your password. Please make sure that the online mode is enabled. The online mode settings can be found under: Settings->Network->Online Mode.

If you log in for the first time, you will be asked for an activation key. You received the activation key via e-mail and via SMS, after registering for the CertoCloud account. Please enter the activation key in the text field and press the Activatie Account button. Your CertoCloud account is now activated and you can use the CertoCloud account with your autoclave.

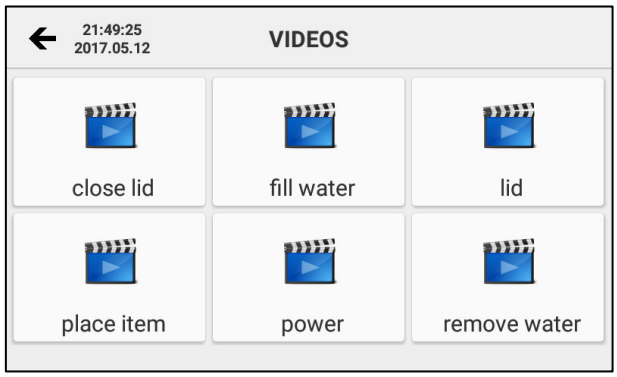
11.2 Information menu

Navigate to the Information tab to contact CertoSupport via email directly from the touchscreen. It is also possible to watch step-by-step videos and open the CertoClav web shop.



11.2.1 Tutorial videos

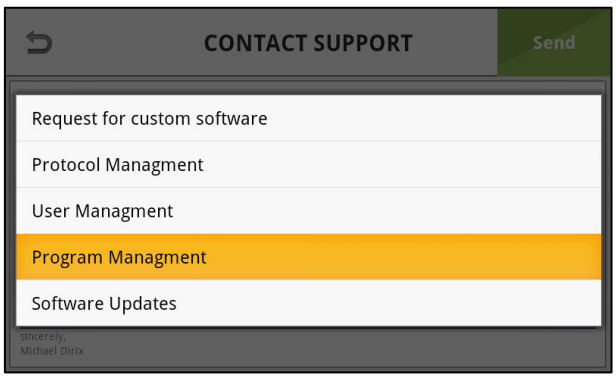
To scroll through the list of available videos, click on the video section in the information tab. Click on the desired video to watch the video in full screen.



11.2.2 How to send an email to CertoSupport

The device must be connected to the internet to send an e-mail to CertoSupport directly from the device. To connect the device to the internet you can use the ethernet port of the device or a WiFi network.

Click on the Support button to open the e-mail window.

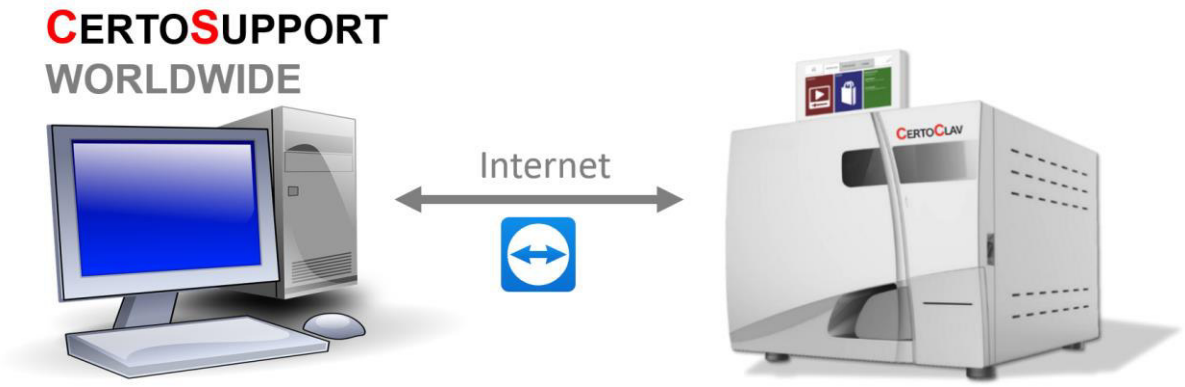


Choose a subject for your message to CertoSupport from the drop-down menu.

Afterwards enter your message to CertoSupport in the message text field. To send the message, click on the Send button. A reply to your request will be sent to the e-mail address of your autoclave account within twenty-four hours.

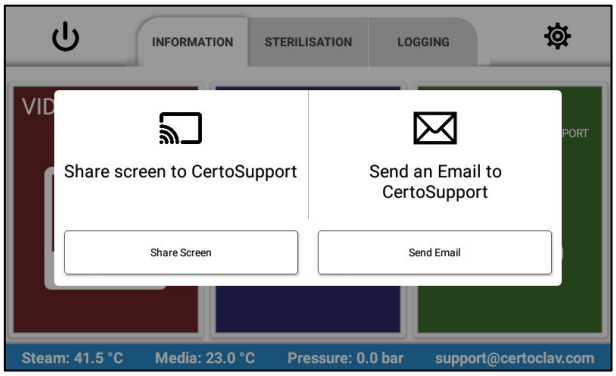
11.2.3 TeamViewer remote support via screen sharing

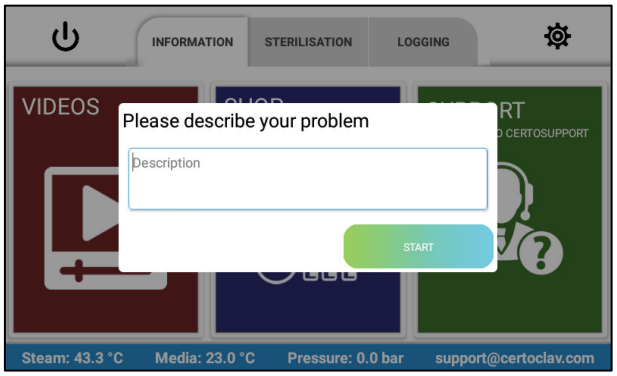
To start a TeamViewer screen-sharing session with CertoSupport, navigate to the Information tab and press the Support button. On the following dialog, choose the screen-sharing option. The TeamViewer request will only be accepted if a specific time has been agreed to by your distributor or CertoSupport via e-mail or phone. To request a time-frame for the TeamViewer session, please navigate to the Information tab and press the Support button. Choose the option to send an e-mail to CertoSupport and ask for a time-frame. Generally your request will be answered within twelve hours.



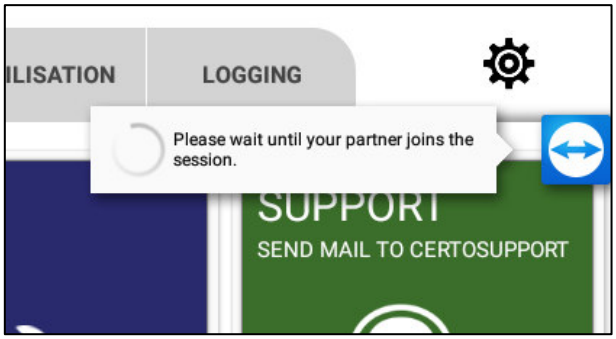
Navigate to the Information tab and press the Support button on the right side of the screen. A dialog will open and ask for the desired method of support. If you don't have an agreed time-frame for TeamViewer screen-sharing with CertoSupport yet, please choose the Send Email option and ask CertoSupport for a screen-sharing appointment. If you already have an appointment for a screen-sharing session with CertoSupport or your distributor, then choose the Share Screen option.

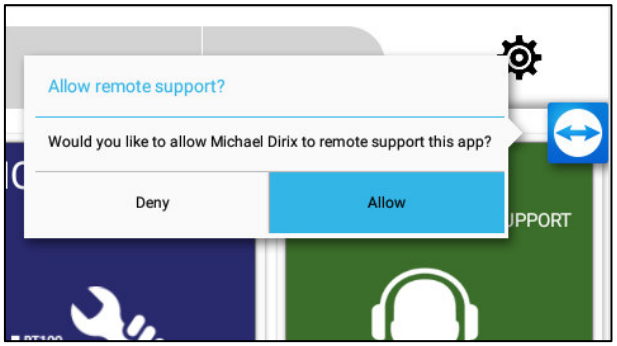
A window will appear, where you can add a problem description to your screen-sharing request optionally.





Press the Submit button and wait until CertoSupport joins the screen-sharing session. In order to share the autoclave screen, press the Allow button. CertoSupport is unable to control the autoclave remotely. To cancel a running screen-sharing session, drag the TeamViewer icon from the bottom of the screen.

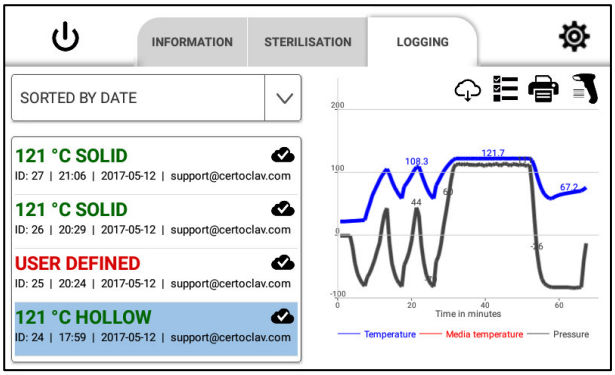




11.3 Logging menu

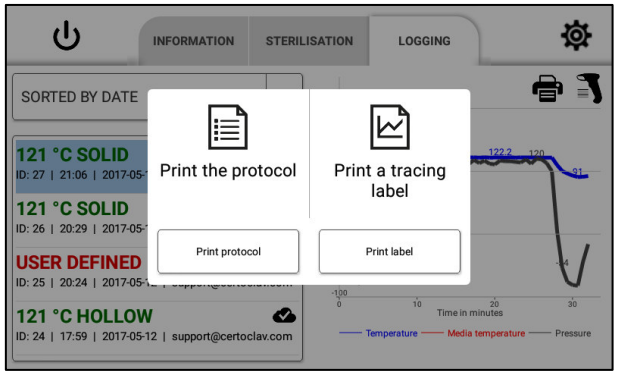
11.3.1 View protocols

Navigate to the Protocols tab to view the sterilization protocols. A list on the left side of the screen shows all the recorded protocols. The cloud icon in the protocol list indicates if the protocols are synchronized with the CertoCloud (www.certocloud.com), or with the CertoClav local server. Click on a list element to show a graphical view of the protocol. To show the protocol as a list, press on the List icon above the graph. The time-stamp from program should start within minutes, and the chamber temperature, media temperature, and pressure in the [kPa] are shown. If the program has finished successfully, the protocol entry is shown in green. If the program has been cancelled, the protocol entry is shown in red.



11.3.2 Print protocols

5) Navigate to the Logging Tab.
6) Scroll to the protocol of your choice in the protocols list on the left side of the screen.
7) Press on the protocol list entry to show a detailed view on the right.
8) Press the Print button on the upper right of the screen to open a print dialog.
9) Press the Print Protocol button to print the protocol via the protocol printer.



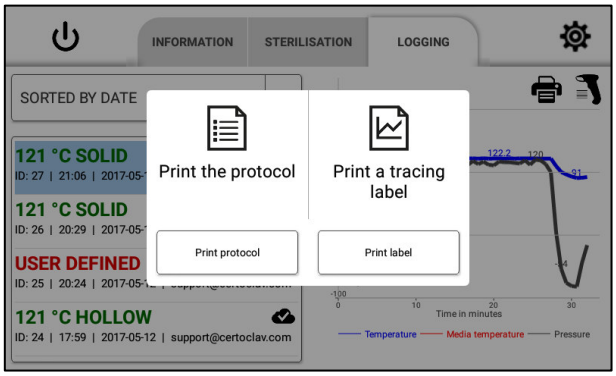
11.3.3 Example printout

```
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 Print the tracing label

5) Navigate to the Logging Tab.
6) Scroll to the protocol of your choice in the protocols list on the left side of the screen.
7) Press on the protocol list entry to show a detailed view on the right.
8) Press the Print button on the upper right of the screen to open a print dialog.
9) Enter the date of expiration of the sterilized item. Per default it is set to six months.
10) Press OK to print the label, including the tracing barcode.



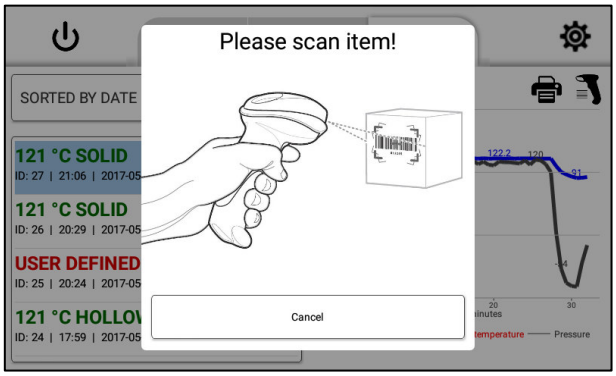
11.3.5 Tracing labeled items

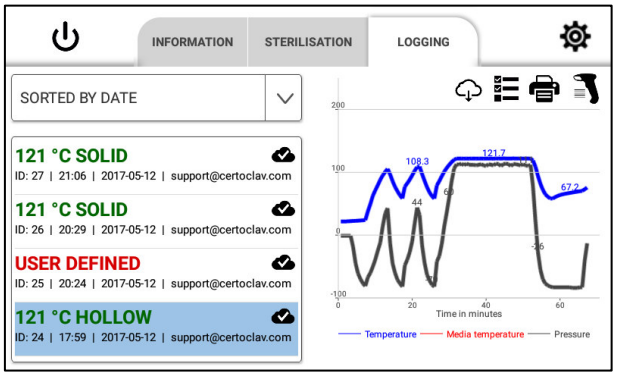
11) Navigate to the Logging tab.

12) Press the Scan icon on the top right of the window.

13) A pop-up window will appear. Please scan the barcode of the labeled sterilized item with the barcode scanner.

14) The protocol of the sterilized item will be highlighted on the left of the screen. On the right side of the screen you can see the graphical view of the protocol. If the sterilization cycle was not successful, an error notification will be shown on the right side of the screen.

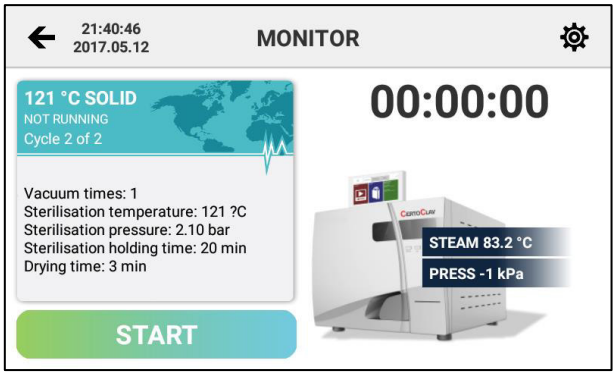


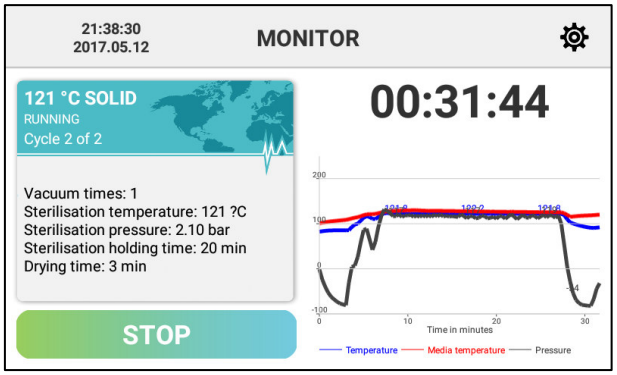


11.4 Monitor menu

During the program's execution, the autoclave monitor 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 level are visible. If the liquid program has been started, the liquid temperature is also visible.

To show a graphical view of the temperature and pressure profile of the current cycle, please hold your finger on the autoclave and swipe it to the left. Then, a graph of the logging history will become visible.





12 Autoclave settings

12.1 User settings

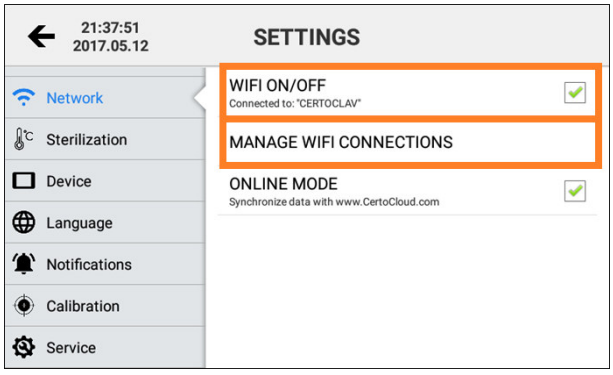
1. Navigate to the Settings menu by clicking the button at the top right corner of the screen.
2. Press User Management to view all user accounts.
3. Press the Edit button to change the user data and the password. You can only modify the account that is currently signed in.
4. Press the Delete button to delete the account.

12.2 Network settings

1. Navigate to the Settings menu by clicking the button at the top right corner of the screen.
2. On the left side of the Settings window, press the Network list entry.

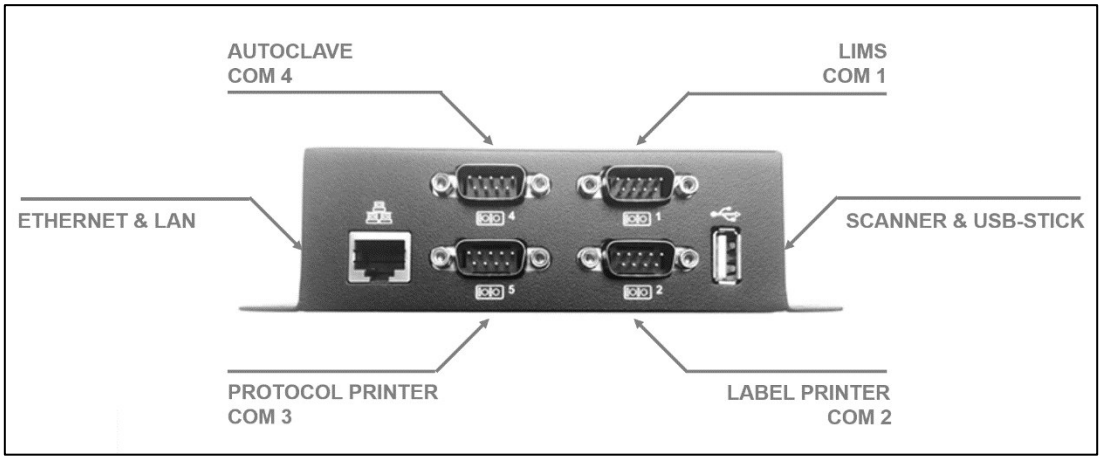
12.2.1 Connect to WIFI network

1. Navigate to the Settings menu by clicking the button at the top right corner of the screen.
2. On the left side of the settings window, press the Network List entry.
3. If the WIFI ON/OFF checkbox is deactivated, click on the checkbox to activate WiFi.
4. Afterwards click on the Manage WiFi Connections entry to show a list of the available networks. Press on a WiFi network to enter the password and further parameters. The WiFi network will be saved. The autoclave will connect to wireless automatically.
5. Press the Return button on the right side of the screen to close the WiFi settings and return to the the settings window.



12.2.2 Connect to LAN

The autoclave can be connected to a local area network and internet via an ethernet cable. Plug the ethernet cable into the ethernet socket on the extension cable.

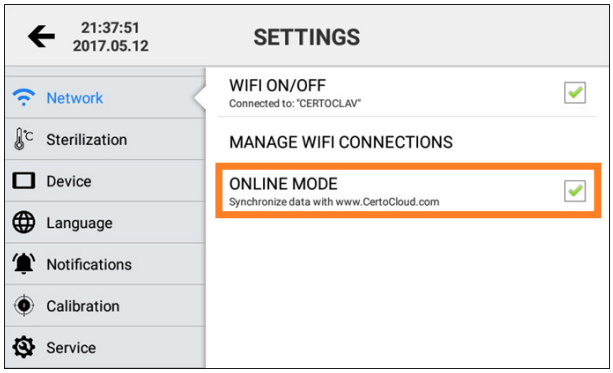


12.2.3 Enable or disable online mode

If the user creates a CertoCloud account directly on the device or on www.CertoCloud.com, a backup of all their protocols and parameters can be saved to the secure CertoCloud online storage. In the Settings menu it is possible to enable or disable communication with the CertoCloud:

1. Navigate to the Settings menu by clicking the button at the top right corner of the screen.
2. Press the Network entry.
3. Press on the Online Mode entry to check or uncheck the Online Mode checkbox. A checked checkbox means that the online mode has been enabled.

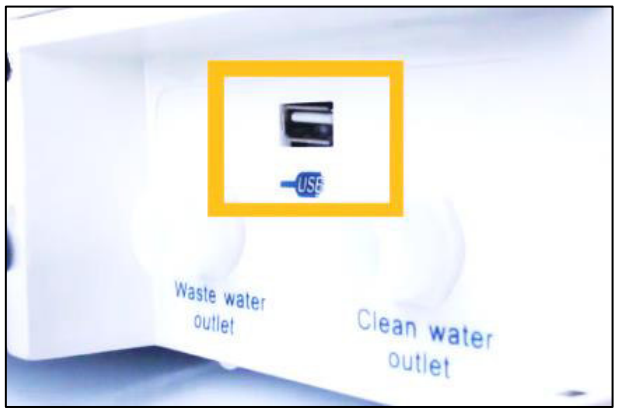
Please note: In offline mode, no backup of the protocols will be uploaded to CertoCloud. In this case, the protocols are stored locally on the autoclave only. If the user wants to create a backup of their protocol data, it must be done manually via a USB stick, SD card or printer. If the user enables the online mode, all local protocols that have not yet been uploaded to CertoCloud will be uploaded.



12.3 Sterilization settings

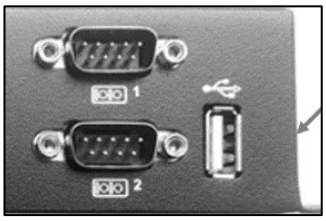
12.3.1 Record a running cycle via USB

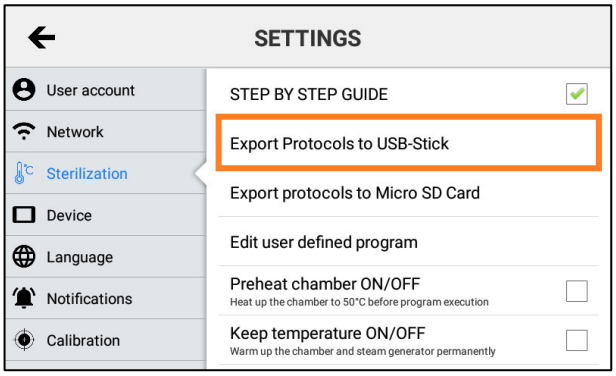
For redundant logging, use a USB flash drive to store the sterilization protocols in real time during the sterilization process. Please insert the flash disk into the USB port at the front USB port of the autoclave.

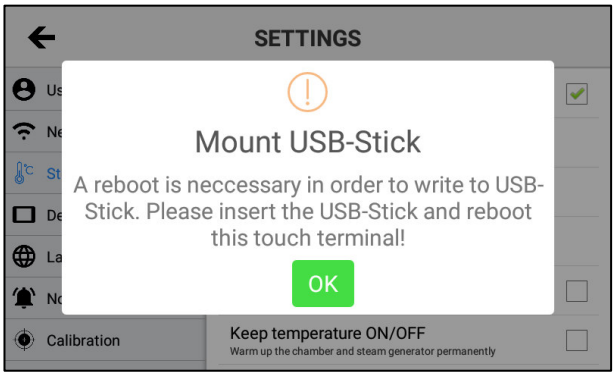


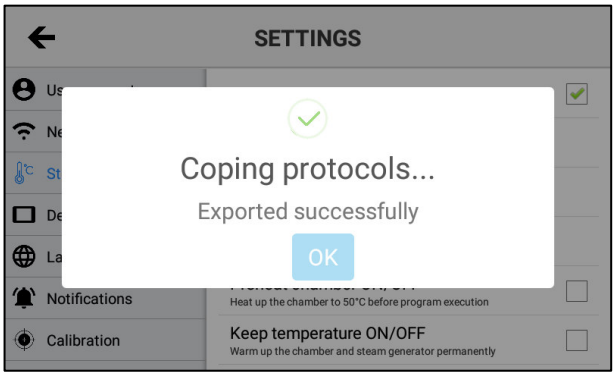
12.3.2 Export all protocols to USB flash drive

1. Navigate to the Settings menu by clicking the button at the top right corner of the screen.
2. On the left side of the settings window, press the Sterilization list entry.
3. Plug in a USB stick into the USB host of the extension wire.
4. Press the list entry: Export Protocols to USB Stick.
5. A few USB sticks can't be written immediately. If the export fails, leave the USB Stick plugged in and reboot the touchscreen.



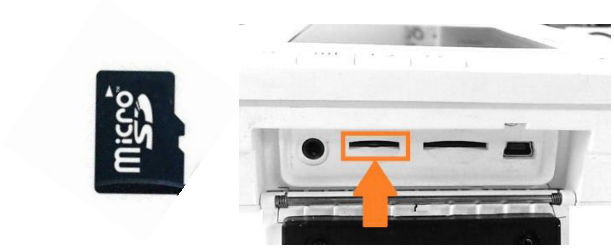


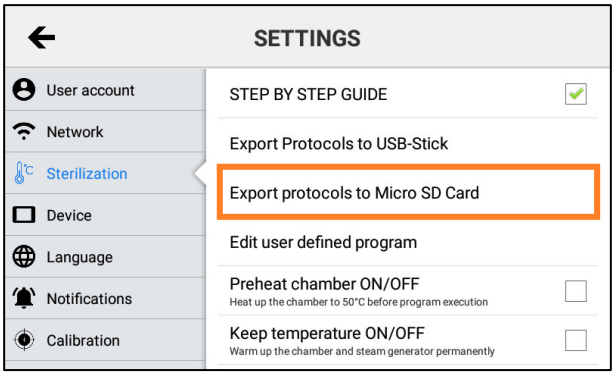


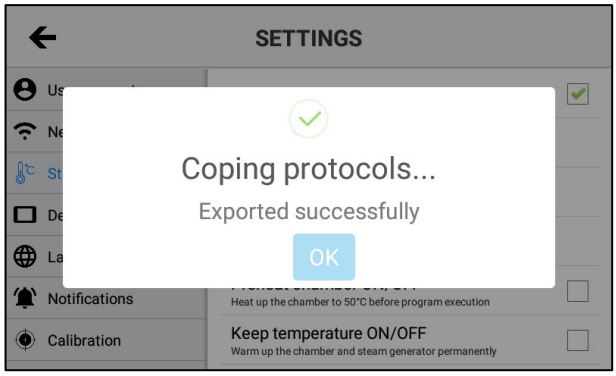


12.3.3 Export all protocols to SD-Card

1. Navigate to the Settings menu by clicking the button at the top right corner of the screen.
2. On the left side of the settings window, press the Sterilization list entry.
3. Plug in a micro SD card into the SD card slot of the touchscreen.
4. Press the list entry: Export Protocols to Micro SD Card

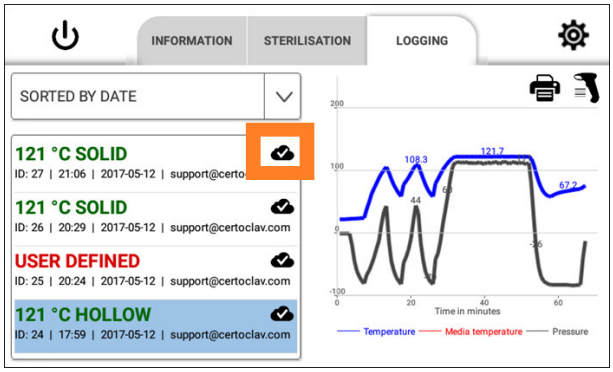






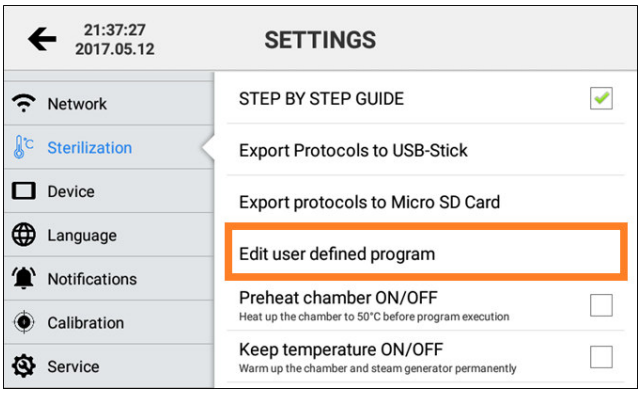
12.3.4 Export all protocols to CertoCloud online storage

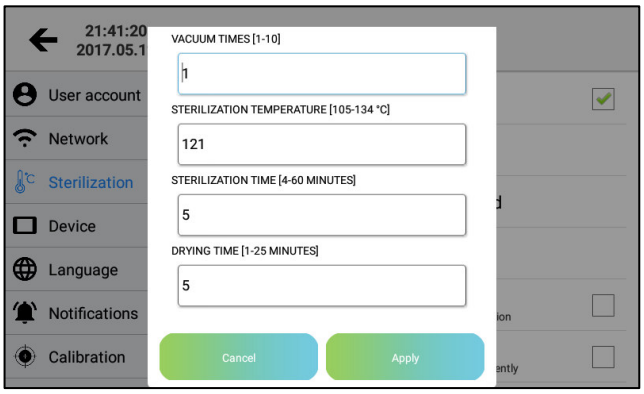
3. Sign in into the touch terminal with a CertoCloud account. A backup of all protocols will be automatically uploaded to your CertoCloud online storage. The upload has been successful if the cloud icon next to each protocol in the Logging tab is checked:



12.3.5 Change user defined program

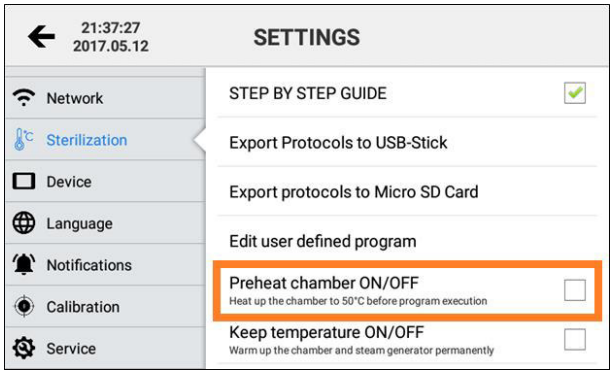
1. Navigate to Settings -> Sterilization ->Edit User Defined Program.
2. A window opens where it is possible to edit the program parameters.
3. Enter a number of vacuum times between 1 and 10.
4. Enter a sterilization temperature between 105 °C and 134 °C.
5. Enter a sterilization time between four and sixty minutes.
6. Enter a drying time between one and twenty-five minutes.
7. Press the Apply button to save the parameters or press Cancel to abort the process and return to the Setup menu.





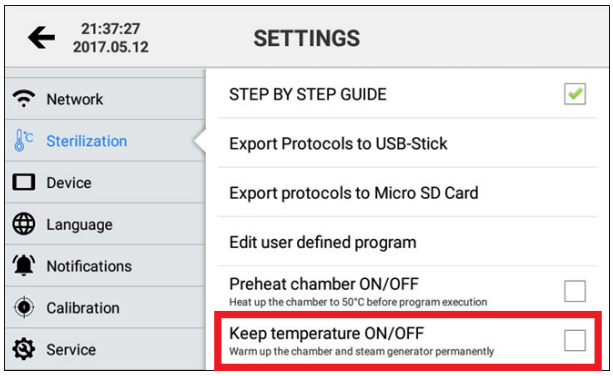
12.3.6 Preheating ON/OFF

It is advised to heat up the chamber to 50°C before the start of the vacuum time. In some countries, this is required by law in the medical field. To activate this function, navigate to the Settings->Sterilization->Preheat Chamber ON/OFF and activate the Checkbox.



12.3.7 Keep autoclave at operation temperature ON/OFF

You can keep the chamber of the autoclave at 50°C for at maximum six hours on stand-by to optimize the batch time. To activate this function, navigate to Settings->Sterilization->Keep Temperature ON/OFF and activate the Checkbox.

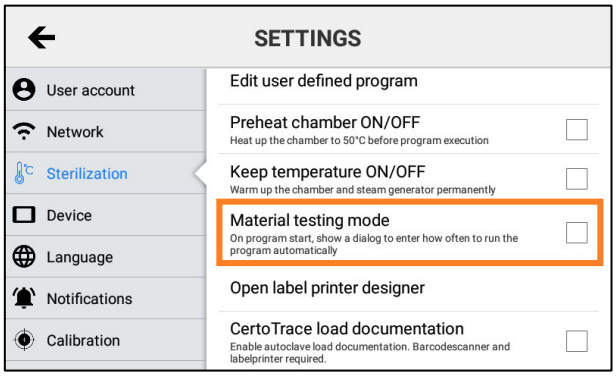


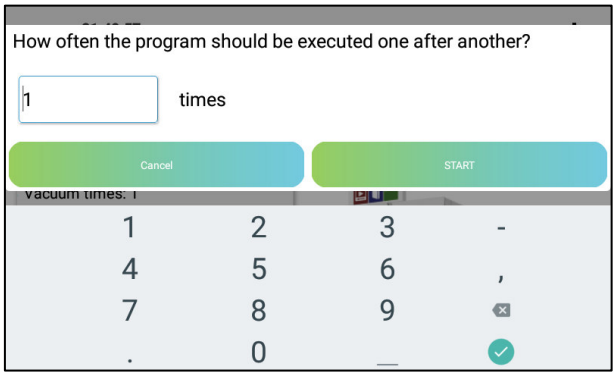
12.3.8 Step by Step assistant

1. Navigate to the Settings Menu.
2. Choose the entry Sterilization on the left side of the Settings screen.
3. Click on the step-by-step assistant to activate or deactivate the step-by-step assistant.

12.3.9 Material-testing mode – Automatic repeating start

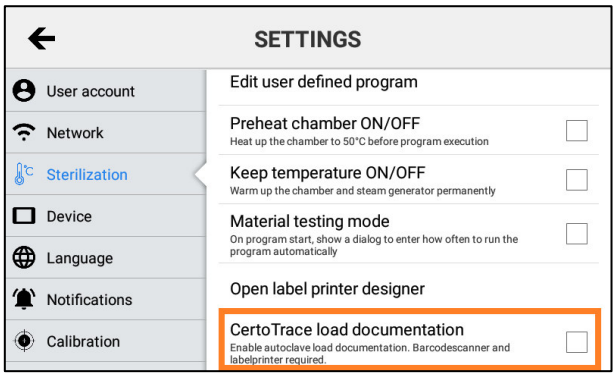
If material-testing mode is enabled (Settings -> Sterilization -> Material-Testing Mode), an additional dialog will be shown after starting a program. The autoclave will ask the user how often a program should be executed after another automatically.

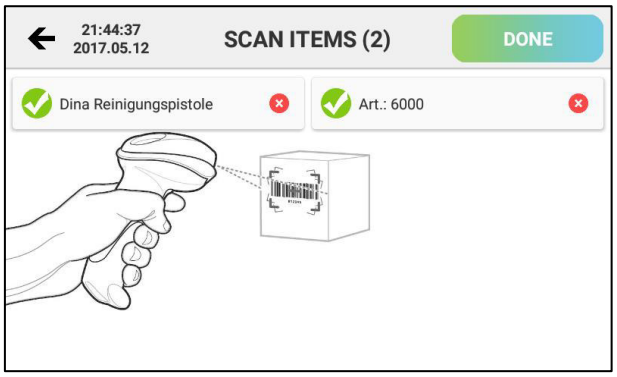




12.3.10 CertoTrace - Decontamination process documentation

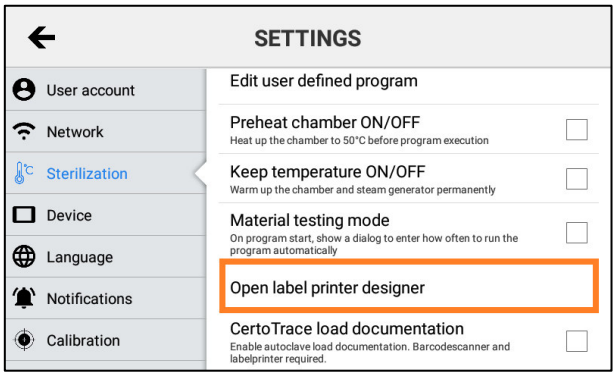
1. If CertoTrace is enabled (Settings -> Sterilization -> CertoTrace Load Documentation), the CertoTrace assistant will be shown after starting a program. Please note: The CertoClav barcode scanner and label printer is necessary in order to take advantage of the CertoTrace load documentation system.
2. With CertoTrace, it is possible to track which item has been sterilized. The label printer will print all necessary information on the label after sterilization.

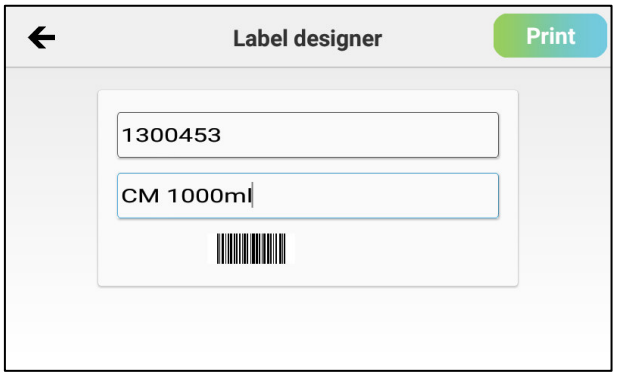




12.3.11 Label printer designer

If no barcode label for a specific item exists yet, the user can use the label printer designer tool to print custom labels. The label printer designer is located under Settings->Sterilization->Label Printer Designer.

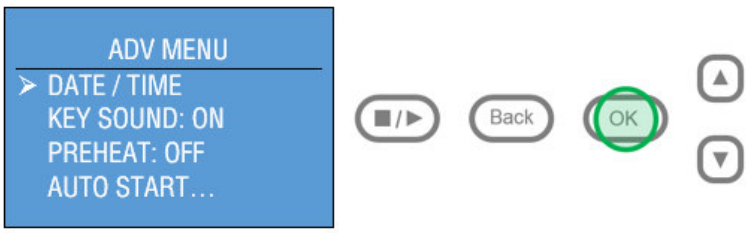




12.4 System settings

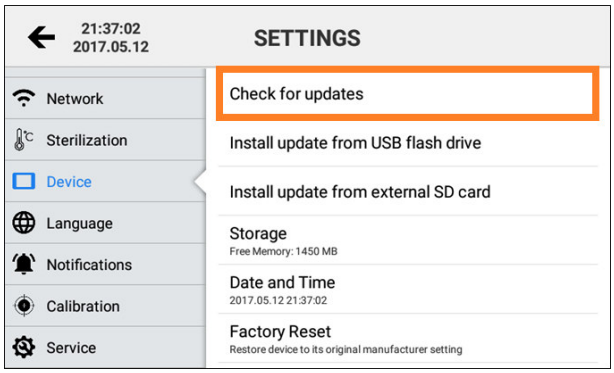
12.4.1 Change date and time

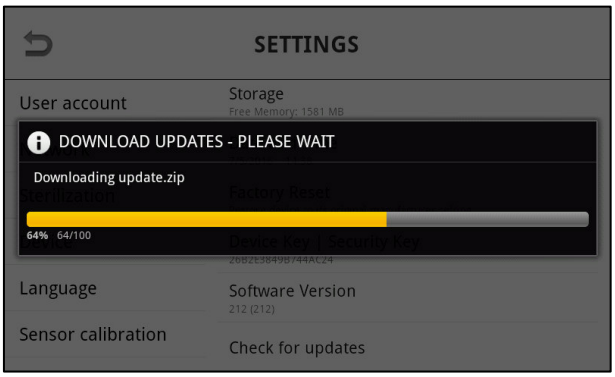
To change the date and the time of the autoclave, you have to use the built-in LCD screen at the front of the autoclave. Under ADV->DATE/TIME the real time clock of the autoclave can be changed. For the navigator use the OK, UP and DOWN keys.



12.4.2 Check for updates over internet

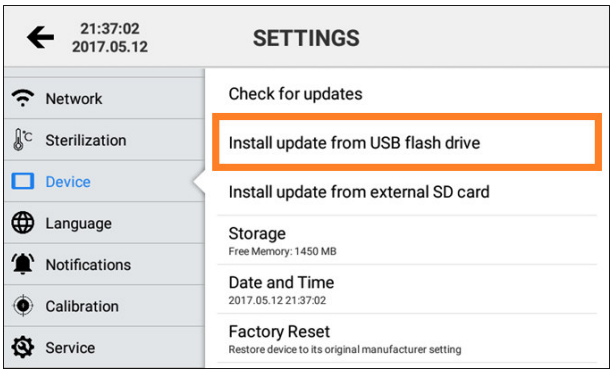
1. Make sure that the autoclave is connected to the Internet.
2. Go into the Settings menu by clicking the -button at the top right corner of the screen.
3. Please enter the “Device” section by selecting the entry “Device” on the left list.
4. On the detail view on the right, please scroll to “Check for updates” and select this entry.
5. A progress bar with the download progress will pop up. Once all updates have been downloaded, they will be installed. If a new software version is available, an installation wizard will guide you through the installation process





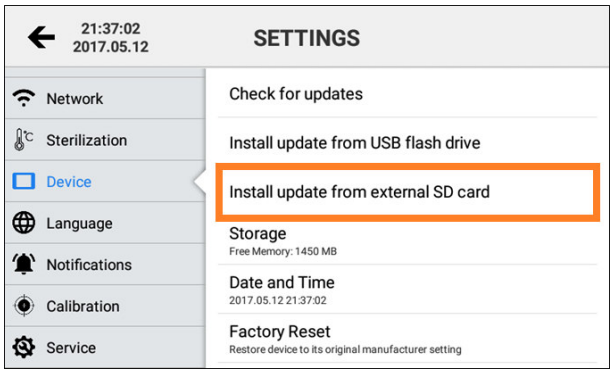
12.4.3 Install updates from USB flash drive

1. Load the newest update from www.certoclav.com or ask for the newest update for your device per mail to support@certoclav.com. Please tell our support team the serial number of the autoclave. You can find the serial number on the type label of the autoclave, or under Settings->Device->Serial Number. Copy the “update.zip” to the main directory of the USB stick and plug in the USB stick to the extension cable of the touchscreen.
2. Navigate to the Settings menu by clicking on the icon at the top right corner of the screen.
3. Click on the entry Device.
4. Scroll through the detailed view on the right side of the screen to the entry Install Update from USB Flash Drive and click on that entry.
5. If the USB stick isn’t recognized, restart the touchscreen and try it again.
6. Follow the instructions that are displayed on the screen to install the updates.



12.4.4 Install updates from external SD card

1. Load the newest update from www.certoclav.com or ask for the newest update for your device per mail to support@certoclav.com. Please tell our support team the serial number of the autoclave. You can find the serial number on the type label of the autoclave or under Settings->Device->Serial Number. Copy the “update.zip” to the main directory of the USB stick and plug in the USB stick to the extension cable of the touchscreen.
2. Navigate to the Settings menu by clicking on the icon at the top right corner of the screen.
3. Click on the entry Device.
4. Scroll through the detailed view on the right side of the screen to the entry Install Update from External SD Card” and click on that entry.
5. If the USB stick isn’t recognized, restart the touchscreen and try it again.
6. Follow the instructions that are displayed on the screen to install the updates.



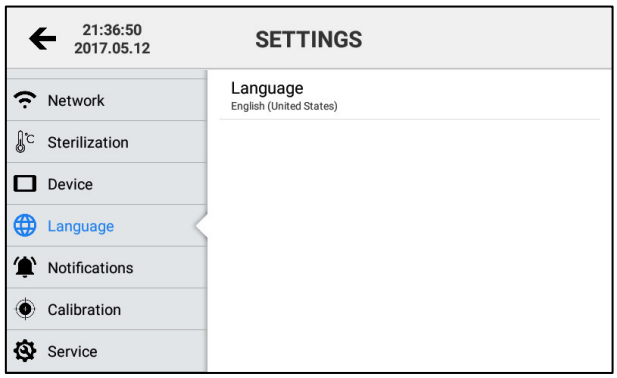
12.4.5 Factory reset

⚠	If you do a factory reset, all of the unexported protocols and user accounts that are not synchronized with CertoCloud will be deleted.

1. Navigate to Settings -> Notification.
2. Click on the entry Device.
3. Scroll through the detailed view on the right side of the screen until the entry Factory Reset, and click on that entry.

12.5 Language settings

1. Go to the Settings menu by pressing the -icon in the top right corner of the screen.
2. In the Settings menu, open the language setting by clicking the Language button.
3. In the details view on the right side of the screen, press on Current Language Setting.
4. See a scrollable list of supported languages. Please select by clicking the desired one.

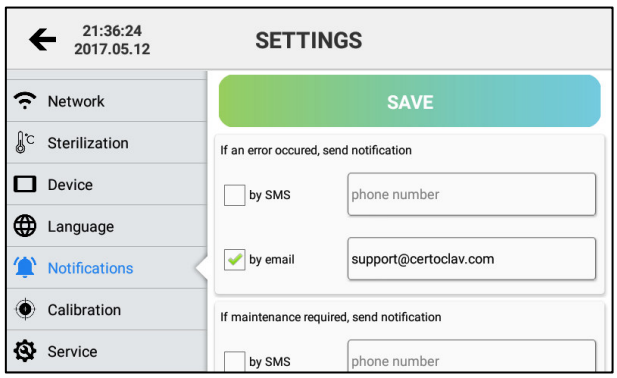


12.6 SMS and e-mail notification settings

Log in to your autoclave with your CertoCloud account. If you don't have a CertoCloud account yet, you can create a new account at the login screen. Note: To create a CertoCloud account the autoclave has to be connected to the internet.

Navigate to Settings -> Notifications to Configure SMS and E-mail Notifications.

If you want to receive an e-mail when a program has been aborted, service is due, or a program was finished successfully, than activate the corresponding checkbox. Enter any desired e-mail address which should receive the notifications. If you have a CertoCloud premium account, you can also deposit a mobile phone number, which should receive the SMS notifications.

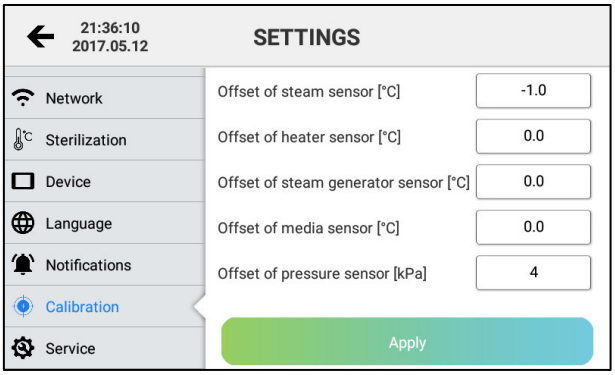


Afterwards press the Save button, and apply the changes.

12.7 Sensor calibration settings

⚠	This should only be done by the distributor and trained staff.

4. Navigate to Settings -> Calibration to show the sensor offset parameters of the chamber temperature sensor, the heater temperature probe, the steam generator probe or the pressure temperature probe.
5. Click on the offset value of the sensor that you want to adjust and edit the offset with an interval of maximum of -3°C to +3°C, respectively -10kPa to 10kPa.



13 Troubleshooting

If an error occurs during the sterilization, the sterilizer will give an acoustic and visual alarm. If configured, the autoclave will also send an SMS and e-mail to the service staff. The autoclave will release the pressure and stop heating automatically. The error code will be displayed on the screen and saved into the protocol record. This safety system takes care of the safety of the user. Please power off the device after an error has been displayed and wait until the autoclave has been cooled down. Do not open the door and wait until the pressure is at atmospheric level.

	We suggest running a program once more to see if the error happens again.
	Please contact your local distributor or CertoClav support (support@certoclav.com) after an error has occurred. The autoclave repair must be done by trained service staff.

List of alarms:

Code	Condition	Possible reason	Troubleshooting
E31	The temperature of the chamber is higher than 150 °C.	The sensor of the steam generator is defective.	Check if the temperature sensor (PT1000) in the chamber is plugged in correctly. Change the temperature sensor, if necessary.
E32	The temperature of the chamber heating is higher than 280 °C.	The sensor of the steam generator is defective.	Check if the temperature sensor (PT1000) of the chamber heating is plugged in correctly. If necessary, replace the temperature sensor.
E51	The temperature of the chamber is lower than 0 °C.	The sensor of the steam generator is defective or the temperature of the chamber is too low.	Check if the chamber temperature is above 0 °C. Check if the temperature sensor (PT1000) in the chamber is plugged in correctly. If necessary, replace the temperature sensor.
E52	The temperature of the chamber heating is lower than 0 °C.	The sensor of the steam generator is defective or the temperature of the chamber is too low.	Check if the chamber temperature is above 0 °C. Check if the temperature sensor (PT1000) in the chamber is plugged in correctly. If necessary, replace the temperature sensor.

E63	The temperature of the steam generator is lower than 0 °C. The temperature of the steam generator is higher than 230 °C.	Steam generator temperature sensor is defective. Steam generator temperature is higher than 230 °C. Steam generator controller unstable because the temperature is higher than 230 °C.	Check if the steam generator temperature sensor (PT1000) is plugged in correctly. Check steam generator temperature sensor (PT1000). If necessary, replace the temperature sensor.
E2	The sterilization pressure is more than 40 kPa higher than planned.	Vacuum pump defective.	Check the vacuum pump and afterwards perform a vacuum test.
E61	The temperature regulation is unstable. The temperature in the chamber is 6 °C higher than the required temperature.	The chamber temperature sensor is defective.	Check if the temperature sensor (PT1000) is plugged in correctly. If necessary, replace the temperature sensor.
E62	The temperature of the chamber heating is higher than 155 °C. Temperature regulation is unstable.	Chamber temperature sensor is damaged. Mainboard isn't working.	Check if the chamber temperature sensor (PT1000) is plugged in correctly. If necessary, replace the temperature sensor. Check the mainboard.
E41	In preheat period, after 8 mins warm-up, the temperature chamber heater is < 100 °C, the chamber heater damaged	Chamber heater damaged.	Check the chamber heater. Check the resistance of the heating rod. Check the heating rod wiring.
E42	In the preheat period, after 8 mins warm-up, the temperature chamber heater is < 110 °C, the chamber heater is damaged.	Chamber heater is damaged.	Check the chamber heater. Check the resistance of the heating rod. Check the heating rod wiring.
E5	When the period of "exhaust", after working 10 mins, the pressure in the chamber is still over 0.5bar : air relief instability.	Output solenoid valve is blocked.	Check the waste water valve. If necessary, clean or replace the valve.
E6	The door is opened during working. Door sensor is damaged.	Door is damaged.	Check the door sensor.
E7	The local air pressure is < 70KPa Local air pressure is too low.	Wrong air pressure. Cannot use in these areas.	Pressure sensor calibration. Open the door navigator to Settings->Calibration->Pressure Offset to change the relative pressure to 0 kPA.
E8	In pre-vacuum period, every 5 mins The temperature raises < 3 °C	Air leakage. No water inside the tank.	Check the water pump, heating rod, control board. Check the water level inside the tank.

E9	In the sterilization period, sterilization pressure is 0.3 bar.	No water inside the tank. Heater inside steam generator is broken.	Check heaters, water pump, water level. Water pump is damaged.
E10	The electronic locker is in the wrong condition.	Electronic locked damaged. Circuit board damaged.	Check the electronic locker and circuit board.
E11	The electronic locker is in the wrong condition	Electronic locked damaged. Circuit board damaged.	Check the electronic locker and circuit board.
E12	The vacuum has not reached -70Kpa during at least 3 vacuum phases.	Vacuum pump is damaged, fan is damaged.	Check the vacuum pump and the fan.
E99	Communication between the front display and the mainboard isn't working.	Cable is not connected. The CPU IC has loosened.	Check the cable between the front display and the mainboard. Check if the microcontroller IC at the mainboard is not loose.
E-1	The program has been canceled by the user.	User pressed the STOP button during the sterilization.	-
E-2	Communication between the external touchscreen and the mainboard isn't working.	The serial cable (COM 4) between the touchscreen and the autoclave has become loose.	Screw the COM4 cable in the RS232 socket at the back of the autoclave. If the problem still persists, restart the touchscreen and the autoclave. If the problem afterwards still persists navigate to Settings->Device->Factory Reset to perform a factory reset.

14 Maintenance

The below parts must be checked or replaced regularly:

1. Germ filter
2. Seal ring
3. Safety valve

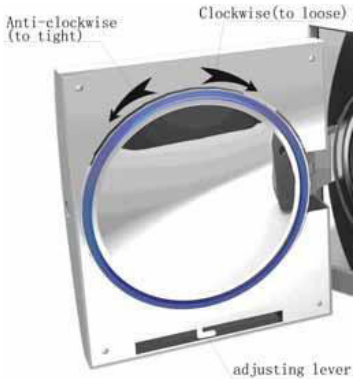
Check schedule:

Part name	Checked by	Checking period	Maintenance
Door	Trained engineer	2 years	See user manual. Chapter 14.1
Seal ring	User	1 year	See user manual. Chapter: 0 and 14.3
Printer paper	User	After printer paper is empty	See the user manual of the printer
Savety valve	Trained engineer	1 year	See user manual. Chapter: 14.4
Germ filter	User	Every 300 cycles	See service manual

14.1 Door tightness adjustment

⚠	The door adjustment must be done by a trained engineer only.

1. Open the door
2. Push down the lever and rotate the door to adjust tightness. As shown in the below picture, a counter-clockwise turn will tighten the door, i.e. the door will be closer to the chamber. A clockwise turn will loosen the door.



1. Release the lever.

2. Release the lever.
3. Keep turning the door to a place where the door cannot move anymore.

⚠	After the door adjustment, it is necessary to perform a vacuum test. If there is a leakage, the engineer shall adjust it again.
⚠	If the door is too loose, the sealing ring might explode with a big bang. Please make sure that the door isn't too loose by starting the SOLID 134°C program.

14.2 Cleaning the seal ring

The user needs to clean the seal ring regularly with distilled water. If leakage still happens after cleaning, the user may have to replace the seal ring.

14.3 Replacement of the seal ring

1. Hold the seal ring and use another hand to hold a screwdriver carefully to separate the door and the seal ring. Then take the seal ring out slowly.
2. After the user takes the seal ring out, clean and check it. If it is damaged, the user must replace it.
3. After the seal ring is cleaned, assemble it.
4. Attention: if the user finds it hard to put the seal ring back, use the screwdriver, press it carefully until it is done.

14.4 Regular check of the safety valve

⚠	The door adjustment must be done by a trained engineer only.

The safety valve must be checked regularly for visible defects. If the safety valve is damaged, it must be replaced.

1. Remove the pipe clamp (Part 1 in the figure). Afterwards remove the pipe which is connected to the safety valve.
2. Remove the srew-nut (Part 2 in figure).
3. Remove the safety valve and replace it with a new one.

⚠	The new safety valve should be of the same model. If you need any help, please contact your local distributor or CertoSupport (support@certoclav.com)
⚠	Make sure that the power supply is disconnected during maintenance. Only maintain the autoclave when it has cooled down, and only by a well-trained person.

15 Transportation and storage

15.1 Preparation

Cool down the sterilizer and disconnect the power supply.

15.2 Drainage

Empty all tanks: Assemble the pipe without joints into the bleeder valve. Then turn the drainage switches counter-clockwise.

15.3 Terms of transportation

Because of differences between countries and distributors, contact your distributor for terms of transportation.

15.4 Terms of storage

The autoclave should be stored in a clean, well-ventilated warehouse where the room temperature is 5℃~40℃, the relative humidity is no more than 80%, and there are no corroding gases.

⚠	Don't drag the autoclave during transportation.

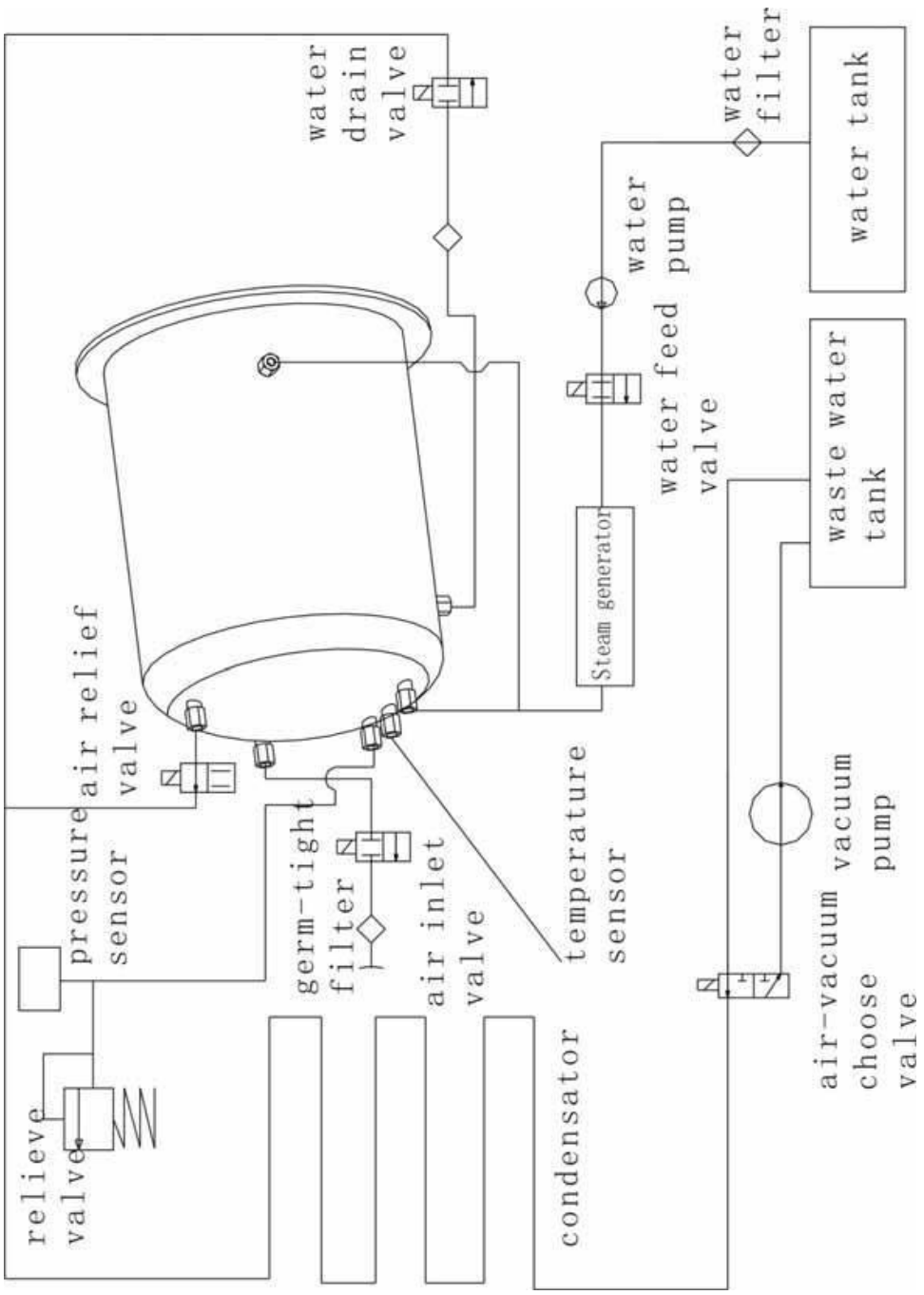
16 Warranty

Warranty: two years. Any claims to warranty expire if any of the following conditions aren't fulfilled:

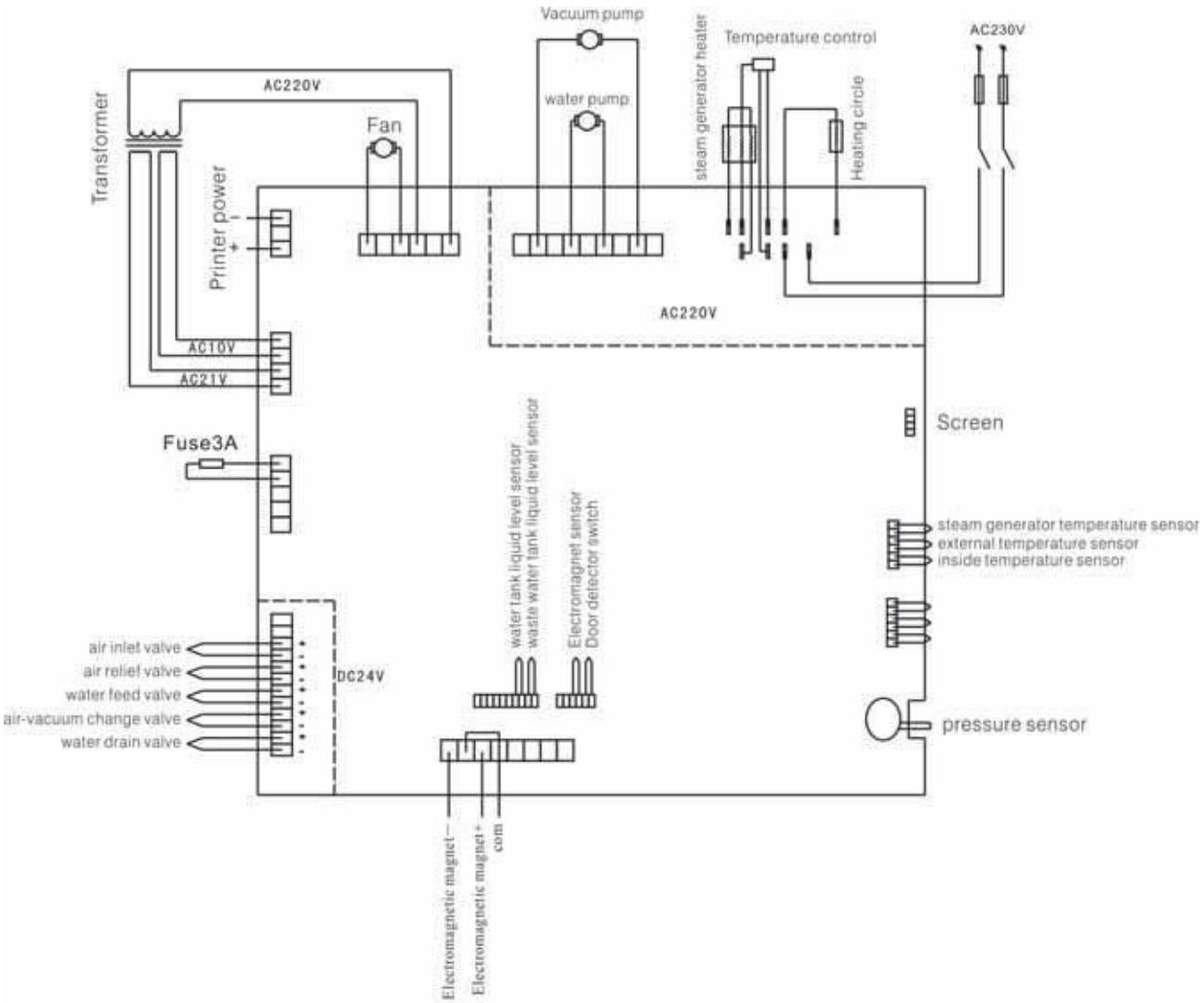
- The damage is caused by incorrect installation.
- The damage is caused by negligent behavior.
- The damage is caused by being dropped or impacts caused by carelessness.
- The damage is caused by customer's installation or repair.
- The damage is caused by force majeure such as abnormal voltage, fire etc.

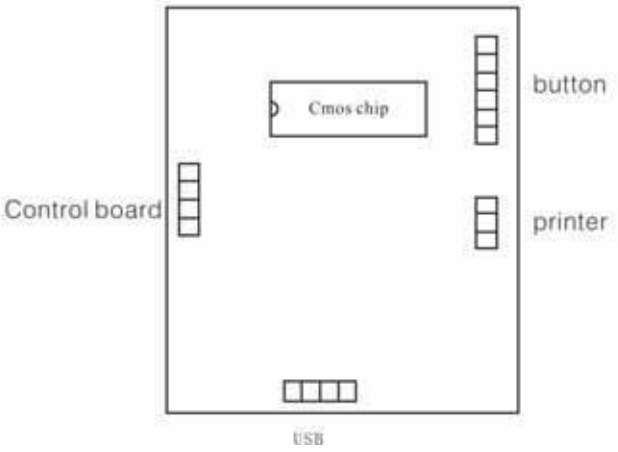
17 Appendixes

17.1 Appendix 1：Structure diagram



17.2 Appendix 2：Circuit diagram





Vacuum pump power: AC: 230V 50Hz 70W
Water pump power: AC: 230V 50Hz 47W
Heating circle: AC: 230V 50Hz 1500W
Heating rod: AC: 230V 50Hz 750W
Electromagnetic valve: DC: 24V 5W

17.3 Appendix 3：EMC

Electromagnetic emissions

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 the public low-voltage power supply network that supplies 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	Mains power quality should be that of a typical commercial or hospital environment.
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 on power supply input lines IEC 61000-4-11	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (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	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (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 power quality should be that of a typical commercial or hospital environment. If the user of the Steam sterilizer requires continued operation during power mains interruptions, it is recommended that the Steam sterilizer be powered from 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 assure 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 150 kHz to 80 MHz 3 Vrms 3 V/m 80 MHz to 2,5 GHz 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 $\sqrt{P}$ 80 MHz to 800 MHz d = 2,3 $\sqrt{P}$ 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, a should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol:

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 a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast 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	Separation distance according to frequency of transmitter		
power of transmitter		m	
W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1,2$	$d = 1,2$	$d = 2,3$
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

Model _____

Serial Number _____

Distributed by _____