# Instruction Manual

# CertoClav Vacuum Pro Series

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





Distributed by:



Tallaght Business Park Whitestown, Dublin 24, Ireland D24 RFK3

Tel: (01) 4523432 Fax: (01) 4523967 Web: www.labunlimited.com

Quatro House, Frimley Road, Camberley, United Kingdom GU16 7ER

Tel: 08452 30 40 30 Fax: 08452 30 50 30 E-mail: info@labunlimited.com E-mail: info@labunlimited.co.uk Web: www.labunlimited.co.uk

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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

(marker

Mag. Moritz Gruber Geschäftsführer

Traun, 29.10.2016

## **1** Using range of this instruction manual

This instruction manual is for models:

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

Ĩ	Please do not operate the device according to other instruction manuals
Ĩ	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.
<u>.</u>	Please operate the autoclave strictly according to this manual.
Ĩ	Please keep this manual on a reachable place near the autoclave.
<u>.</u>	Please contact your local distributor or CertoClav Support (support@certoclav.com) if there's any problem with the autoclave.
<u>.</u>	The person who operate and maintain the autoclave shall be specified and well trained.
Ĩ	Please appoint specific person to operate and maintain the device. The person must be well trained.

## 2 Explanation of symbols

	Symbol for "CAUTION!"
	Symbol for "PROTECTIVE CONDUCTOR TERMINAL"
<u></u>	Symbol for "HOT SURFACE, KEEP AWAY"
Ā	Symbol for "ENVIRONMENTAL PROTECTION – Electrical wastes should not be disposed together with household wastes. If possible, please contact local distributor or government to recycle it."
***	Symbol for "MANUFACTURER"
CE	Symbol for "Communauté européenne"
~~~	Symbol for "DATE OF PRODUCTION"
SN	Symbol for "SERIAL NUMBER"
EC REP	Symbol for "EUROPEAN REPRESENTATIVE"
<u>11</u>	Symbol for "THIS SIDE UP"
Ť	Symbol for "KEEP AWAY FROM RAIN"
Æ	Symbol for "DO NOT ROLL"
<u>اتلا</u>	Symbol for "STACKING LIMITED 3"
X	Symbol for "ROOM TEMPERATURE: 5°C~40°C"
2007	Symbol for "RELATIVE HUMIDITY: ≤80%"

## 3 Safety warnings - Please read carefully

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

- 1. Please use 3-hole socket, and ensure the socket has been connected well with the ground. Do not put the autoclave on a place that the power are difficult to be cut off.
- 2. Do not use power with different voltage with that stated in this manual.
- 3. Do not touch the plug or socket with wet hands.
- 4. Do not pull, change, over-bend or twist the wires, and do not put heavy things on the wires.
- 5. Do not put the autoclave on an unstable table.
- 6. Do not block the door of autoclave, and cover the ventilation holes and radiation holes.
- 7. Do not put anything on the top of autoclave.
- 8. If you find any abnormal smell or sound during operation, please cut off the power immediately and contact your local distributor or us.
- 9. 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.
- 10. Plug in only the mobile touchscreen from CertoClav into the serial port on the back. No other devices.
- 11. Never manipulate the safety devices. Operate only mobile touchscreen and autoclave of the same series.
- 12. Use only in accordance with this manual. Store the manual in a space accessible to all users.
- 13. Must not be installed in a space that is subject to the danger of explosions
- 14. Use only with rated voltage.
- 15. Only for use in laboratories. Operate only by trained personnel. Do not use in domestic settings.
- 16. Do not autoclave tightly sealed containers (especially glass bottles) since there is no pressure compensation.
- 17. Fill only distilled water into the water tank.
- 18. Please fill bottles always at maximum half full with liquid.
- 19. If the pressure is released quickly when autoclaving liquids, there is a possibility that the liquid will boil.
- 20. Do not transport when filled. Do not open with force.
- 21. This autoclave must only be maintained by CertoClav or authorized retailers. Always use original spare parts.
- 22. Use original spare parts from 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  $0^{\circ}$ 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 othersubstances that are 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 water in the chamber and wipe up all water around the lid gasket.

## 5 Introduction

This autoclave is an automatic vacuum steam sterilizer. The autoclave can perform all kinds of cycles known from 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 an 7" touch interface and a digital built in front panel LCD screen. 4 independent temperature sensors, a flexible media temperature sensor, a high precision pressure sensor, vacuum pump made-in-Germany, safety valves, electrical locker, safety switches and two independent microcontrollers ensure safe operation and automatic monitoring of the autoclave. The

autoclave detects errors automatically. If an error occurred, the autoclave cuts off the power automatically and ensures the safety of operator.

#### 5.1 Using range of the autoclave

#### Sterilization:

This autoclave can be used in laboratory practices for 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 RO System (Order number 8500499), the autoclave can automatically perform up to 300 cycles without any need of user interaction. The status of the autoclave can be monitored via network. The autoclave alarm system sends notifications via sound, SMS and email.

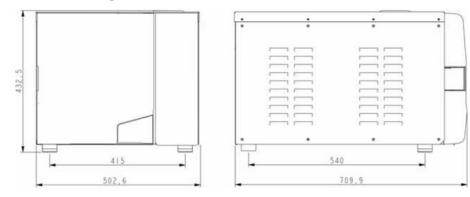
#### 5.2 Technical data

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

#### 5.3 Requirements of transportation and storage

- Environmental temperature range: 5~40°C
- 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	

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

#### Please check the product box for the following items

## 7 Installation and commissioning

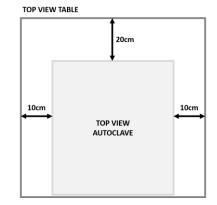
#### 7.1 Unpacking the autoclave

- 1. The autoclave is packed by 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 2 persons.

#### 7.2 Installation of the autoclave

 When installing the autoclave on top of a table, please keep the autoclave at least 10cm away from surroundings. 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. It is recommended to install the autoclave in a wellventilated location. Don't block the radiator of the sterilizer. Keep the table stable & horizontal.





- 2. Open the autoclave and take out the tray set and accessories out of the chamber to unwrap it.
- 3. Mount the stand bracket to the touchscreen with 4 screws. The screws are included with the stand bracket.

4. The assembled touchscreen must look like the screen on the following picture.

- 5. Connect the extension cable with the touchscreen.
- 6. Plug the power supply into the extension cable.
- 7. Place the touchscreen only on levelled, stable surfaces. The waterproof industrial touchscreen can be placed on top of the autoclave or next to it.



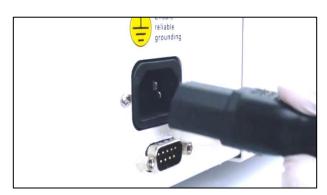






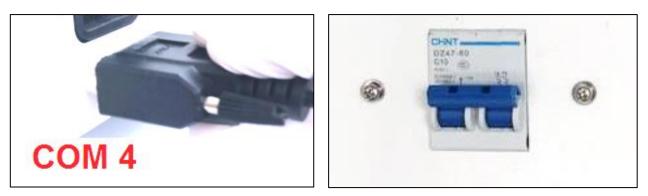
Please ensure that the table of installation is strong enough for an autoclave including water and load weight.

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





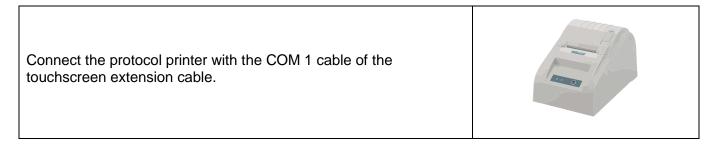
9. Connect the RS232 cable "COM 4" with the RS232 port on the back of the autoclave.



- 10. Turn on the touch screen.
- 11. If the login screen appears after a few seconds, the touch screen has been connected correctly.
- 12. If a connection error message appears on the touch screen the touchscreen is not able to connect with the autoclave. Please check if the touch screen has been connected correctly with the "COM 4" cable. If the problem still remains, please perform a factory reset on the touch screen. Navigate to Settings -> Device->Factory Reset and confirm the warning dialog.

#### 7.3 Installation of optional accessories

#### 7.3.1 Connection of protocol printer



#### 7.3.2 Connection of barcode scanner

Connect the barcode scanner with the USB-host connector of the touchscreen extension cable.	
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#### 7.3.3 Connection of label printer

Connect the label printer with the COM 2 connector of the touchscreen extension cable.



#### 7.3.4 Connection of R/O System

	CERTOCLAV
Please read the user manual of the R/O System, how to connect the R/O System with the autoclave	

#### 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.

#### Adjust method:

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

<b>4</b> 21:36:10 2017.05.12	SETTINGS	
Network	Offset of steam sensor [°C]	-1.0
<b>₿</b> <sup>C</sup> Sterilization	Offset of heater sensor [°C]	0.0
Device	Offset of steam generator sensor [°C]	0.0
Hanguage	Offset of media sensor [°C]	0.0
Notifications	Offset of pressure sensor [kPa]	4
Calibration		
Service	Apply	

4. 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 sensors of the autoclave have been validated on date of manufacture. For calibration purposes, the autoclave has an G1/4 calibration port on the chamber. If a calibration on place of installation is required, please contact your distributor or directly <a href="mailto:support@certoclav.com">support@certoclav.com</a> to get a detailed service manual with instructions for validation and calibration of the internal sensors.

## 8 List of available sterilization programs

Program name	Number of Pre- vacuum times	Sterilizing time [min]	Sterilizing temperatur e [°C]	Sterilizin g pressur e [kPa]	Vakuum persist time [min]	Drying time [min]
121°C SOLID	1	20	121	110	-	3
121°C POROUS	3	20	121	110	-	7
121°C HOLLOW	3	20	121	110	-	10
134°C SOLID	1	4	134	210	-	3
134°C POROUS	3	4	134	210	-	7
134°C HOLLOW	3	4	134	210	-	10
USER DEFINED	1-10	1-60	105-134	20-210	-	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 121°C program. The program parameters:
  Number of pre-vacuum-times, sterilizing time, sterilizing temperature, sterilizing pressure, 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: Number of pre-vacuum-times, sterilizing time, sterilizing temperature, sterilizing pressure, drying time can be adjusted.
- The 121°C Porous and 134°C Porous programs can sterilize materials which are made of porous material. The program parameters: Number of pre-vacuum-times, sterilizing time, sterilizing temperature, sterilizing pressure, drying time can be adjusted.
- The 121°C Hollow and 134°C Hollow programs can sterilize the hollow bodies of type A and B according to EN ISO 13060. The program parameters: Number of pre-vacuum-times, sterilizing time, sterilizing temperature, sterilizing pressure, drying time can be adjusted.
- User-defined program: The program parameters, Number of Pre-vacuum-times, sterilizing time,

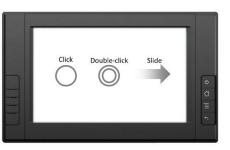
sterilizing temperature, sterilizing pressure, drying time can be adjusted. The user defined program can't be used for liquid sterilization with media temperature sensor.

- 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 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. It's recommended to perform the vacuum test regularly.
- 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 bottles. It's recommended to place the flexible media sensor into one reference bottle with liquid. Only in this case, a proper sterilization of liquids can 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.

<u>!</u>	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 in 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 overpressure.
<u>.</u>	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 <a href="mailto:support@certoclav.com">support@certoclav.com</a> directly.

## 9 Basic operation

Click and slide





#### 9.1 Turning on the autoclave

- 1. Press the **U**-button at the front right of the touchscreen for at least 3 seconds.
- 2. Turn the green power switch of the autoclave on.





## 9.2 Turning off the autoclave

Please press the **O**-button at the front right of the touchscreen for at least 3 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

Short press the  $\mathbf{\Phi}$ -button at the front right of the touchscreen. The background light will be switched off. Press the  $\mathbf{\Phi}$ -button again to wake up the touchscreen.

You can keep the chamber of the autoclave at 50°C for at maximum 6 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.

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

## 10 Instructions for daily use

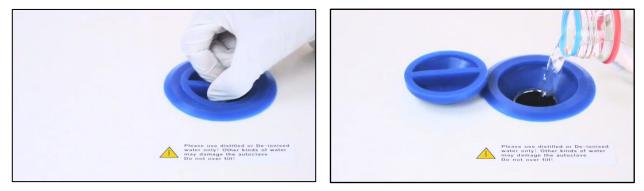
## 10.1 Preparation before using

- 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 in the message will disappear and the autoclave is ready to use.

## 10.2 Refilling water



If the LCD shows "Please fill water", the water inside of the autoclave is not enough to start a new sterilization cycle. It's required to fill 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 refill water firstly. To refill water, open the water tank lid on top of the autoclave and fill in distilled or de-ionised water only. See picture above.

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

1	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.
Ĩ	Before filling water, please turn on the autoclave and ensure the autoclave is horizontal. After filling water, if possible, please drain the waste water.
Ĩ	Only fill demineralized or distilled water in the fresh water tank. A water quality sensor continuously monitors the water quality of the filled in water. A warning notification appears on the integrated LCD screen appears if quality of the filled in 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

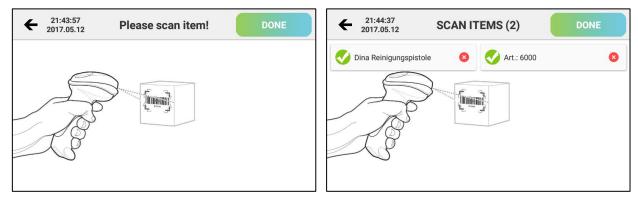
- 1. After login, navigate to the sterilization tab.
- 2. In the middle are 4 programs visible. Please scroll the vertical scrollable list down to browse through all 12 available programs.
- 3. Click on the "Start"-Button to choose and start a program.
- 4. Please confirm the dialog to start the program.
- 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 opened.



#### 10.3.2 CertoTrace – Decontamination process documentation

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

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



- 3) 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.
- 4) After scanning all items, press the Done-button.
- 5) To cancel the CertoTrace Assistant, press the Back-button on the top left corner of the screen.
- 6) 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. The Label printer designer is located under Settings->Sterilization->Label printer designer.
- 7) 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 steps, necessary to prepare and load the autoclave correctly.



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

#### 10.3.4 Load the autoclave

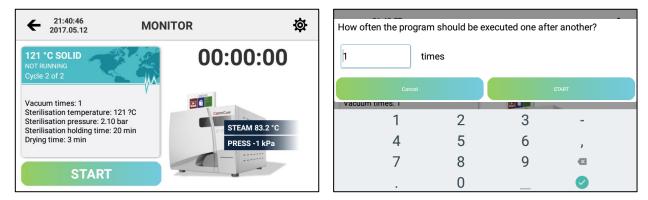
	Ensure the total CBM of the loads is less than 70% of the CBM of the chamber.
	Keep the loads away from the surface, air outlet of chamber. Keep the loads at least 10mm away from the inner side of the chamber
	When putting into and taking out the loads, you shall use the tool attached to prevent your hands from touching the hot surface.
Â	If you do B&D test, you need to put the test paper at the center of the sterilization package to ensure the reliable test result.

#### 10.3.5 Close the autoclaves door

If the temperature and pressure inside the chamber are high, the door will be difficult to be closed. We suggest to close the door quickly, or, you can wait 30 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 choose program should be executed after another fully automatically.



It's possible to enter any desired number from 1 to 1000. If an warning or error occurs during execution, the autoclave is able to report 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 <u>www.certocloud.com</u> from PC, tablet-PC and smartphone to check the current status of the material test.

We recommend to order the CertoClav R/O-System (Order number: 8500499) together with the autoclave in order to take maximum advantage from the material testing mode. The R/O System refills the autoclave fully automatically with distilled whater, so that no staff is 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 is information about the current cycle listed. On the right side of the screen are the current steam temperature and pressure visible. If the liquid program has been started, also the liquid temperature is visible.

To show a graphical view about 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 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 3 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 scald. 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 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.



r

The waste water might be very hot, please be careful when you are draining them

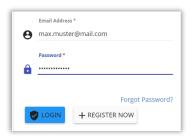


#### 10.6 CertoCloud software for PC

The CertoCloud is a web based management software for your autoclaves. CertoCloud can be reached at on any browser at <u>www.certocloud.com</u> via PC, Smartphone and Tablets.

On CertoCloud you can easily access, control and manage your laboratory devices from everywhere.	CLOUD
Certocloud Features	Email Address * emo@certoclav.com
Link your Devices with cloud Create and Manage Programs	
Store all Protocol information in the cloud	Password *
Review the history and status of Protocol	

Register a user account, direct at the autoclave or at www.certocloud.com.



View Real-time data of the autoclave via the internet



Management of SMS and e-mail notifications. For instance, if a service is due.

lf An Error (	Occured, Send Notif	ication
SMS	0123456789	×
EMAIL	max.muster@mail.com	×

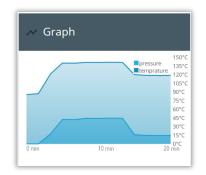
Prove the validity of the

exported protocols.

#### Download of all sterilisationprotocols as signed PDF, Excel and ZIP file.

List of Protocols		
Cycle 个	Program Name	Start
76	cloud generated	7/22/ PM
75	121°C SOLID	7/22/ PM
74	Neues Programm	7/22/ PM
74	121°C SOLID	7/22/ PM

View graphical representation, a list or a detailed view of all protocols.



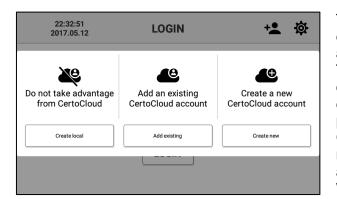
Protocol Verification		
0	Protocol ID *	
		0/24
	Device Key *	
		0/17
Ô	Security Code *	
		0 / 40
	VERIFY	

## 11 Autoclave menu overview

## 11.1 Login menu

	2:32:31 17.05.12	LOGIN	+2	墩
[	support@cer	LOGIN		

After switching the Certotouch on, the login window will appear. In order to login with the administrator account, enter the standardpasswort "admin". This password can afterwards be changed in the user settings. To login with your personal account, press 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 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.

Û	14:12:01 2016.03.10	REGISTER NEW USER	
		Last Name	
		Mobile number	]
		Password	
		Password	
		Register	

To create a local account, enter your user date. The textfields can be selected and edited by a click on the textfield. Enter the complete mobile phone number including the international prefix. That number is necessary if the status messages per SMS are enabled. Please choose a password with at least 4 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

⇒         14:12:01 2016.03.10         Add CertoCloud Account	
demo@certoclav.com	To add an existing CertoCloud account, enter the e-mail address and the password. Afterwards press the "Add account" to confirm the account. To abort the registration, press the back button on the left top of the screen.
⇒       14:12:01 2016.03.10       REGISTER NEW USER         Last Name	To create a new CertoCloud account, enter your user data into the appropriate textfields. Please enter your phone number with the international prefix. To validate your phone number and e-mail address an e-mail and a SMS will be send to your e-mail and your phone. Please enter your password twice and press the "Register"-button.
22:32:31 2017.05.12       LOGIN       LOGIN         support@certoclav.com       Image: Compared to the second seco	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.
<ul> <li>Activate max.wagner@mylab.com</li> <li>Activation key</li> <li>Activate account</li> <li>Send activation key to max.wagner@mylab.com</li> </ul>	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 the registration of the CertoCloud account. Please enter the activation key in the textfield and press the "Activatie account"-button. Your CertoCloud account is now activated and you can now use the CertoCloud account with your autoclave.

#### 11.2 Information menu

Please navigate to the "Information" tab to contact CertoSupport via email directly from the touch screen. It is also possible to watch step-by-step videos and to 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.

21:49:25 2017.05.12	VIDEOS	
close lid	fill water	lid
place item	power	remove water

#### 11.2.2 How to send an e-mail to CertoSupport

The device must be connected to the internet to send an e-mail to CertoSupport direct 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.

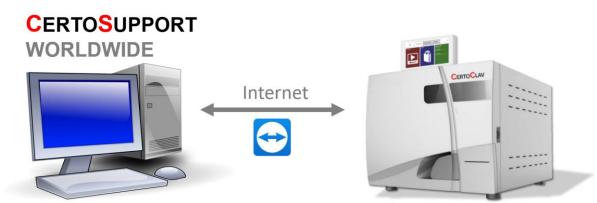
← 21:49:05 2017.05.12 CONTACT SUPPORT Send	CONTACT SUPPORT Send
SUBJECT:	Request for custom software
Protocol Managment	Protocol Managment
MESSAGE	User Managment
Is a backup of my protocols saved at CertoCloud online storage?	Program Managment
	Software Updates
	sincerély, Michael Dirix

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

Afterwards enter your message to CertoSupport in the message textfield. To send the message, click on the "Send"-button. A reply to your request will be send to the e-mail address of your autoclave account within 24 hours.

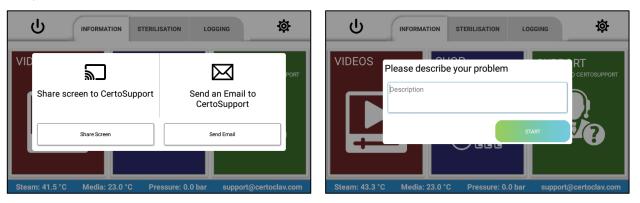
#### 11.2.3 TeamViewer remote support via screen sharing

To start a TeamViewer screen sharing session with CertoSupport, navigate to 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 by your distributor or CertoSupport via E-Mail or phone. To request a time frame for the team-viewer 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 an time frame. Generally your request will be answered within 12 hours.

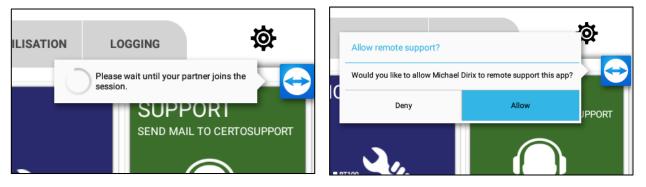


Navigate to the Information-Tab and press the Support-button on the right side of the screen. A dialog will open and asks for the desired method of support. If you don't have agreed a time frame for TeamViewer screen sharing with CertoSupport yet, please choose the Send Email option and ask CertoSupport 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.

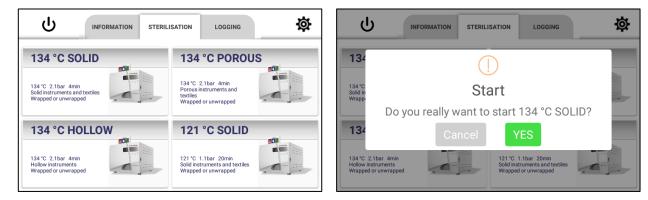
A window will appear, where you can add a problem description to your screen sharing request optionally.



Press the Submit-button and wait until CertoSupport joins the Screen sharing session. In order to share the autoclave screen, press the Allow-button. Not the CertoSupport is able to control the autoclave remotely. To cancel a running screen sharing session, drag the TeamViewer-icon from into the bottom of the screen.



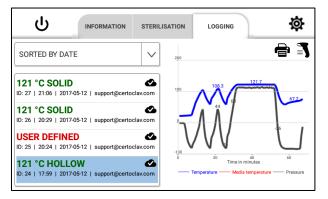
- 1. After login, navigate to the sterilization tab.
- 2. In the middle are 4 programs visible. Please scroll the vertical scrollable list down to browse through all 12 available programs.
- 3. Click on the "Start"-Button to choose and start a program.
- 4. Please confirm the dialog to start the program.
- 5. If CertoTrace is enabled, the tracing assistant will be opened after start.
- 6. If the step-by-step guide is enabled, a video step-by-step guide will be opened after start.



## 11.4 Logging menu

#### 11.4.1 View protocols

Navigate to the protocols tab to view the sterilization protocols. A list on the left side of the screen shows all recorded protocols. The cloud icon in the protocol list indicates if the protocols are synchronized with the CertoCloud (<u>www.certocloud.com</u>) or not. An internet connection is required for the synchronization. Click on the drop-down menu above the protocol list to change the order criteria. Click on a list element to view the details and graphical view. The graphical course is displayed on the right side of the screen.



#### 11.4.2 Print protocols

- 1) Navigate to the Logging-Tab
- 2) Scroll to the protocol of your choice in the protocols list on the left side of the screen
- 3) Press on the protocol list entry to show a detail view on the right
- 4) Press the print button on the upper right of the screen to open a print dialog
- 5) Press the Print protocol-button to print the protocol via the protocol printer

19.05.2017

	STERILI	SATION	LOGGING	\$
SORTED BY DATE 121 °C SOLID ID: 27   2106   2017:05 121 °C SOLID ID: 26   2029   2017:05 Print the pr			a tracing label	1222 120
ID: 24   20:74   20:745         Print proto           USER DEFINED         Print proto           ID: 25   20:24   20:745	<b>\$</b>	-100		20 n minutes lla temperature — Pressure

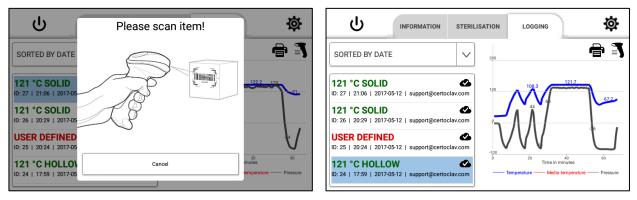
#### 11.4.3 Print tracing label

- 1) Navigate to the Logging-Tab
- 2) Scroll to the protocol of your choice in the protocols list on the left side of the screen
- 3) Press on the protocol list entry to show a detail view on the right
- 4) Press the print button on the upper right of the screen to open a print dialog
- 5) Press the Print label-button
- 6) Enter the date of expiration. Of the sterilized item. Per default it is set to 6 months
- 7) Press OK to print the label including tracing barcode.

SORTED BY DATE       Image: Constraint of the protocol         121 °C SOLID       Print the protocol         10: 26   20:29   201705       Print protocol         ID: 25   20:24   201705       Print protocol         ID: 25   20:24   201705       Print protocol         ID: 24   17:59   20170512   support@certoclex.com       Image: Constraint of the protocol	SORTED BY DATE Please enter time until expiration b D: 27   21:06   2017:05 CANCEL D: 25   20:24   2017:05-12   support@certoclav.com D: 24   17:59   2017:05-12   support@certoclav.com D: 24   27:59   2017:05-12   35   25   25   25   25   25   25   2

#### 11.4.4 Tracing of labeled items

- 8) Navigate to the Logging-Tab
- 9) Press the scan-icon on the top right of the window
- 10) A popup window appears. Please scan the barcode of the labeled sterilized item with the barcode scanner
- 11) 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.



#### 11.5 Monitor menu

During program execution, the autoclave monitor screen is visible. On the left side is information about the current cycle listed. On the right side of the screen are the current steam temperature and pressure visible. If the liquid program has been started, also the liquid temperature is visible.

To show a graphical view about 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 logging history becomes visible.



## **12 Autoclave settings overview**

#### 12.1 User settings

- 1. Navigate to the Settings menu by clicking the <sup>2</sup>-button at the top right corner of the screen.
- 2. Press the user management entry to view all user accounts.
- 3. Press the edit-button to change the user data and the password. You can only modify the account, which is currently signed in.
- 4. Press the delete-button to delete the account.

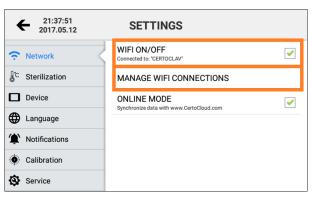


#### 12.2 Network settings

- 1. Navigate to the Settings menu by clicking the <sup>S</sup>-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 *screen*-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 available networks. Press on a WiFi network to enter password and further parameters. The WiFi network will be saved. The autoclave will connect to the wireless LAN automatically
- 5. Press the Return-button on the right side of the screen to close the WiFi settings and to return to the settings window.



#### 12.2.2 Connect to LAN

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



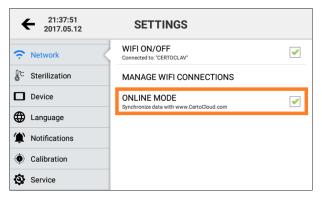
#### 12.2.3 Enable or disable online mode

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

1. Navigate to the Settings menu by clicking the <sup>C</sup>-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 is 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 his protocol data, it must be done manually via USB-stick, SD-card or printer. If the user enables the online mode, all local protocols which are not uploaded to CertoCloud yet, will be uploaded.



#### 12.3 Sterilization settings

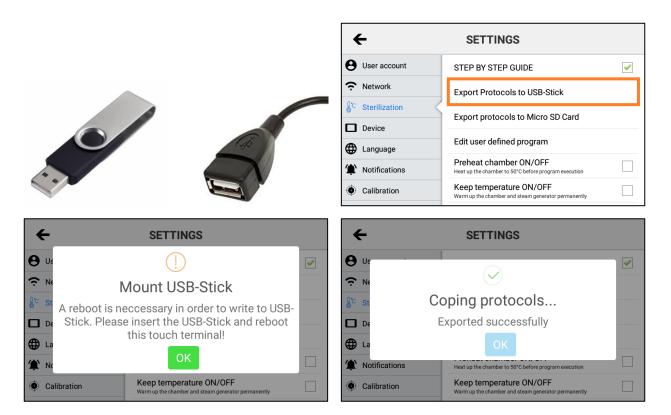
#### 12.3.1 Record a running cycle via USB

For redundant logging, use an USB flash drive to store the sterilization protocols in real time during the sterilization process. Please insert the flash disk into 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 *screen*-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, let the USB-Stick plugged in and reboot the touch screen.



#### 12.3.3 Export all protocols to SD-Card

- 1. Navigate to the Settings menu by clicking the *screen*-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 touch screen.

4. Press the list entry: Export Protocols to Micro SD card



#### 12.3.4 Export all protocols to CertoCloud online storage

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

ს	INFORMATION	STERILIS	ATION	LOGGING	礅
SORTED BY DATE		$\sim$	200		<b>r</b>
121 °C SOLID ID: 27   21:06   2017-0	5-12   support@certo	ø	100	∧凇ᡘ	67.2
<b>121 °C SOLID</b> ID: 26   20:29   2017-0	5-12   support@certo	Clav.com	<u> </u>	ΛΪΪ	
USER DEFINED		Clav.com	.100	////	
<b>121 °C HOLLO</b> ID: 24   17:59   2017-0		clav.com	о́ —— та	<sup>20</sup> Time in m emperature —— Media t	40 60 inutes temperature Pressure

#### 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 4 and 60 minutes.
- 6. Enter a drying time between 1 and 25 minutes.
- 7. Press the "apply"-button to save the parameters or press the "Cancel" to abort the process and return to the setup menu.

← <sup>21:37:27</sup> <sup>2017.05.12</sup>	SETTINGS	← 21:41:20 2017.05.1 vacuum TIMES[1-10]
Network	STEP BY STEP GUIDE	User account STERILIZATION TEMPERATURE [105-134 *C]
Sterilization	Export Protocols to USB-Stick	Network     121
Device	Export protocols to Micro SD Card	Sterilization STERILIZATION TIME (4-60 MINUTES)
Language	Edit user defined program	Device Drying Time [1-25 MINUTES]
Notifications     Calibration	Preheat chamber ON/OFF Heat up the chamber to 50°C before program execution	Xotifications
Service	Keep temperature ON/OFF Warm up the chamber and steam generator permanently	Calibration     Cancel     Apply     antly

#### 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 a law in medical field. To activate this function, navigate to the Settings->Sterilisation->Preheat chamber ON/OFF and activate the checkbox.

← 21:37:27 2017.05.12	SETTINGS	
	STEP BY STEP GUIDE	<b>~</b>
Sterilization	Export Protocols to USB-Stick	
Device	Export protocols to Micro SD Card	
Hanguage	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	

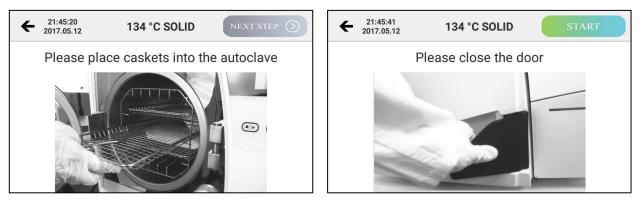
#### 12.3.7 Keep autoclave at operation temperature ON/OFF

You can keep the chamber of the autoclave at 50°C for at maximum 6 hours in stand-by to optimize the batch time. To activate this function navigate to Settings->Sterilization->Keep temperature ON/OFF and activate the Checkbox.

<b>4</b> 21:37:27 2017.05.12	SETTINGS	
Network	STEP BY STEP GUIDE	<b>~</b>
€ <sup>℃</sup> Sterilization	Export Protocols to USB-Stick	
Device	Export protocols to Micro SD Card	
Language	Edit user defined program	
1 Notifications	Preheat chamber ON/OFF	
Calibration	Heat up the chamber to 50°C before program execution	
Service	Keep temperature ON/OFF Warm up the chamber and steam generator permanently	

#### 12.3.8 Step by Step assistant

- 1. Navigate to Settings -> Notification.
- 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 fully automatically.

+	SETTINGS	How often	the progra	m should be ex	ecuted one aft	er another?
<b>e</b> User account	Edit user defined program	h	ti	mes		
Network	Preheat chamber ON/OFF Heat up the chamber to 50°C before program execution	[ <sup>1</sup>				
€ Sterilization	Keep temperature ON/OFF Warm up the chamber and steam generator permanently	vacuum tin	Cancel			START
Device	Material testing mode		1	2	3	-
Language	program automatically		4	5	6	
(1) Notifications	Open label printer designer		7	8	9	
Calibration	CertoTrace load documentation Enable autoclave load documentation. Barcodescanner and labelprinter required.		•	0	_	

#### 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 every necessary information on the label after sterilization.

<b>←</b>	SETTINGS	← 21:44:37 2017.05.12 SCAN ITEMS (2) DOM
<b>e</b> User account	Edit user defined program	Dina Reinigungspistole 🛛 🐼 Art.: 6000
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	
🕀 Language	On program start, show a dialog to enter how often to run the program automatically	
Notifications	Open label printer designer	
Calibration	CertoTrace load documentation Enable autoclave load documentation. Barcodescanner and labelprinter required.	

#### 12.3.11 Label printer designer

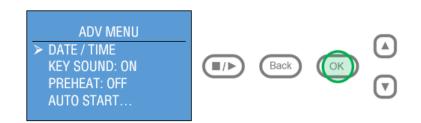
If no barcode label for a specific item exists yet, the user can use the label printer designer tool to print custom labels. The Label printer designer is located under Settings->Sterilization->Label printer designer.

<b>←</b>	SETTINGS	<b>←</b>	Label designer	Print
<b>e</b> 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.			

### 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 build 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 <sup>C</sup>-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

← 21:37:02 2017.05.12	SETTINGS	5	SETTINGS
Network	Check for updates	User account	Storage Free Memory: 1581 MB
Sterilization     Ste	Install update from USB flash drive	DOWNLOAD UPDAT	ES - PLEASE WAIT
Device	Install update from external SD card	Downloading update.zip	Factory Reset
Hanguage	Storage Free Memory: 1450 MB	<b>64%</b> 64/100	Device Key   Security Key
Notifications		-	2682£38498744AC24
Calibration	Date and Time 2017.05.12.21.37.02	Language	Software Version
Service	Factory Reset Restore device to its original manufacturer setting	Sensor calibration	Check for updates

#### 12.4.3 Install updates from USB flash drive

- Load the newest update from <u>www.certoclav.com</u> or ask for the newest update for your device per mail to <u>support@certoclav.com</u>. 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  $e^{5}$  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

- Load the newest update from <u>www.certoclav.com</u> or ask for the newest update for your device per mail to <u>support@certoclav.com</u>. 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 <sup>C</sup> 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.

<b>4</b> 21:37:02 2017.05.12	SETTINGS
Retwork	Check for updates
C Sterilization	Install update from USB flash drive
Device	Install update from external SD card
Language	Storage
Notifications	Free Memory: 1450 MB
•	Date and Time
Calibration	
Service	Factory Reset Restore device to its original manufacturer setting

#### 12.4.5 Factory reset



If you do a factory reset, all of the not exported and not with CertoCloud synchronized protocols and user accounts 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 the current language setting.
- 4. See a scrollable list of supported languages. Please select by clicking the desired one.

← 21:36:50 2017.05.12	SETTINGS
Network	Language English (United States)
Sterilization	
Device	
🕀 Language	
1 Notifications	
Calibration	
Service	

### 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 an e-mail notifications.

If you want to receive an e-mail if a program was 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.

← 21:36:24 2017.05.12	SETTING	S
Network		SAVE
€ <sup>C</sup> Sterilization	If an error occured, send	Inotification
Device	by SMS	phone number
Language		
1 Notifications	🖌 by email	support@certoclav.com
Calibration	If maintenance required, send notification	
Service	by SMS	phone number

Afterwards press the "Save"-button save and apply the changes.

## 12.7 Sensor calibration settings



This should be only done by the distributor and trained staff

- 1. Navigate to Settings -> Calibration to show the sensor offset parameters of the chamber temperature sensor, the heater temperature probe, steam generator probe or pressure temperature probe.
- 2. 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

← 21:36:10 2017.05.12	SETTINGS	
Network	Offset of steam sensor [°C]	-1.0
€ <sup>C</sup> Sterilization	Offset of heater sensor [°C]	0.0
Device	Offset of steam generator sensor [°C]	0.0
Hanguage	Offset of media sensor [°C]	0.0
Notifications	Offset of pressure sensor [kPa]	4
Calibration		
Service	Apply	

# **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 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 the error will be saved into the protocol record. This safety system takes care about 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 program once more to see if the error happens again.
Ì	Please contact your local distributor or CertoClav support ( <u>support@certoclav.com</u> ) iafter an error occurred. The autoclave repair must be done by trained service staff.

Code	Condition	Possible reason	Troubleshooting
E31	The temperature of the chamber is higher than 150 °C	The sensor of the steam generator is defect.	Check if the temperature sensor (PT1000) in the chamber is plugged in correct. 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 defect.	Check if the temperature sensor (PT1000) of the chamber heating is plugged in correct. If necessary, replace the temperature sensor.
E51	The temperature of the chamber is lower than 0 °C.	The sensor of the steam generator is defect or the temperature of the chamber is to low	Check if the chambertemperature is above 0 °C. Check if the temperature sensor (PT1000) in the chamber is plugged in correct. 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 defect or the temperature of the chamber is to low	Check if the chambertemperature is above 0 °C. Check if the temperature sensor (PT1000) in the chamber is plugged in correct. If necessary, replace the temperature sensor.

		iniout	19.05.2017
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 defect. Steam generator temperature is higher than 230 °C. Steam generator controller instable because of the temperatures higher than 230 °C.	Check if the steam generator temperature sensor (PT1000) in the is plugged in correct. 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 defect	Check vacuum pump and afterwards perform a vacuum test.
E61	The temperature regulation is instable. The temperature in the chamber is 6 °C higher than the required temperature	The chamber temperature sensor is defect.	Check if the temperature sensor (PT1000) in the is plugged in correct. If necessary, replace the temperature sensor.
E62	The temperature of the chamber heating is higher than 155 °C. The temperature regulation is instable.	Chamber temperature sensor is damaged. Mainboard isn't working.	Check if the chamber temperature sensor (PT1000) is plugged in correct. If necessary, replace the temperature sensor. Check the mainboard.
E41	In preheat period, after 8mins warm- up, temperature chamber heater is < 100 °C, chamber heater damaged	Chamber heating damaged	Check the chamber heater. Check the resistance of the heating rod. Check the heating rod wiring.
E42	In preheat period, after 8mins warm- up, temperature chamber heater is < 110 °C, chamber heater damaged	Chamber heating 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 10mins, the pressure in chamber is still over 0.5bar : air relief instability	Output solenoid valve is blocked	Check the waste water valve. If necessary clean the valve or replace the valve.
E6	The door is opened during working. Door sensor damaged	Door damaged	Check the door sensor

			19.00.2017
E7	The local air pressure is < 70KPa Local air pressure is too low.	Wrong air pressure. Cannot use in these area.	Pressure sensor calibration. Open the door navigator to Settings->Calibration->Pressure offset change the relative pressure to 0 kPA.
E8	In pre-vacuum period, every 5mins temperature raise < 3 °C	Air leakage. No water inside tank.	Check water pump, heating rod, control board. Check water level inside tank.
E9	In sterilization period, the sterilization pressure is 0.3 bar	No water inside tank. Heater inside steam generator is	Check heaters, water pump, water level. Water pump damaged.
E10	The electronic	Electronic locked damaged.	check electronic locker and
	locker is in wrong condition.	Circuit board damaged.	circuit board
E11	The electronic	Electronic locked damaged.	check electronic locker and
	locker is in wrong condition	Circuit board damaged.	circuit board
E12	The vacuum not reach -70Kpa during at least 3 vacuum phases	Vacuum pump damaged, fan damaged.	Check the vacuum pump and the fan
E99	The communication between the front	Cable is not connected. CPU IC has loosened	Check the cable between the front display and the mainboard.
	display and the mainboard isn't working		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	The 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

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: 14.2 and 14.3
Printer paper	User	After printer paper is empty	See 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 trained engineer only.

- 1. Open the door
- 2. Push down the lever and rotate the door to adjust tightness. As shown in below picture, anticlockwise turning will tighten the door, i.e., the door will be closer to the chamber. Clockwise turning the door will loosen it.



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

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

## 14.2 Cleaning of the seal ring

The user needs to clean the seal ring regularly by 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 by a hand and use another one 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 screwdriver press it carefully until it is done.



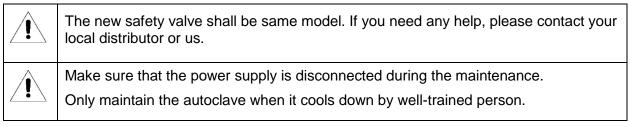
### 14.4 Regular check of the safety valve

The door adjustment must be done by 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





# **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 joint into bleeder valve. Then turn the drainage switches towards anti-clockwise.



### 15.3 Terms of transportation

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

## 15.4 Terms of storage

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



Don't drag the autoclave during transportation.

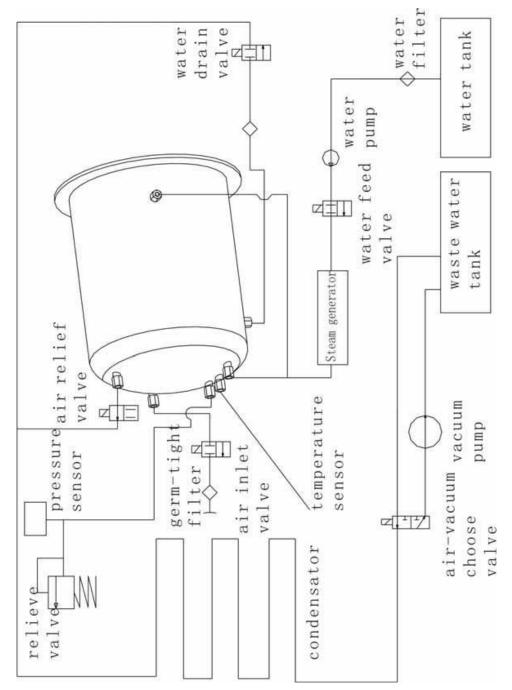
## 16 Warranty

Warranty: 2 years. Any claims to warranty expires if any of the following conditions aren't fulfilled:

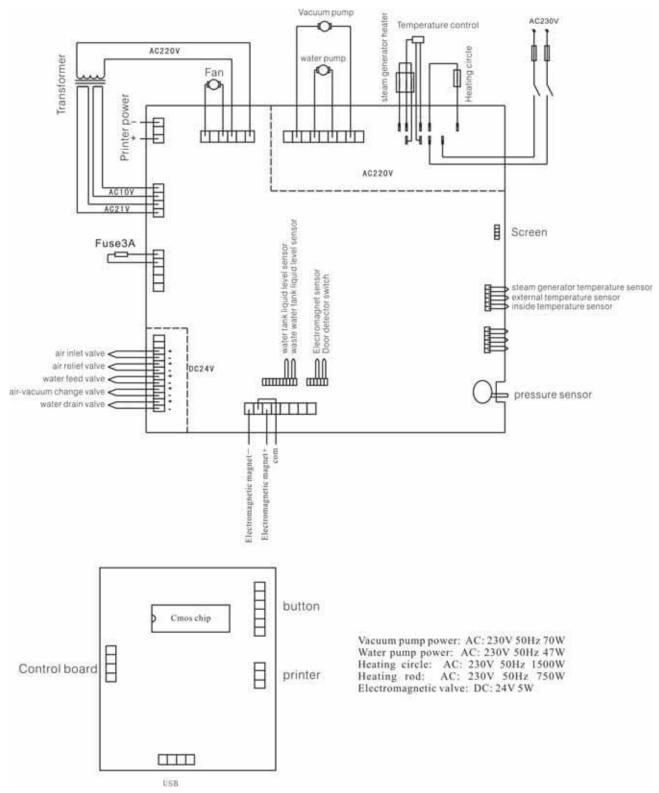
- The damage is caused by incorrect installation
- The damage is caused by negligent behavior
- The damage is caused by fall down or impact by carelessness. The damage is caused by customer's install or repair
- The damage is caused by force majeure such as abnormal voltage, fire etc.

# **17 Appendixes**

## 17.1 Appendix 1: Structure diagram



## 17.2 Appendix 2: Circuit diagram



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

#### Instruction Manual CertoClav Connect

#### 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)	6 kV contact	6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered
IEC 61000-4-2	8 kV air	8 kV air	with synthetic material, the relative humidity should be at least 30 %.
Electrical fast	2 kV for power	2 kV for power	Mains power quality should be that
transient/burst	supply lines	supply lines	of a typical commercial or hospital
IEC 61000-4-4	1 kV for input/output	1 kV for input/output	environment.
120 01000-4-4	lines	lines	
Surge	1 kV line(s) to line(s)	1 kV line(s) to line(s)	Mains power quality should be that
IEC 61000-4-5			of a typical commercial or hospital
	2 kV line(s) to earth	2 kV line(s) to earth	environment.
interruptions and	<5 % <i>U</i> T	<5 % <i>U</i> T	Mains power quality should be that
voltage variations	(>95 % dip in <i>U</i> T)	(>95 % dip in <i>U</i> T)	of a typical commercial or hospital
on power supply	for 0,5 cycle	for 0,5 cycle	environment. If the user of the Steam sterilizer requires continued
input lines	40 % <i>U</i> T	40 % <i>U</i> T	operation during power
	(60 % dip in <i>U</i> T)	(60 % dip in <i>U</i> T)	mains interruptions, it is
IEC 61000-4-11	for 5 cycles	for 5 cycles	recommended that the Steam sterilizer be powered from an uninterruptible power supply or a
	70 % <i>U</i> T	70 % <i>U</i> T	uninterruptible power supply or a battery.
	(30 % dip in <i>U</i> T)	(30 % dip in <i>U</i> T)	Sauci y.
	for 25 cycles	for 25 cycles	
	<5 % <i>U</i> T	<5 % <i>U</i> T	
	(>95 % dip in <i>U</i> T)	(>95 % dip in <i>U</i> T)	
	for 5 sec	for 5 sec	
Power frequency			Power frequency magnetic fields
(50/60 Hz)	3 A/m	3 A/m	should be at levels characteristic of a typical location in a typical
magnetic field			commercial or hospital
IEC 61000-4-8			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	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Steam

IEC 61000-4-6	150 kHz to 80 MHz 3 V/m	150 kHz to 80 MHz 3 Vrms 3 V/m	sterilizer including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80 MHz to 2,5 GHz	80 MHz to 2,5 GHz 3 V/m	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
	<i>d</i> = 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