

# Instruction Manual CertoClav Vacuum Pro 45

Steam Steriliser Model STE-45-T



Dear customer,

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

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

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

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

#### Instruction Manual CertoClav Vacuum Pro 45

CertoClav Valid for model STE-45-T Issue 1 June 2019 Responsible for content: CERTOCLAV Sterilizer GmbH Peintner Straße 10 A-4060 Leonding Austria Email: support@certoclav.com www.certoclav.com © 2019 CertoClav

Last change: 11.06.2019

Document: BA\_VACPRO45\_D.doc / Revision: 8

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# 1 General Information



Dear customer,

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

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

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

### 1.1 Intended use

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

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

Comply consistently with all safety regulations in this instruction manual.

# 1.2 Environmental protection



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



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

### 1.3 Customer Service

If you have any questions or problems regarding the autoclave, please contact your dealer or the manufacturer by email to <a href="mailto:support@certoclav.com">support@certoclav.com</a>.

# 1.4 Ordering spare parts and special accessories



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

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

### 1.5 Guarantee

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

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

# 2 Meaning of the Symbols on the Autoclave



# 3 Safety Information

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



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

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

# 4 Non-autoclavable Substances

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

### **Explosive substances**

- Nitroglycol, nitroglycerin, nitrocellulose and other explosive nitric acid esters
- Trinitrobenzene, trinitrotoluene, picric acid and other explosive nitro compounds
- Peracetic acid, methyl ethyl ketone peroxide, benzoyl peroxide and other organic peroxides

### **Combustible substances**

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

### **Oxidising agents**

- Potassium chlorate, sodium chlorate, ammonium chlorate and other chlorates
- Potassium perchlorate, sodium perchlorate, ammonium perchlorate and other perchlorates
- Potassium peroxide, sodium peroxide, barium peroxide and other inorganic peroxides
- Potassium nitrate, sodium nitrate, ammonium nitrate and other nitrates
- Sodium chlorite and other chlorites
- Calcium hypochlorite and other hypochlorites

### Flammable substances

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



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

# 5 Initial Start-up

Check whether all parts are provided when unpacking. If any parts or missing or you discern transport damage during unpacking, please contact your dealer or the manufacturer immediately by email to <a href="mailto:support@certoclav.com">support@certoclav.com</a>.

### 5.1 Device description

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

### 5.2 Device dimensions



# 5.3 Scope of supply

### Standard scope of supply

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

#### Recommended accessories

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

### 5.4 Before initial start-up

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

# 6 Installation

### 6.1 Setting up the autoclave

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

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



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

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

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

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



## 6.2 Unlocking the autoclave door

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

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



### 6.3 Touchscreen assembly



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



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



Connecting the touchscreen to the interface box.



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

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

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



Switch on the touchscreen.

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

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

### 6.4 Installing accessories

Optionally available accessories.

6.4.1 Connecting the protocol printer



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

6.4.2 Connecting the barcode reader



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

6.4.3 Connecting the label printer



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

### 6.4.4 Connecting the CertoServer



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

### 6.5 Pressure sensor calibration

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

#### Calibration method:

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





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

# 6.6 Validation and calibration

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



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

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

# 7 Sterilisation Programs

# 7.1 Default settings

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



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

The VACUUM TEST program performs a pressure leak test.

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

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

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

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



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

Only fill the glasses to maximum half their capacity.

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

All programs can be customised by the user.

### 7.2 Editing program parameters

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

Use the arrow keys to toggle between the menu entries.

Use the M key to confirm and save an entry.

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

Retention time: 1-59 minutes.

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



# 8 Basic Operation





### 8.1 Switching on the touchscreen

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

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



### 8.2 Switching off the touchscreen

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



### 8.3 Standby Mode for the touchscreen

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





Please make sure that the autoclave is earthed.

### 9.1 Preparations before use

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

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



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

### 9.2 Replenishing with distilled water

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



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

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



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



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



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

### 9.3 Opening the autoclave door

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



### 9.4 Steps to start a sterilisation process

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

### 9.4.1 Selecting the sterilisation program on the screen

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



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



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

#### 9.4.2 CertoTrace - Documentation and load management

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

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

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



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

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

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

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

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

### 9.4.3 Step-by-step video assistant

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

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



### 9.4.4 Loading the autoclave



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

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



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

9.4.5 Closing the autoclave door

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



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

#### 9.4.6 Material tests and automatic repetitions

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

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

← 21:40:46 2017.05.12 M	ONITOR	ø	How often the pro	gram should be	executed one a	fter another?	
121 °C SOLID NOT RUNNING Cycle 2 of 2	00:00:00	)	1	times			
Vacuum times: 1			Can	cel		START	
Sterilisation temperature: 121 ?C Sterilisation pressure: 2.10 bar Sterilisation holding time: 20 min	STEAM 83.2 °C		1	2	3	-	
Drying time: 3 min	PRESS -1 kPa		4	5	6	,	
OTADT			7	8	9		
START				0			

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

#### 9.4.7 Status screen

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



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



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

### 9.5 Unloading the autoclave

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



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

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

# 9.6 Emptying the used water tank

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





Used water may be hot.

### 9.7 PC software

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

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

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

### 9.7.1 Functions of the CertoCloud

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



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

Pr	otocol Verification		
0	Protocol ID *		Validity verification of exported protocols.
	Device Key *	0 / 24	
Ĩ	Security Code *	0/17	
	VERIFY	0 / 40	

9.7.2 Display of sterilisation protocols via web browser

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

CLOUD						PPORT@CERTOCLAV.CC
E DEVICES	NEW CERTOCLAV	> () PROTOC	OLS > PR	OTOCOL-63FBE298		
≡ Details				CS/	PDI	F 💽 ZIP
Cycle Number <b>3</b>	Device Name New Certoclav	Program Na LIQUID		ime Started /2/17 6:41 PM	Date Finished 8/2/17 8:11	
~ Graph						
					<b>—</b> ;	ressure emperature media temperature 120°C
						105°C 90°C
//						75°C
						45°C
						30°C 15°C
	20 Mins 3	0 Mins 40 Min	ns 50 Mins	60 Mins	70 Mins 8	
Mins 10 Mins		0 Mins 40 Min	s 50 Mins ⊗ Data		70 Mins 8	15°C 0°C
Mins 10 Mins		0 Mins 40 Min			70 Mins 8 Pressure	15°C 0°C
Mins 10 Mins Drogram Program Short Description Liquid sterilization 121 °C 1.1bar 20min		0 Mins 40 Min	× Data	Points		15°C 0°C
Mins 10 Mins Drogram Nort Description Liquid sterilization 121 °C 1.1bar 20min With media sensor		0 Mins 40 Min	☆ Data TimeStamp	Points Temprature	Pressure	15°C 0°C Media Temperature
Mins 10 Mins Program Short Description Liquid sterilization 121 °C 1.1bar 20min With media sensor Vacuum times: 1 Sterilisation temperar Sterilisation temperar Sterilisation temperar	ature: 121°C e: 2.10 bar	0 Mins 40 Min	S Data TimeStamp	Points Temprature 62.8	Pressure 1.03	30.2
Mins 10 Mins Program Short Description Liquid sterilization 121 °C 1.1bar 20min With media sensor Vacuum times: 1 Sterilisation tempera Sterilisation tempera	ature: 121°C e: 2.10 bar	0 Mins 40 Min	Data TimeStamp 0 0.35	Points Temprature 62.8 65.3	Pressure 1.03 0.69	15°C         0°C           80 Mins         0°C           30.2         30.3
Mins 10 Mins Program Short Description Liquid sterilization 121 °C 1.1bar 20min With media sensor Vacuum times: 1 Sterilisation tempera Sterilisation tempera	ature: 121°C e: 2.10 bar	0 Mins 40 Min	Contraction Contra	Points Temprature 62.8 65.3 67.3	Pressure 1.03 0.69 0.49	15°C 0°C 30 Mins 30.2 30.3 30.5
Mins 10 Mins Program Short Description Liquid sterilization 121 °C 1.1bar 20min 121 °C 1.1bar 20min With media sensor Vacuum times: 1 Sterilisation pressure Sterilisation pressure Sterilisation holding 1	ature: 121°C e: 2.10 bar	0 Mins 40 Min	Data     TimeStamp     0     0.35     0.68     1.02	Points Temprature 62.8 65.3 67.3 68.7	Pressure 1.03 0.69 0.49 0.36	15°C 0°C 30 Mins 30.2 30.3 30.5 30.6
Mins 10 Mins Drogram Nort Description Liquid sterilization 121 °C 1.1bar 20min With media sensor Vacuum times: 1 Sterilisation tempera Sterilisation tempera Sterilisation pressure	ature: 121°C e: 2.10 bar	0 Mins 40 Min	Data     TimeStamp     0     0.35     0.68     1.02     1.35	Points Temprature 62.8 65.3 67.3 68.7 69.9	Pressure 1.03 0.69 0.49 0.36 0.26	15°C 0°C 30 Mins 30.2 30.3 30.5 30.6 30.9

# 10 Control Panel of the Autoclave

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

### 10.1 Login Menu

22:32:31 017.05.12	LOGIN	∲.
support@c	ertoclav.com	<b>4</b> 8
•••••		
	LOGIN	

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



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

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

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



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

Û	14:12:01 2016.03.10	Add CertoCloud Account	
		demo@certoclav.com	
		••••••	
		Add account	

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

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

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



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

# 10.2 Support Menu

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



### 10.2.1 Tutorial videos

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



### 10.2.2 Send email to CertoSupport

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



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

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

#### 10.2.3 TeamViewer, remote support and share screen

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

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



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

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


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



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

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

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

### 10.3 Protocols Menu

#### 10.3.1 Viewing protocols

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

	SATION LOGGING	墩	
SORTED BY DATE	· 4	シ┟┙╋╶┓	SORTED BY DATE 🗸 🖓 🔁 🖥
121 °C SOLID	TimeStamp Chamber [min] temp. [°C]	Media temp. Pressure [°C] [kPa]	121 °C SOLID
ID: 27   21:06   2017-05-12   support@certoclav.com	1.00 48.92	0.0 2.00	ID: 27   21:06   2017-05-12   support@certoclav.com
121 °C SOLID	2.00 48.59 3.Successfully 4.00 47.89	0.0 2.00 completed 2.00 0.0 2.00	121 °C SOLID
USER DEFINED	5.00 47.52	0.0 2.00	USER DEFINED 🔹 \/\/\/
ID: 25   20:24   2017-05-12   support@certoclav.com	6.00 47.14	0.0 2.00	ID: 25   20:24   2017-05-12   support@certoclav.com
121 °C HOLLOW	7.00 46.76	0.0 2.00	121 °C HOLLOW
ID: 24   17:59   2017-05-12   support@certoclav.com	8.00 46.36	0.0 2.00	D: 24   17:59   2017-05-12   support@certoclav.com Temperature Media temperature Pressure

#### 10.3.2 Printing protocols

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



10.3.3 Example of a protocol printout



10.3.4 Print barcode

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

ር በ	INFORMATION STERIL	ISATION	LOGGING	尊
SORTED BY DATE 121 °C SOLID ID: 27   21:06   2017-05 121 °C SOLID			a tracing	1222 120
ID: 26   20:29   2017-05 USER DEFINED ID: 25   20:24   2017-05 121 °C HOLLOV ID: 24   17:59   2017-05	Print protocol	-100		zio zio minutes a temperature — Pressure

Now enter the shelf-life of the sterilised products.

ር	INFORMATION	STERILISATION	LOGGING		ø
SORTED BY DATE	Please en expiratior	iter time unt	til	122.2 12	
121 C SOLID ID: 27   21:06   2017-05 121 °C SOLID ID: 26   20:29   2017-05	6	MONT	HS		
USER DEFINED	CANCEL		ок		
ID: 25   20:24   2017-05- <b>121 °C HOLLOV</b> ID: 24   17:59   2017-05-	V	-1 <u>00</u> 0	<sup>10</sup> Time i Temperature —— Mec	20 n minutes dia temperature —	30 Pressure

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

10.3.5 Tracing marked products

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



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

ባ	INFORMATION	STERILISATION	LOGGING	竛
SORTED BY DAT	Ξ	200	Ģ	= 🖶 🕄
121 °C SOLID ID: 27   21:06   2017-0	05-12   support@certoo	Clav.com		67.2
<b>121 °C SOLID</b> ID: 26   20:29   2017-0	05-12   support@certod	clav.com	Λ̈́, Ϊ	
USER DEFINE	-	clav.com	JVV	U
<b>121 °C HOLLO</b> ID: 24   17:59   2017-1		Š 🕹	<sup>20</sup> Time in minutes Temperature — Media tempe	

# 11 Settings

#### 11.1 User administration

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

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

#### 11.2 Network settings

11.2.1 Connecting to a WLAN network

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

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



#### 11.2.2 Connecting to a LAN network

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



#### 11.2.3 Network communication

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

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



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

#### 11.2.4 Connecting to the CertoServer

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

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

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

← SETTINGS				
<b>e</b> User account	WIFI ON/OFF WIFI disabled			
Network	MANAGE WIFI CONNECTIONS			
C Sterilization	ONLINE MODE Synchronize data with www.CertoCloud.com			
Device	CHOOSE SERVER			
Hanguage	CertoCloud Server			
The Notifications				
Calibration				
STEAM: 76.28 °C	/IEDIA: 73.28 °C Pressure: 1.0 kPa support@certoclav.com			

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



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



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



11.2.5 Connecting to the CertoCloud server

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

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



Select the "CertoCloud Server" option.



### 11.3 Sterilisation settings

#### 11.3.1 Customising sterilisation programs

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

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

Now define the program parameters individually corresponds to your requirements:

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

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

<b>4</b> 21:41:20 2017.05.1	VACUUM TIMES [1-10]
B User account	STERILIZATION TEMPERATURE [105-134 °C]
Network	
Sterilization	STERILIZATION TIME [4-60 MINUTES]
Device	5
Hanguage	DRYING TIME [1-25 MINUTES]
1 Notifications	ion
Calibration	Cancel Apply antly

11.3.2 Material tests and automatic repetitions

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

How often the program should be executed one after another?					
[ <b>h</b> ]	times				
Cancel			START		
vacuum times: 1					
1	2	3	-		
4	5	6	,		
7	8	9			
	0		<b>I</b>		

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

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

<b>e</b> User account	Edit user defined program				
	Preheat chamber ON/OFF Heat up the chamber to 50°C before program execution				
Sterilization	Keep temperature ON/OFF Warm up the chamber and steam generator permanently				
	Material testing mode On program start, show a dialog to enter how often to run the program automatically				
<ul><li>Language</li><li>Notifications</li></ul>	Open label printer designer				
Calibration	CertoTrace load documentation Enable autoclave load documentation. Barcodescanner and labelprinter required.				

#### 11.3.3 CertoTrace — Your support during material tests

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

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

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

#### 11.3.4 Label designer

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

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

÷	SETTINGS	← Label designer	Print
<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 how often to run the program automatically		
1 Notifications	Open label printer designer		
Calibration	CertoTrace load documentation Enable autoclave load documentation. Barcodescanner and labelprinter required.		

#### 11.3.5 Real-time protocolling to USB

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



11.3.6 Exporting all protocols to a USB

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

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



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



11.3.7 Exporting all protocols to an SD card

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



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

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

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

#### 11.3.8 Exporting all protocols via a network

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



#### 11.4 System settings

#### 11.4.1 Changing the date and time

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

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

#### 11.4.2 Installing updates via the Internet

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

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

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

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

#### 11.4.3 Installing updates via USB

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

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

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



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

#### 11.4.4 Installing updates via SD card

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

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

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



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

11.4.5 Restoring the default settings

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



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

#### 11.4.6 Changing the language

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

← <sup>21:36:50</sup> 2017.05.12	SETTINGS
	Language English (United States)
Device	
🕀 Language	
1 Notifications	
Calibration	
Service	

#### 11.5 Configuration of SMS and email notifications

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

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

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

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

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

<b>4</b> 21:36:24 2017.05.12	SETTING	S	
Network		SAVE	
€ <sup>°</sup> C Sterilization	If an error occured, send notification		
Device	by SMS	phone number	
Language			
(1) Notifications	< by email	support@certoclav.com	
Calibration	If maintenance required, send notification		
Service	by SMS	phone number	

#### 11.6 Sensor calibration



The sensor calibration should be calibrated by trained personnel only.

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

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



### 11.7 GLP and GMP data

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

#### 11.7.1 Header

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

#### 11.7.2 Autoclave designation

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

#### 11.7.3 Project designation

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

#### 11.7.4 Advanced GLP and GMP settings

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

Setting	<b>Option</b> (Default value is bold)
Print autoclave designation	YES, NO
Print user identification	YES, NO
Print project designation	YES, NO
Print application name	YES, NO
Print signature fields	YES, NO
Print header	YES, NO
Print date	YES, NO
Print autoclave serial number	YES, NO

#### 11.8 Locking settings

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

# 12 Error Messages

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



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

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



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

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

### 13 Maintenance



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

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

Make sure that autoclave is at room temperature.

The following components need to be checked or replaced regularly:

- Sealing ring
- Safety valve

Inspection plan:

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

# 14 Transport and Storage



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

#### 14.1 Preparations

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

#### 14.2 Emptying the water containers

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



#### 14.3 Transport conditions

Please contact your dealer.



Do not drop the autoclave during transport

#### 14.4 Storage conditions

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

# 15 Technical Data

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

# 16 Appendix

### 16.1 Appendix 1: Structural diagram



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

### 16.2 Appendix 2: Circuit diagram



16.3 Appendix 3: CE Declaration of Conformity for Autoclave

### EU/EG Declaration of Conformity

The	manufacturer	
rne	manulacule	

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

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

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

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

	guideline	Description of the
$\mathbf{V}$	2014/68/EU	Directive on the availability of pressure equipment on the market
•	2014/30/EU	Electromagnetic Compatibility Directive
•	2014/35/EU	Directive on the making available on the market of electrical equipment for use within certain voltage limits

Harmonised standards and technical specifications:

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

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

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

Conformity assessment procedure applied: Category: II Module: E1

EU Certificate of Conformity

No. 0B170816.NIMDW08

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

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

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

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

I'm Hui

Management Representative

Page: 1 of 1

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

### 16.4 Appendix 4: CE Declaration of Conformity for Safety Valve

T NUO	VA GENERAL		<b>N.</b> from 018023	901 to 018026900		
	<b>RUMENTS</b> s.r.l.		Tipo: D7//	<b>Α</b> ΟΤ		
http:// www.nuovageneral.it - E-m	VALTIDONE (PC) Italy - Tcl. +39 0523994629 - Fax +39 0523997219 ail: info@nuovageneral.it - P.IVA 01337040339 - C.F. 01317650065 t. Imp.PC 01317650065 - Capitale Sociale € 100.000,00 i.v.		(Typ.): Dis. N°	041-1 Rev. 20/05/08		
DICHIARAZIONE DI CONFORMITÁ Allegato IV D. E. 2014/68/UE DECLARATION OF CONFORMITY Annex IV, E. D. 2014/68/EU				DI SICUREZZA SAFETY VALVE		
DESIGN, MANUFACT PROJEKT , KONSTRUKTION UI	E E COLLAUDO CONFORME ALLA DIRETTIV URE AND TEST ACCORDING TO 2014/68/EU D ND ABNAHMEPRUFUNG GEMAB EG-RICHTLIN ERIFICATION CONFORME A LA DIRECTIVE 2	IRECTIVE	- 15/05/14 CLASS IV M EU-15/05/14 KATEGOR	odule H1 IE IV Formblatt H1		
Garanzia qualità totale Nr. : Garantie gesamte Qualität Nr. :	Full quality assurance system Nr. : Garantie qualité totale Nr. :	Mo	dule H1: DGR-0036-	QS-1180-15		
	or spec.ref.): (Angewandte normen und spezifik lerkblatt Sicherheitsventil 100 / Racc. "E" ed.1		(Regulements et 26 - 1 / AS1271-2003 / EN	-		
Notified body): We	V SÜD Industrie Service GmbH estendstraße 199 80686 Munich		0036	CE		
Marchio del costruttore:	- P.N.: 60 - D.N.:	- Entrata:	- Use			
Manifacturer's Mark):	(Nenndruck): (Nominal Diameter):	(In): (Eintritt):	G.1/4" ISO 228 (Out (Aus			
lerstellerzeichen):	- h / do: 0.28571 (Anschlusgewinde):	(Entre):		rtie):		
Marquae du constructeur)	- II / do: 0,285/1 (D.N):	-	Area:	•		
- Materiali: (Material): (Material): (Matériaux):	- Diametro orifizio: do (Opening diameter): do 7 mm	(0	Area): 0,385 Dffnung): 0,385 Surface):	cm <sup>2</sup>		
1	(Innen durchmrsser): do			ilizzati a pracciona		
	(Diametre orifice):do	- Limit atmosfe	i di temperatura di esercizio dei materiali u erica:	niizzati a pressione		
	- Alzata: h	(Opera	ting temperature limits for materials us			
	(Valve Lift): h 2 mm	pressu (Rotric	re): bstemperaturgrenze der unter Luftdruc	-20 / +200 °C		
8 4.1	(Hub): h	Materi		, , , , , , , , , , , , , , , , , , ,		
APPENDER I	(Haussement): h		tes de température de fonctio			
5	- Coefficiente di efflusso :	matér	iaux utilisés sous pression a	(tmospherique):		
	(Flow coefficient.): Kd 0,90		ficiente di efflusso ridotto :			
	(AusfluBziffer.):			lr = 0,9xKd = 0,81		
9-5-5	(Coefficient d'écoulement		<i>uzierte Ausflußziffer):</i> fficient d'écoulement rée	duit		
	- Pressione di taratura:		abilità campo di taratura:			
	(Setting Pressure): 2,6 bar	(Varia	ability Setting Filed):	2, <b>4 - 3,01</b> bar		
	(Abgleichungssdruck):	(Abgi	eichungsberelch):			
	(Pression de tarage):	(Var	iabilite champ de tara	ge):		
	- Sovrappressione: % della pressione di taratura	-	Scarto di chiusura: %	della pressione di taratura		
10	(Overpressure): (% of Setting Pressure)	(0		of Setting Pressure)		
	(Uber-Unterdruck): 10% (% Abgieichungsdruck)	(	Unterdruck): 15% (%	Abgieichungsdruck)		
	(Surpression): (% De la pression de	tarage) (	Ecart de fermature): (%	De la pression de taraç		
	TIPO FLUIDO: (FLUID TYPE): (MEDIUM):	(Type de fi	luide): ARIA-AIR-LUFT	Temper. : 0		
	- Scarico in atmosfera:					
ch.Z0	(Discharge in Atmosphere):		3			
	(AbfluB gegen Atmosphare): 105,87	kg/h	81,9 Nm / h	1364,92 lt/min.		
1- UNI EN12164 CW614N R360	(Decharge en atmosphere):					
3- UNI EN12164 CW614N R360	TIPO FLUIDO: (FLUID TYPE): (MEDIUM):	(Type de fi	uide): VAPORE SATURO	-STEAM-DAMPF		
5- UNI EN12164 CW614N	- Scarico in atmosfera:					
8- UNI EN12164 CW614N	(Discharge in Atmosphere): (Abfluß gegen Atmosphere): 64,12	ka/h	0 Nm / h	o It/min.		
9- UNI EN 10270-1 SM	(nonab gegen nanopharo).		U MALE I	0 1011111.		
	(Decharge en atmosphere):					
		(Type de fi	luide):			
	- Scarico in atmosfera:					
<sup>10</sup> VITON (-20 / +200 °C)	(Discharge in Atmosphere):	kg/h	3 Nm / h	lt/min.		
Anno sosterio	(Abliub gegen Athosphare).		1907/1	within.		
Anno costruzione:	(Decharge en atmosphere):					
(Year of manufacture):	Si dichiara che la valvola ha subito con buon esito il controllo finale compresa la We declare that this valve has passed suscessfully the test, and the hydro-					
(Baujahr ):	We declare that this valve has passed successfully the test, and the hydra Hiermit bestätigen wir, dass das Ventil die Abschlusskontrolle einschließlid			5 x Nenndruck bestanden bat		
(Annee de fabrication):	Hiermit bestatigen wir, dass das Ventil die Abschlusskontrolle einschließlic On declare que la soupape a ete soumise avec resultat s					
2018	EN 10204 3.1 Cod :			NUOVA GENERAL		
			(F)	100 TA GENERAL		
Ord. : E-MAIL	S.V. Code :			NSTRUMENTS SRL		

Orders Dealer verification Instruction manuals Technical Support



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