# Clave 16+ Instruction Manual **Steam Sterilizer**



Distributed by



Clave 16+ Instruction Manual v1.4

Thank you for choosing our steam sterilizer.

Prior to operating this device, please read the instruction manual carefully and follow all installation instructions.

#### **Regular maintenance:**

If error code E88 appears on the screen when the device is powered on or if it appears on the sterilization report, please contact your dealer or local service company for a maintenance service. This device requires regular maintenance. Error code E88 will be displayed after 1 year of use or after a certain number of cycles, whichever comes first. This is programmed into the maintenance screen.

The Clave 16+ is the same as a Clave 16 except it has a built in compressor that speeds up the drying process. It also has a bacteria filter that requires replacement approximately every 3 months.

Use only distilled water with this device.

Do not re-use the used water from this machine.

**Power on the unit with the door open.** This will allow the unit to get a initial zero pressure reading. The machine may not start a cycle and only beep when the start button is pressed if it has a non-zero pressure reading on powering up.

## Table of Contents

Clave 16+ Quick Guide	4
1. General	. 5
2. Technical specifications	. 6
3. Package contents	. 6
4. Installation	.7
5. Operation	7
5.1 Setup	7
5.2 Preparation of sterilization materials	8
5.3 Selecting the sterilization program	8
5.4 Running the sterilization program	9
6. Advanced settings	. 10
7. Maintenance	. 13
8. Error codes	. 15
9. Transportation and storage	. 16
10. Safety devices	. 16

## Appendix

1.	Water properties and characteristics	17
2.	Diagrams of the sterilization programs	18
3.	Wiring diagram	20
4.	Hydraulic diagram	21
5.	Warranty	22
6.	Contact Information	23

#### **Clave 16+ Quick Guide**

#### Set the Time and Date

- 1. Power on while pressing and holding the Start button for 5 seconds.
- 2. The S1 screen will be displayed. Press Start to enter S1.
- 3. Press the Program button to advance to the Time and Date units. It will start blinking.
- 4. Press the Temperature button to change the number. The time is a 24 hr. Clock.
- 5. Advance to the Date and change the same way.
- 6. Press Start to save.
- 7. Power off.

#### **Retrieve Record on USB Stick**

- 1. Power on. Press the Program button repeatedly until you enter the prior program storage screen. This will show the cycle numbers.
- 2. Press the Temperature button to select a cycle. Insert a USB stick correctly into the USB connector.
- 3. Press the Start button to print or transfer the record to the USB key. Wait at least 10 seconds for the transfer to complete. Repeat procedure (select and start) for any other records to be transferred to the USB stick.

#### **Checking Maintenance Screen**

Hold the 'P' button while powering on. Release it after entering the S1 screen. Press the start button to enter that screen. On a new install, press the 'P' button to select the number to change. Press the temp button to change the number. Set the cycle count to 500 and the date to 1 yr in the future. E88 will come up when either value is reached. Press the start button to save. Don't make changes on a unit already in use for a while.

#### **Changing Drying Time**

- 1. Power on while pressing and holding the Start button for 5 seconds.
- Press the Program button till you get to the S3 screen. Press the Start button to select S3. Press the Program button to select the program to change. Press the Start button. Press the Temperature button to select the temperature of the program.
- 3. The top number will be the holding time. It's not recommended to change the default holding time. The bottom number will be the drying time. Press the Program button to get to the number to be changed. Change the number by using the Temperature button. Press Start to save.

#### 1. General

The steam sterilizer described in this manual is intended for the sterilization of instruments and tools in the medical, dental, beauty, veterinarian and tattoo fields. It is a fully automatic steam sterilizer with 134 °C and 121 °C sterilization temperatures. This sterilizer is in compliance with the European Directive 93/42/CEE, Health Canada, ISO 13485, ETL, CSA and it has been produced in accordance with the EN 13060.



#### **Security Notice**

For safe operation, please pay close attention to the warning symbols below which can be found throughout this manual. Please read carefully and understand the contents of this manual prior to operating this instrument.

Protective conductor terminal

This symbol is for grounding protection inside the machine.



#### HOT SURFACE

This symbol is visible on the front of the panel after opening the door and on the rear enclosure near the exhaust outlet of the fan.



Important safety information.

This symbol is used to draw the attention of the reader to particularly important notions for operator safety.



This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1.

### 2. Technical Specifications

Item	Parameter
Chamber	Ф230mm x 360mm (9" x 14.2")
Rated Voltage	110 VAC 60 Hz
Circuit breaker	F20A
Nominal power	1600VA
Sterilization	121 °C / 134 °C
Consolity of the distilled water tenk	~ 2.5 L (water at maximum level)
Capacity of the distined water tank	~ 0.5 L (water at minimum level)
Operation temperature	5 °C ~ 40 °C
Exterior dimensions	440mm (W) x 400mm (H) x 620mm (D) 17.3" (W) x 15.75" (H) x 24.4"(D)
Net weight	45kg. (99.2 lbs)
Noise level	< 70db
Relative humidity	Maximum 80%, non-condensing
Atmospheric pressure	76kPa ~ 106kPa

#### **3.** Package Contents

No.	Item	Quantity
1	Steam sterilizer	1
2	Instrument tray	3
3	Instrument tray rack	1
4	Instrument tray handle	1
5	Door adjustment tool	1
6	Draining hose	2
7	Instruction manual	1
8	Door seal	1
9	USB Drive	1
10	Power cord	1
11	'O' Ring kit	1

#### 4. Installation

\* Ensure that the sterilizer is installed with 10cm (4") ventilation space on all sides of the sterilizer and 20cm (8") on the top. The clearance required to open the door is 40cm (16"). \* The sterilizer should be placed on a level work table.

\* Do not cover or block the door or any ventilation areas on the sterilizer.

\* Do not install the sterilizer near a sink or in a location where it is likely to be splashed with water.

\* Do not install the sterilizer near a heat source.



#### 5. Operation

#### 5.1 Setup

5.1.1 Open the door and remove all of the inner contents.

5.1.2 Connect the power cord to an outlet of the appropriate voltage.

5.1.3 Power on. The switch is located underneath the control panel on the front of the machine. After turning on the machine, the LCD screen will turn on and show the door position, water level, working program, date, time, etc.



distilled water tank with distilled water.

5.1.4 Filling the distilled water tank

Open the cover and fill the tank with distilled water. When you hear the beep signal, it means that the water level has reached the maximum level. The icon  $\Im$  will be displayed. Please stop filling immediately.

The water level should not exceed this port.



#### **5.2 Preparation of Sterilization Materials**

For the most effective sterilization and to preserve the instrument and tools, please follow the suggestions below:

\* Arrange the instruments of different materials on different trays or with at least 3cm of space between them.

\* Always insert a sterilization paper or cloth between the tray and instrument to avoid direct contact between the different materials.

\* Arrange the containers (glasses, cups, test-tubes, etc) on one side or in an inverted position to avoid water pooling.

\* Don't stack the trays one above the other or put them in direct contact with the walls of the sterilization chamber.

\* Always use the instrument tray handle.

\* Wrap the instruments one by one or, if more tools have to be set in the same bag, verify that these are made of the same material.

\* Don't use metallic clips, pins, or other similar things as this jeopardizes the maintenance of the sterilizer.

\* Don't overload the trays over the stated limit (see Appendix 2).

#### **5.3 Selecting the Sterilization Program**

5.3.1 LCD: The panel displays the cycle temperature, pressure, error code, sterilization state and program.

5.3.2 Temperature button 🖡

Press this button to toggle between 121 °C and 134 °C. 5.3.3 Program button **₽** 

Press this button to toggle between available sterilization programs (see below).

5.3.4 Start/Stop button 🐼

Press this button to start the sterilization cycle. To stop a cycle, press and hold this button for 5 seconds.





**Notice:** All buttons will be locked for the initial 10 seconds after powering up for system initialization.

#### 5.4 Running the Sterilization Program

After selecting the program, the materials to be sterilized can now be placed on the tray and placed inside the chamber, using the tray handle.

5.4.1 After the instruments are loaded, you may close and lock the door by turning the door handle clockwise until it stops. The icon will be illuminated 🗒.



**Caution:** You must turn the door handle to the maximum position, otherwise the alarm On the machine will sound and prevent the cycle from starting.

5.4.2 Starting the sterilization program

Press the start button on the machine and it will start the cycle automatically. It will take  $30 \sim 60$  minutes (see appendix 2).



**Caution:** When you press the  $\bigotimes$  button but the door has not been fully closed, you will see the blinking on the screen. A cycle cannot be started until you close the door completely. Once the door is completely closed, press the  $\bigotimes$  button again. 5.4.3 Sterilization Cycle Completion

After the cycle is complete, the printer will be activated and print out a report of the cycle (if the optional printer has been connected) or save the report on the USB drive (optional).





**Caution:** Always use the tray handle to load or unload the trays from the sterilizer in order to avoid injury or burning.

**Notice:** If you need to interrupt a cycle and remove materials urgently, you may hold the N button for 5 seconds after completing the holding time to skip the dry cycle. This will result in the program skipping directly to the last step and eliminating the drying stage. After one minute, the cycle will end.

#### 6. Advanced Settings

#### **6.1 Entering the Advanced Settings**

6.1.1 Power on the machine while holding the button for 5 seconds. This will enter into the advanced setting mode.
6.1.2 Select the state (state 1 to state 3) by pressing the program button. Press the button to enter the setting.

# S1

#### 6.2 S1 State

If you select the S1 state, you may change the unit of **temperature** and **pressure**, and adjust **time** and **date**.



6.2.1 The first option is to select the unit of temperature. Press **I** button to select the unit. The unit you selected will be blinking. Press the **R** button to get to the next item.

6.2.2 You may select the unit of pressure in the same manner.

6.2.3 Then press  $\mathbb{P}$  button to get to the next item to adjust the time and date. After the date or time is set, then the data can be saved. If you want to save the settings you have programmed, then press  $\mathbb{P}$  to save. It will return to the screen of selecting stages.

#### 6.3 S2 State

6.3.1 You can check the number of sterilization cycles run on the machine. It cannot be changed by the operator.

6.3.2 Set the parameter for high altitude (if above 2.0 km or atmospheric pressure is below 80 kPa, you may need to adjust for this parameter).



The Serial # and Cycle # cannot be changed by the operator.

#### 6.4 S3 State

6.4.1 Adjust the length of the sterilization and drying time. Press 🚱 program button to select the program. 🔏 👔 🛱 💾 Press temperature button to select the temperature of program. Then press 🗐 to adjust the drying time and holding time.



holding time  $\rightarrow$   $\theta\theta$  s3 drying time  $\rightarrow$   $\theta\theta$ 

Language

Serial #

**Notice:** The default sterilization parameters have been chosen to provide optimal sterilization results. We do not suggest adjusting these parameters unless it is necessary.

#### 6.5 Printer (Optional)

6.5.1 Connect the printer data cable 6.5.2 Connect the printer power cable.

#### 6.6 USB Drive (Optional)

A USB drive can be used as a method of storing the sterilization cycle report. To do so, insert the USB drive in the slot on the right side panel. The information will be automatically recorded to the USB drive after the cycle has completed. The name of the file is determined by the serial number of the machine and the cycle number. For example: The serial number is E00001. The cycle number is 00012. The file name on the USB drive is 01001200.txt. The first 2 numbers represent the machine serial number. The middle 4 numbers represent the cycle number. The last 2 numbers represent the error code. 00 is no error, 01 is E01....

#### 6.7 Retrieving Information from a Prior Cycle

Press F repeatedly until you enter the prior program storage screen. This will show the cycle #. Press the **b** button to toggle between different cycles. To print or send details to the USB drive, press the **b** button. The most recent 20 cycle records are stored.



When viewing printed data records, refer to the diagram below:



v 2N08231C \_\_\_\_\_ T3: 15:11:30 086.8C 050.5kPa T4: 15:11:50 083.5C 009.9kPa 15:15:50 108.2C 101.1kPa 15:16:30 097.2C 009.7kPa 000.0C 000.0kPa Max. Temperature:000.0C Min. Temperature:000.0C Max. Pressure:000.0kPa Min. Pressure:000.0kPa

- T7: 15:16:00 000.0C 000.0kPa
- T8: 00:00:00 000.0C 000.0kPa
- End 15:22:17 116.8C 083.4kPa

#### \_\_\_\_\_

Ster. Value: Failure E20 Date: 2018-06-05 v 2N08232C

\_\_\_\_\_

#### 7. Maintenance

Frequency	Maintenance operation
	Clean the door seal
Daily	Clean the external surface
	Drain the used water tank
Weelder	Clean the distilled water tank (drain tank)
weekiy	Clean the sterilization chamber
Monthly	Clean the filter in the chamber and tank
Every 3 months	Replace the bacteria filter
Every 6 ~ 12 months	Replace the door seal

# 7.1 Clean the distilled water tank every week with isopropyl alcohol or a medical disinfectant. Drain unused water.



#### 7.2 Clean the chamber weekly.

- 7.2.1 Remove all trays and the tray rack from the chamber.
- 7.2.2 Clean the chamber with a smooth cloth saturated with distilled water.
- 7.2.3 Apply the same procedure to the trays and rack.



#### 7.3 Clean the door seal.

7.3.1 Clean the door seal weekly with a smooth cloth saturated with distilled water.



#### 7.4 Door adjustment

Under normal circumstances, the chamber door does not require adjustments. However, if the seal fails (resulting in steam leaking from the front of the chamber), you may use the spanner tool to tighten the door seal.

7.4.1 Open the door.

7.4.2 Insert the spanner tool in the gap beneath the plastic cover. Use the spanner to grip the adjusting nut (Fig. 1). Turn the nut counter clockwise as in the figure below (Fig. 2). This will tighten the sealing plate.

7.4.3 Turn the nut until the sealing plate is tight. If the door knob is too tight, you may also turn the nut clockwise to loosen it.



Caution: Never adjust the chamber door while the door is closed.

#### 7.5 Replacement of the door seal

- 7.5.1 Open the chamber door.
- 7.5.2 Remove the door seal ring carefully by hand.
- 7.5.3 Clean the door seal ring carefully with a smooth cloth saturated with distilled water.
- 7.5.4 Moisten the new seal with medicinal disinfectant or isopropyl alcohol or distilled water.
- 7.5.5 Insert the new door seal and press in sequence as follows:





**Caution:** Please insure the chamber and the door have cooled prior to replacing the door seal.

#### 7.6 The Drain Valve



#### **8.** Error Codes (Power off and on to clear error)

Code	Description	Proposed Solution
E01	Steam generator temperature is too high	Power off. Wait 5 minutes. Power on & run a new cycle. Contact dealer if error returns.
E02	Inner chamber temperature is higher than 140 °C	Power off. Wait 5 minutes. Power on & run a new cycle. Contact dealer if error returns.
E03	Outer chamber temperature is higher than 160 °C	Power off. Wait 5 minutes. Power on & run a new cycle. Contact dealer if error returns.
E04	Takes too long to reach holding time	Power off. Wait 5 minutes. Power on & run a new cycle. Contact dealer if error returns.
E05	Over pressure inside chamber, unable to release	Power off. Wait 5 minutes. Power on & run a new cycle. Contact dealer if error returns. On a Plus version, replace V1 if error occurs at 8 minutes.
E06	Door lock fault	Make sure you have turned the door handle to the maximum position. Check the door switch.
E09	Pressure leak, takes too long to reach pressure and temperature	Check if the distilled water tank is empty. Check for leaks. Contact dealer if error returns.
E10	Door lock problem	Try again. Open and close the door. Contact dealer if error returns.
E11	Steam generator element not heating	Power off. Wait 5 minutes. Power on & run a new cycle. Contact dealer if error returns.
E12	Chamber element not heating	Power off. Wait 5 minutes. Power on & run a new cycle. Contact dealer if error returns.
E20	Program cycle was ended manually	Power off, wait, and power back on.
E21	Failure to enter the holding time	Power off. Wait 5 minutes. Power on & run a new cycle. Contact dealer if error returns.
E24	Pressure leak, lower than 30kPa when the temperature is 120 °C	Power off. Wait 5 minutes. Power on & run a new cycle. Contact dealer if error returns.
E34	Plus version only, back pressure too high at the drying phase	Power off. Contact dealer. Clean or replace V1.

ЕОО	Maintenance request from the	Contact dealer or service company and have a		
E00	machine	maintenance done.		

#### 9. Transportation and Storage

**1.** Turn off the sterilizer before transportation or storage. Pull out the plug. Let the machine cool down.

**2.** Drain the distilled water tank and the used water tank.

**3.** Conditions for transportation and storage:

Temperature:  $-20 \degree C \sim +55 \degree C$  (all water must be removed if below  $0 \degree C$ ) Relative humidity:  $\leq 85\%$ Atmospheric pressure: 50kPa ~ 106kPa.

**4**. If shipped, the unit must be strapped to a pallet. Do not ship in the box alone.

#### **10. Safety Devices**

**1. Circuit breaker:** Protects the sterilizer against possible failures and damage to the internal components.

Action: Interruption of the power supply. Requires a manual reset. If it trips again, contact a service person.

**2. Thermal cutouts on the main transformer windings:** Protection against possible short circuit and overheating of the main transformer winding. **Action:** Interruption of the power to the transformer. Contact a service person.

**3. Safety valve:** Protection against possible sterilization over pressure. **Action:** Releases steam and restores pressure inside the chamber to a safe level.

**4. Safety micro-switch for the door status:** Informs the user if the door is incorrectly closed. **Action:** Signal indicates that the door is not closed properly.

**5. Thermal switch on chamber heating elements.** Protection against possible overheating of the chamber.

Action: Interruption of the power supply to the chamber elements. Resets when it cools.

# **6. Thermal switch on steam generator heating elements.** Protection against possible overheating of the steam generator.

Action: Interruption of the power supply to the steam generator element. Resets when it cools.

**7. Door safety lock.** Protection against accidental opening of the door. **Action:** Prevents accidental opening of the door during a sterilization cycle.

**8. Self-leveling pressure system:** Pressure system adjusts to a neutral pressure level in case of a manual cycle interruption, alarm or power loss.

Action: Automatic restoration of the atmospheric pressure inside the chamber.

## Appendix 1

## Water Properties / Characteristics

Description	Description Feed Water		
Evaporate residue	$\leq 10 mg/L$	$\leq$ 1.0mg/kg.	
Silicon dioxide (SiO <sub>2</sub> )	$\leq 1$ mg/L	$\leq$ 0.1mg/kg	
Iron	$\leq$ 0.2mg/L	$\leq$ 0.1mg/kg.	
Cadmium	$\leq$ 0.005mg/L	$\leq$ 0.05mg/kg	
Lead	$\leq$ 0.05mg/L	$\leq$ 0.1mg/kg.	
Rest of heavy metals	$\leq$ 0.1mg/L	$\leq$ 0.1mg/kg.	
Chloride	$\leq 2$ mg/L	$\leq$ 0.1mg/kg	
Phosphates	$\leq$ 0.5mg/L	$\leq$ 0.1mg/kg.	
Conductivity	$\leq 15 \mu s/cm$	$\leq 3\mu s/cm$	
PH Value	5 ~ 7.5	5 ~ 7	
Appearance	Colorless, clean	Colorless, clean	
Hardness	$\leq$ 0.02mmol/L	$\leq$ 0.02mmol/L	

#### Appendix 2

#### **Diagrams of the sterilization programs**

Pro	ograms	Temp °C	Pressure kPa	Holding time	Total time (min)	Туре	Max. load (kg)	Max. load per tray (kg)
×		134	210	4	14~30	Unwrapped solid	4.00	1.20
Unw	rapped	121	110	20	30~45	material	4.00	1.20
T ↓ ↓ I	Liquid	134	210	10	30~55	Liquid	1.00	0.20
EE	Plastic	121	110	30	35~60	Plastic	1.00	) 0.30
	A	134	210	6	30~45	Wrapped porous material	4.00	1.20
Wr	apped	121	110	20	35~55	Single wrapped solid or hollow material	3.00	1.00
						Unwrapped porous material	1.00	0.30
						Single wrapped porous material	0.75	0.25
Prion		134 210	210	18	35~55 Dual wrapped porous material Single wrapped hollow material	Dual wrapped porous material	0.50	0.15
	non					Single wrapped hollow material	3.50	1.00
						Dual wrapped solid and hollow material	1.50	0.50
D: (op	rying tional)				1~20			

The time required for the sterilizer to be ready for routine use after the power is switched on is less than 5 minutes.

The maximum temperature of the 134 °C sterilization cycle is 137 °C.

The maximum temperature of the 121 °C sterilization cycle is 124 °C.



#### **APPENDIX 3**

#### WIRING DIAGRAM



- TP1: Steam generator temperature sensor
- TP2: Inner temperature sensor
- TP3: Chamber wall temperature sensor
- V1: Air release valve (normally open)
- V4: Water release valve (normally closed)

#### Appendix 4

#### **Hydraulic Diagram**



V1: Air release valve (normally open) P/N 90012024 V4: Water release valve (normally closed) P/N 90012025



New version V1



Air release valve V1



Water release valve V4

## Certificate of Warranty

All new Clave16 (+) or Clave 23 (+) or Class B autoclaves installed by a Flight Dental Systems authorized dealer are covered for a period of two (2) full years from the time of purchase. The warranty covers defects in parts, workmanship and materials for two (2) years except for door gaskets and filters which are wear and tear items. This warranty does not include labor or installation. This warranty does not apply to any device that has been subjected to improper use or accident; nor shall it extend to autoclaves that have been repaired or altered by an unauthorized dealer or technician. The warranty also does not include routine cleaning or preventive maintenance.

Flight's obligation is limited to the repair or replacement of parts for the autoclave. No other warranties or obligations are expressed or implied. The user must follow the instructions for use as outlined in the user manual. To activate the warranty, the registration card must be completed and mailed or faxed to Flight within fourteen (14) days of purchase or you may call our customer service department at the number listed below. Products will only be received and accepted for repair from an authorized dealer and only with prior return authorization from Flight.

All Transportation charges to and from Flight must be paid for by the owner of the Autoclave. Flight will not accept COD shipments. If repairs are needed during the first 90 days after purchase of an autoclave and a local authorized service dealer is not available, Flight will arrange pick up of the unit at Flight's expense. This will be on an individually evaluated basis and ONLY with pre-approval. Note: If you have any questions or there are any difficulties with this instrument and the solution is not covered in this manual, please contact your dealer or Flight Dental Systems. Do not attempt to service this device yourself.

Authorized Dealer:				
Installed by:				
Product Serial Number:				
Product Description:				
Product Model:				
Purchased Date:	Invoice Number:			
End User Name:				
Telephone:	Fax:			
Email:				
Address:				
City:	_State/Province:			
Zip/Postal code:	Country:			

#### **Contact Information**

Thank you for taking the time to review the Flight Dental Unit's Instruction Manual. Your feedback or comments regarding the document is welcomed. For any comments and concerns please mail, e-mail or phone us at:

#### **Sales and Marketing**

sales@flightdentalsystems.com 1-866-799-0517 905-799-0517

#### **Technical Support**

1-866-799-0517 905-799-0517

#### **Parts and Warranty**

1-866-799-0517 905-799-0517

#### Mailing and Shipping Address (Office)

21 Kenview Dr, Unit 11 Brampton, ON Canada L6T 5G7 L6T 5G7