

Instruction Manual

AG Neovo Autoclave LouieP Séries Model: P-M10T / P-M10TR

Please read this manual carefully before use.

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1. Important Safety Instructions

WARNING: DO NOT place high temperature objects on top of the equipment to prevent objects dropping and causing fire or smoke.

L WARNING: Please install, operate and maintain the sterilizer in accordance with this Instruction Manual. Failure to do so could result in serious injury or damage to the unit.

WARNING: Use only FDA-cleared chemical & biological indicators designed for steam sterilization that are compatible with the particular sterilization cycle temperature and exposure time being monitored.

Use sterility monitors with each sterilization load. If a sterilizing cycle is terminated prematurely, reprocess instruments (loads) to ensure sterility of the load. Follow manufacturer's instructions for proper disposal of used indicators.

WARNING: Use only FDA-cleared accessories are intended to be used with this autoclave model P-M10T and P-M10TR. Using other trays could restrict air / steam flow to items resulting in inadequate sterilization and drying.

WARNING: When pouching or wrapping items, use only sterilization pouches and wraps that have been cleared by the FDA and labeled for use with the steam sterilization cycle being used. Follow the manufacturer's instructions for use.

WARNING: DO NOT overload the chamber! Adequate space is required around items in trays for steam circulation and drying. Failure to allow adequate space will compromise sterilization and drying. Items and packaging should be completely dry when removed from the sterilizer to minimize the potential for recontamination.



WARNING: DO NOT place alcohol or other flammable items in the sterilizer. An explosion could occur, causing personal injury.

Gasoline Alcohol Gas Chemical <u>Figure 1</u>

WARNING: A separate (dedicated) circuit is recommended for the sterilizer. The sterilizer should not be connected to an electrical circuit with other appliances or equipment.



Figure 2

WARNING: Always check the status of the electric wire; unplug the power cord if breakage occurs. If needed, contact your supplier for service support.

WARNING: DO NOT allow children use or play with this sterilizer.

WARNING: DO NOT insert fingers into the gap on the hinge side of the door.

WARNING: The pressure gauge must be checked before opening the door. If the pressure is not zero (0), DO NOT try to open the door.

WARNING: In an event of emergency, or before carrying out any maintenance, always disconnect the power cord from the socket-outlet.



WARNING: Use sterilization indicator test strips to check if sterilization has been successful.



- WARNING: If the ALARM LED indicator light illuminates, the machine is overpressured or overheated. The sterilizer will shut down automatically. Contact your supplier for service support.
- WARNING: Use only distilled water. Normal tap water contains minerals, especially chlorides, which have corrosive effects on stainless steel. Failure to use distilled water will invalidate the warranty.

Pure water City water Groundwater...



Figure 5

CAUTION: DO NOT place any objects on the power plug or power cord.

CAUTION: The case and metal surface of the sterilizer become very hot during the operation process. Please DO NOT touch it.

CAUTION: DO NOT place any objects on water reservoir cap.

CAUTION: Always check the water level in the reservoir before running a sterilization cycle. If the LOW WATER LED indicator light illuminates, add distilled water. If the water is sufficient, but the LOW WATER LED indicator light is still illuminating, refer to the Troubleshooting guidelines.



CAUTION: The water level must remain between the green "FULL LEVEL " and " MINIMUM LEVEL " labels on the right side of the sterilizer.



CAUTION: The ADD WATER LED indicator will illuminates during the sterilization process. This is a part of the normal operation and does not require users to take any steps.



CAUTION: After the sterilization cycle completed, when opening the door, there will be steam and hot water present avoid contact.

CAUTION: DO NOT place any objects on top of the sterilizer.

CAUTION: DO NOT turn the sterilizer up-side-down or let it to drop on the power plug.

CAUTION: It takes at least two (2) or more people to carry the sterilizer in order to prevent it from dropping.

CAUTION: Always wait at least 20 minutes between each sterilization cycle.

CAUTION: Please unplug the power cord and drain off water from the water reservoir if the sterilizer will not be used regularly.

CAUTION: Always keep the sterilizer clean.

2. Explanation of Safety Symbols and Notes

\wedge	Caution, consult instruction manual for use
	Protective earth (ground)
\sim	Alternating Current
	ATTENTION, Hot surface
Â	CAUTION, risk of electric shock.
X	Disposal of Electrical & Electronic Equipment (WEEE): This equipment should be handed over to an applicable collection point for the recycling of electrical and electronic components or parts. For more detailed information about the recycling of this equipment, please contact your local city office, household waste disposal service or the retail store where you purchased this equipment. (European community only)
EC REP	Authorized representative in the European Community
	Manufacturer
	Date of manufacture It is a 6-digit number. The first 4 digits represent the year and the last 2 digits represent the month.
Ĩ	Consult instructions for use
	ON (Power), connection to the mains
\bigcirc	OFF (Power), disconnection from the mains
Power	Power switch
NOTE	Indicates information that user should pay special attention to

3. Unboxing

WARNING: It takes at least two (2) or more people to carry the sterilizer in order to prevent it from dropping.





- A Cut the drawstrings.
- B Lift the top cover of the cardboard box.
- C Remove the body circumference of the cardboard box and the packaging materials inside.
- D Lift the sterilizer from the base of the package carefully.
- E Check whether all accessories are as follows (the accessories are packed inside the sterilizer):
 - Instruction manual x 1
 - Heater Cover x 1
 - Tray Rack x 1 (standard)*
 - Tray x 3 (standard)*
 - Tray Holder x 1 (standard)*
 - USB flash drive (optional for P-M10TR only)*
 - Cleanser for chamber x 2 (standard)*
 - Pouch Holder (optional)*
 - * Accessories will vary according to the order requirements.

CAUTION: We recommend keeping all packaged materials for future use.

3.1 Shipping Symbols

Symbol	Description	Symbol	Description
<u><u><u></u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u></u>	Face up	X	Stacking limited to four layers
	Fragile, handle with care	Ť	Keep away from rain
R	DO NOT use hooks		

4. Installation

4.1 Environment

The design of this sterilizer complies with international EMC (Electromagnetic Compatibility) standards. Perform operations according to the explanations below if necessary for different environments to eliminate interference.

- Move the equipment or turn its direction.
- Expand the space between the equipment and other machines.
- Insert the plug into other socket-outlets.
- Consult your local dealer or a qualified electrician.
- Refer to the "12 Specifications " for the ambient temperature of the installation.

4.2 Water Quality

NOTE:

Distilled water or mineral-free water supplied to the sterilizer should have the physical characteristics and maximum acceptable contaminant level listed in the table below:

Physical characteristics and maximum acceptable contaminant Ingredient content of the sterilizer.

Element	Condensate – allowable content
Evaporate residue	≤15 miligrams/liter (mg/l)
Silica	≤2 mg/l
Iron	≤0.2 mg/l
Cadmium	≤0.005 mg/l
Lead	$\leq 0.05 \text{ mg/l}$
Rest of heavy metals	≤0.1 mg/l
Chloride	≤3 mg/l
Phosphate	≤0.5 mg/l
Conductivity	≤50 μs/cm
pH value	6.5 to 8
Appearance	Colorless, clean, without sediment
Hardness	≤0.1 mmol/l

(ANSI / AAMI ST46 ref.).

Authorized laboratories should test for compliance with the data described above using recognized analytical methods.

It is recommended to perform water quality test once per month. Using water that does not comply with the table above will have a severe impact to the lifespan of the sterilizer, and may invalidate the warranty from the manufacturer.

CAUTION: Failure to change water may result in sterilizer malfunction. DO NOT use bleaching agents or any abrasive materials / substances in chamber (i.e. bleach, steel wool, wire brush, scouring powder, etc.). Failure to comply may result in damage to the chamber and / or other components.

4.3 Sterilizer Installation

Following the installation steps from A to G below



CAUTION: Read and follow " 5.2 Sterilizer Overview " to understand the overview of the sterilizer.

- **CAUTION:** Please make sure that the carrying capacity of the mounting table is enough to support the size and weight of the sterilizer during installation. Refer to "12 Specifications " for information of the weight of the sterilizer.
- CAUTION: Place the sterilizer on a stable workbench or work surface, and make sure that there is at least a 4 inches (10 cm) gap between the wall or other equipment components and the side of the equipment, so that air can flow freely.

CAUTION: Make sure that the door can be opened freely after installation.

- WARNING: DO NOT install or operate the sterilizer in areas where flammable objects or volatile substances are used or stored. It may result in explosions and cause physical injuries. A well-ventilated installation location is required.
- A. Open the water reservoir cap. Pour the distilled water into the water reservoir as shown in Figure 10.



Figure 10

CAUTION: Only fill the distilled water into the sterilizer. DO NOT fill the water over the yellow water level mark, as shown in <u>Figure 11</u>.



WARNING: DO NOT add the distilled water into the water reservoir during the sterilization process to prevent overflow. After each sterilization cycle has been completed, all remaining water in the sterilizer will return to the water reservoir automatically.

B. As shown in <u>Figure 12</u> (standard accessories), install the Heater Cover onto the chamber and make sure the round edge faces the back, and that the vertical front edge of the chamber is firmly positioned in the corresponding slot in the lower part of the chamber.



Figure 12

C. Install the tray rack (standard accessory). as shown in Figure 13.

CAUTION: The tray rack should be installed as shown in <u>Figure 13</u> below. The groove of the tray rack will pass through the bushing in the chamber.



D. Install the trays as shown in Figure 14 (standard accessory).



Figure 14

- E. Close the door and rotate the "Door handle "90° clockwise to lock it.
- F. Make sure the "POWER switch " is set in the OFF " O " position, and then insert the power cord into an independent (dedicated) power outlet.



WARNING: The power plug is one of the emergency disconnection measures. Make sure that the power plug can be accessed easily after installation.

G. Turn the "POWER switch " to the ON " I " position, and the power LED indicator should turn on. The "DOOR OPEN" LED indicator should go off. If the above requirements cannot be achieved, turn the power off and unplug the power, and then repeat steps from A to F of " 4.3 Sterilizer Installation ". If problems still persists, switch off the power and unplug the power plug of the sterilizer. Contact your local dealer for help.

5. Introduction

5.1 Indication for Use

The AG Neovo Autoclave LouieP Series (models P-M10T and P-M10TR) is intended to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable equipment. Dental handpieces can be sterilized in the models P-M10T and P-M10TR. The AG Neovo Autoclave LouieP Series (models P-M10T and P-M10TR) is not recommended for sterilization of liquid intended for direct patient contact.

5.2 Sterilizer Overview









5.2.2 Inside of the chamber



5.2.3 Control Panel



6. Operation

6.1 Operation Overview

6.1.1 Sterilization and RE-DRY Program



6.1.2 Vacuum Test / B. D. Test / Hanpieces



6.1.3 Maximum Load

	<u> </u>	Program				
		Unwrapped	Wrapped	Wrapped	Handpieces	
Ter	mperature	270 °F (132 °C)	250 °F (121 °C)	270 °F (132 °C)	270 °F (132 °C)	
F	Pressure	27.2 psi (186 kPa)	15 psi (104 kPa)	27.2 psi (186 kPa)	27.2 psi (186 kPa)	
Steri (r	lization time minutes)	3	30	4	4	
Dry tir	me (minutes)	30	30	30	30	
	Solid Instrument	9.0 lbs (4080 grams)	-	-	-	
	Textile Packs	-	2.9 lbs (1300 grams)	-	-	
Max.	Pouches		-	2.9 lbs (1300 grams)		
	Handpieces	-	-	-	9 handpieces with other instruments 4.5 lbs (2040 grams)	

Test program:

	\ \	Program			
		Devia Diekteet	Pum		
		Bowle-Dick test	P-M10T	P-M10TR	Re-ary
Te	emperature	273 °F (134 °C)	-	-	320 °F (160 °C)*
	Pressure	29.5 psi (203.4 kPa)	60 cmHg (80 kPa)	60 cmHg (80 kPa)	-
Ster (ilization time (minutes)	3.5	-	-	-
Dry time (minutes) -		-	-	-	10
Va (cuum Time (minutes)	-	10	10	-
Max.	Solid Items	Bowie-Dick-type	NI/A		9.0 lbs (4080 grams)
load	Packs (Pouched)	test pack	IN/A	IN/A	2.9 lbs (1300 grams)

" * " denotes the temperature is measured on the outside chamber wall, not in the sterilization chamber.

6.1.4 Cycle Parameters

Cycle	Ster. Temp.	Ster. Pressure	Ster. Time (minutes)	Dry Time (minutes)	Items to be Sterilized (always consult the item manufacturer's recommendation for sterilization)
Un- wrapped	270 °F (132 °C)	27.2 psi (186 kPa)	3	30	 Instruments loose on a tray. Loose items manufacturers recommend for exposures at 270 °F (132 °C) for 3 minutes. Note: The sterility of unwrapped items is compromised on exposure to a non- sterile environment.
Wrapped (Pouches)	270 °F (132 °C)	27.2 psi (186 kPa)	4	30	 Pouched or loosely wrapped instruments. Wrapped trays of loose instrument. Wrapped items manufacturers recommend for exposures at 270 °F (132 °C) for 4 minutes.
Wrapped (Textile Packs)	250 °F (121 °C)	15 psi (104 kPa)	30	30	 Textiles and surgical packs wrapped for sterilization. Items except liquids, manufacturers recommend for exposures at 250 °F (121 °C) for 30 minutes.
Handpieces	270 °F (132 °C)	27.2 psi (186 kPa)	4	30	Dental handpieces (wrapped) Note: Verify acceptability of sterilization parameters with handpiece manufacturer.
Bowie-Dick test	273 °F (134 °C)	29.5 psi (203 kPa)	3.5	N/A	N/A
Re-Dry	N/A	N/A	N/A	10	N/A
Pump test	N/A	N/A	N/A	10	N/A

6.2 Preparation for Sterilization

- A. Follow "4 Installation " and complete the installation first.
- B. Follow "4.3 Sterilizer Installation " and make sure that there is sufficient water in the water reservoir.
- C. Check that the reading of the pressure gauge returns to zero (0), and then rotate the "Door handle " 90° counter-clockwise to open the door.
- D. Place objects for sterilization and the chemical indicator (or biological indicator) onto the tray according to your needs. As shown in Figure 21.



Figure 21

CAUTION: Make sure to clean and rinse the objects for sterilization before loading.

WARNING: Please refer to the maximum allowed load in "6.1.3 Maximum Load". Not following these instructions may cause the sterilizer to malfunction and cause the sterilization cycle to fail.

WARNING: Use only FDA-cleared chemical & biological indicators designed for steam sterilization that are compatible with the particular sterilization cycle temperature and exposure time being monitored.

Use sterility monitors with each sterilization load. If a sterilizing cycle is terminated prematurely, reprocess instruments (loads) to ensure sterility of the load. Follow manufacturer's instructions for proper disposal of used indicators.

- E. Close the door and then rotate the "Door handle "90° clockwise to lock it.
- F. Turn on the "POWER " switch to the "I" (ON) position, and the power indicator should turn on. The " DOOR OPEN " indicator should go off.

WARNING: The door must be closed completely while the equipment is operating. If the "DOOR OPEN " LED indicator turns on as shown in <u>Figure 22</u>, it means that the door is not properly closed.



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6.3 Select a Sterilization Program



WARNING: DO NOT overload the sterilizer! There must be sufficient space between objects on the tray to perform optimal steam sterilization cycle and drying. Sterilization and drying is affected when there is insufficient space between sterilizing materials Objects and packages removed from the sterilizer should be completely dry to minimize the possibility of re-contamination.

- A. Refer to "6.2 Preparation for sterilization "before starting the sterilization program.
- B. Timing diagram for the sterilization program as shown in Figure 23.





C. Press " STERI ITEM " We and select 3 different programs. Related parameters are as follows:

No	Sterilization program	Sterilization temperature	Sterilization time	Drying time
1	Wrapped 250 °F	250 °F (121 °C)	30 minutes	30 minutes
	(Pouches, packs)			
2	Unwrapped 270 °F (Instrument)	270 °F (132 °C)	3 minutes	30 minutes
3	Wrapped 270 °F	270 °F (132 °C)	4 minutes	30 minutes
	(Pouches)			

D. Press the "START" button. The sterilization temperature, sterilization time, and drying time will be displayed two times consecutively, and then the sterilizer will run the selected programs automatically. The program execution status will be displayed on the status indicator, as shown in Figure 24.



The buzzer will sound while the display flashes when completed. When the buzzer stops and the "COMPLETE" LED indicator on the progress status indicator turns on, the execution of the programs has been completed.

WARNING: If the "COMPLETE " LED indicator did not turn on, it means that the cycle failed and should be run again.

E. Open the sterilizer door and remove the sterilization object. Check the status indicator. Repeat the cycle if it failed. Contact the qualified technical personnel to perform calibration if necessary. Please refer to "11. Troubleshooting ".

WARNING: Check that the pressure gauge reading is zero (0) before opening the door.

WARNING: Beware of the steam when opening the door after sterilization has been completed.

WARNING: Be careful when removing the sterilization object because the metal surface may still be very hot. Always wear appropriate hand guards when removing trays or use suitable aiding tools (tray holder) to lift the tray.

WARNING: If the sterilizer is used continuously, let the sterilizer cool down for 20 minutes between each sterilization cycle.

6.4 RE-DRY Program



Press the "RE-DRY " button and the LED indicator will turn on.

Then press the "START " button **WW** and the "RE-DRY " program will run for 10 minutes. During the execution process, the "DRY " LED indicator on the " progress status indicator " will flash.

The buzzer will sound while the display flashes when completed. When the buzzer stops and the " COMPLETE " LED indicator on the progress status indicator turns on, the process has been completed.

6.5 HANDPIECES Program

- WARNING: DO NOT overload the sterilizer! There must be sufficient space between the objects on the tray to perform the optimal steam sterilization cycle and drying. Sterilization and drying will be affected if there is insufficient space between objects. Objects removed from the sterilizer should be completely dry to minimize the possibility of re-contamination.
- A. Refer to "6.2 Preparation for sterilization "before starting the sterilization program.
- B. Timing diagram for the Handpieces sterilization program.





and select "Handpieces Program". Related

sterilization durations are as shown in the table below:

Sterilization temperature	270 °F (132 °C)
Sterilization duration	4 minutes.
Drying duration	30 minutes

D. Press the "START " button **W**. The sterilization temperature, sterilization time, and drying time will be displayed two times consecutively, and then the sterilizer will run the selected program automatically. The program execution status will be displayed on the status indicator, as shown in <u>Figure 27</u>.





The buzzer will sound while the display flashes when completed. When the buzzer stops and the "COMPLETE" LED indicator on the progress status indicator turns on, the execution of the programs has been completed.

WARNING: If the "COMPLETE " LED indicator did not turn on, it means that the cycle failed and should be run again.

E. Open the sterilizer door and remove the sterilization object. Check the status indicator. Repeat the cycle if it failed. Contact the qualified technical personnel to perform calibration if necessary. Please refer to "11. Troubleshooting ".



 Δ **WARNING:** Beware of the steam when opening the door after sterilization has been completed.



WARNING: Be careful when removing the sterilization object because the metal surface may still be very hot. Always wear appropriate hand guards when removing trays or use suitable aiding tools (tray holder) to lift the tray.

WARNING: If the sterilizer is used continuously, let the sterilizer cool down for 20 minutes between each sterilization cycle.

6.6 B.D. TEST Program

A. Refer to "6.2 Preparation for sterilization " before starting the sterilization program.



B. Timing diagram for the B.D. test program as shown in Figure 28.

C. Press " B.D. TEST " button **I** to select " B. D. TEST " program. Related sterilization durations are as shown in the table below:

Sterilization temperature	273 °F (134 °C)
Sterilization duration	3.5 minutes
Drying duration	N/A

D. Press the "START" button . The sterilization temperature, sterilization time, and drying time will be displayed two times consecutively, and then the sterilizer will run the selected program automatically. The program execution status will be displayed on the status indicator, as shown in Figure 29.

NOTE: The DRY step will not be executed.





The buzzer will sound while the display flashes when completed. When the buzzer stops and the " COMPLETE " LED indicator on the progress status indicator turns on, the execution of the programs has been completed.

WARNING: If the " COMPLETE " LED indicator did not turn on, it means that the cycle failed and should be run again.

F. Open the sterilizer door to remove the B. D. test pack and check the indicator. Repeat the cycle if it failed. Contact the qualified technical personnel to perform calibration if necessary. Please refer to "11. Troubleshooting ".

WARNING: Check that the pressure gauge reading is zero (0) before opening the door.

WARNING: Beware of the steam when opening the door after sterilization has been completed.

WARNING: Be careful when removing the sterilization object because the metal surface may still be very hot. Always wear appropriate hand guards when removing trays or use suitable aiding tools (tray holder) to lift the tray.

WARNING: If the sterilizer is used continuously, let the sterilizer cool down for 20 minutes between each sterilization cycle.

6.7 PUMP TEST Program

- A. Refer to "6.2 Preparation for sterilization "before starting the sterilization program.
- B. Timing diagram for the pump test program.



C. Press "PUMP TEST " button is to select "PUMP TEST " program. Related sterilization durations are as shown in the table below:

Sterilization temperature	N/A
Sterilization duration	N/A
Drying duration	N/A
Vacuum suction duration	10 minutes.

D. Press the "START " button . The sterilization temperature, sterilization time, and drying time will be displayed two times consecutively, and then the sterilizer will run the selected programs automatically. The program execution status will be displayed on the status indicator, as shown in Figure 31.

CAUTION: The DRY procedure will not be executed.



The buzzer will sound while the display flashes when completed. When the buzzer stops and the " COMPLETE " LED indicator on the progress status indicator turns on, the execution of the programs has been completed.
WARNING: If the " COMPLETE " LED indicator did not turn on, it means that the cycle failed. Please execute it again.

6.8 VACUUM RELEASE

Press the "VACUUM RELEASE " button



to release the pressure inside the sterilizer.

" will be displayed to indicate operation in progress. Check that the pressure gauge reading is zero (0) before opening the door.

WARNING: Check that the pressure gauge reading is zero (0) before opening the door.

6.9 UNLOCK

After the sterilization cycle has been completed or execution of the process was canceled, press

the "UNLOCK" button **W** to release the lock status. When users press the "UNLOCK" button, there are two condition descriptions, as shown below:

- 1. High temperature inside the sterilizer: The temperature panel displays " means that the door is locked. Now we have to wait until the temperature panel displays
 - " before the door can be opened.
- 2. Safety temperature inside the sterilizer: The temperature panel displays " **Duran**", this means that the door can now be opened.

WARNING: Check that the pressure gauge reading is zero (0) before opening the door.

6.10 EMERGENCY Stop

Press and hold down the "EMERGENCY " button

release the pressure / vacuum. The sterilizer will sound an alarm and display E07 indicating emergency operations. Wait the pressure gauge reading returns to zero (0) to reset the process.





WARNING: The disposal of objects that have not completed sterilization cycle should comply with local regulations. DO NOT treat them as ordinary waste.





If the "EMERGENCY " button had being pressed without the need to open the door, this emergency operation might need to be repeated to release the pressure.

6.11 To Open Door When Power Outage

CAUTION: Unplug the power cord from the socket before starting the following operations, and make sure that the pressure gauge reading is zero (0) before opening the door. If the pressure gauge reading is not zero (0), follow the next procedures carefully to release the chamber pressure and to open the door.

CAUTION: Mind the steam while checking and pulling the ring of the safety valve.

6.11.1 Releasing Chamber Pressure

If the pressure gauge reading is not zero (0), open the "Water reservoir cap" and pull the ring of safety valve by using a screwdriver as shown in <u>Figure 32</u> to release the steam until the pressure gauge reading reaches zero (0).



Figure 32

6.11.2 Opening Door

WARNING: You may only perform the following procedures when sterilizer experiences power outage during operation and when door is locked.

 Δ **WARNING:** Always check the pressure before opening the door. Do not attempt to open the door if the pressure is not at zero (0).

The door releasing mechanism is located beneath the front door as shown in ① of <u>Figure</u> <u>33</u>. Use left hand to pull the metal ring towards ② (front position), at the same time use right hand to grab " Door handle " ③ of <u>Figure 33</u>, turn " Door handle " ③ counter-clockwise to 90 degree (④), then the door can be opened.



6.12 How to place Objects to Sterilization

Place the sterilization objects correctly to achieve optimal drying results.

WARNING: When pouching or wrapping items, use only sterilization pouches and wraps that have been cleared by the FDA and labeled for use with the steam sterilization cycle being used. Follow the manufacturer's instructions for use.

WARNING: Placement of sterilization objects must not exceed the maximum load in the sterilizer! There must be sufficient space around the objects on the tray to perform the steam cycle and drying. Sterilization and drying will be affected if there is insufficient space. Objects removed from the sterilizer should be completely dry to minimize the possibility of re-contamination.

WARNING: To sterilization absorbent cotton or wool, please pack it in sterilization bags to prevent the piping being blocked.

WARNING: Use only FDA-cleared chemical & biological indicators designed for steam sterilization that are compatible with the particular sterilization cycle temperature and exposure time being monitored. Use sterility monitors with each sterilization load. If a sterilizing cycle is terminated prematurely, reprocess instruments (loads) to ensure sterility of the load. Follow manufacturer's instructions for proper disposal of used indicators.

WARNING: When pouching or wrapping items, use only sterilization pouches and wraps that have been cleared by the FDA and labeled for use with the steam sterilization cycle being used. Follow the manufacturer's instructions for use.

WARNING: DO NOT overload the chamber! Adequate space is required around items in trays for steam circulation and drying. Failure to allow adequate space will compromise sterilization and drying. Items and packaging should be completely dry when removed from the sterilizer to minimize the potential for recontamination.

NOTE: Loads must be placed on trays at all times.

WARNING: Use only FDA cleared accessories are intended to be used with this autoclave model P-M10T and P-M10TR. Using other trays could restrict air / steam flow to items resulting in inadequate sterilization and drying.

6.12.1 Instrument Sterilization

Place instruments evenly on the tray according to Figure 34. DO NOT stack or overlap the instruments.



WARNING: If instruments contain sterilization bags, make sure not to stack them. Place them correctly as shown in <u>Figure 35</u>, and DO NOT overlap the small bags as shown in <u>Figure 36</u> in order to ensure the quality for sterilization.



Figure 35



WARNING: Recommend the use of pouch holder for objects placed in sterilization bags in

order to ensure sterilization results. Place each bag individually according to <u>Figure 37</u> or <u>Figure 38</u>. The pouch holder can be provided as an optional accessory.



Figure 37



Figure 38

6.12.2 Sterilization for Wrap

WARNING: To perform sterilization for absorbent cotton or wool, please wrap it with a thin towel, covering cloth, linen, or sterilization bag in order to prevent the piping from being blocked as shown in Figure 39.



- Place the packaging paper on the tray vertically.
- Beware not to let the wrapped object come in contact the chamber's wall.
- Make sure that the opening of the packaging paper is vertical to the tray in order to improve sterilization performance and dryness.
- Align the openings of the packaging paper in the same direction.
- Make sure the medical paper faces up when placing the sterilization bag on the sterilization tray.

6.12.3 Sterilization for Pouched Handpiece

WARNING: To perform sterilization for pouched handpiece(s) loaded on the tray as shown in Figure 40.



Figure 40

- Place the pouched handpiece(s) on the tray with the paper side down.
- Beware not be let the pouched object come in contact with the chamber's wall.
- Never stack pouches because over lapping surfaces and areas cannot be exposed to the steam and will not be sterilized. See Figure 41.



Figure 41

- Pouched handpiece(s) should not touch the chamber wall to allow sufficient space for air circulation.
- Pouched instrument(s) and handpiece(s) should only be loosely packed with single height loaded (not piled or stacked). Insufficient exposure to the steam may result in inadequate sterilization.
- Pouches that are labelled should only use nontoxic ink marking pen and should only marked on the plastic side of the pouch.

7. Recorder (for P-M10TR)

7.1 General description for the recorder

This type of paperless recorder can store the information such as the sterilization temperature, pressure, and time for each cycle. The printer can be purchased optionally. It also records specified information onto a USB flash drive. For reading data, a specific software (PC record reader) must deploy to open data record. Please visit the website (<u>https://healthcare.agneovo.com/us/downloadcenter/download-center/autoclave/louiep-series</u>) and download the latest software by clicking " P-M10TR / P-M10-PC Record Reader " software, or contact your dealer for help.

CAUTION: Before starting the sterilization cycle, please insert a USB flash drive.

CAUTION: It is recommended to have an interval of at least 20 minutes between each sterilization cycle, and make sure that the " Data Download Complete " to USB operation is completed before starting a new sterilization cycle.

7.2 Recorded Contents

Description of the recorded contents:

Two types of record documents will be created for each sterilization cycle. One is detailed contents with the "YYYYMMDD_HHMMSS.std " format, and the other is summary contents with the "SYYYYMMDD_HHMMSS.std " format.

Printed o	utput			Description	ı		
MODEL: P-M10TR				Model	Model		
Version: V0.99				The softwar	The software version installed on this sterilizer		
SN: 161005204-001				Serial number			
Program: 270 Unwrapped				Sterilization	Sterilization program		
Ster. Temp: 270 °F				Sterilization	temperature		
Ster. Time: 4 m				Sterilization	holding time		
Dry Time:	30 m			Drying dura	tion		
Date: 201	9 / 06 / 13			Sterilization	date and time		
Time: 10:4	45:57 AM						
Cycle No.	: 24			Number of t	imes used:		
Stop	Timo	Tomp	Droc	Step	Action description		
Step		remp. ∘⊏	Pies.	Time	mmm: minute		
старт	000.00	Г 79.7		mmm:ss	ss: second		
START	000.00	79.5	0.0	Temp	Temperature of chamber		
	000.01	70.0	0.0	_(°F)	(°F)		
	000.02 ~	70.5	0.1	Pres (psi)	Pressure of chamber (psi)		
P71	000.44	78.6	0 1	START	Activation		
1 2 1	000.44	78.6	-0.2	PZ1	1st pre-vacuum suction		
	000.40	78.6	-0.2	H1	1st heating		
	~	70.0	-0.4	PZ2	2nd pulse		
н1	010.54	110 3	-11 8	H2	2nd heating		
	010:55	110.5	-11.8	PZ3	3rd pulse		
	~	110.0	11.0	H3	3rd heating		
P72	036.42	246 9	12.6	PZ4	4th pulse		
	036.43	246.7	12.0	H4	4th heating		
	~			PZ5	5th pulse		
S00	076:34	270.8	27.3	H5	5th heating		
	076:35	271.0	27.4	S00	Start sterilization		
	~			S02	Record the sterilization		
S01	077:34	271.5	27.5		time once per minute after		
	077:35	271.5	27.5		" S00 ", and the final		
	~				sterilization time		
S02	078:34	272.1	27.7	EXH	Exhaust of water and		
	078:35	272.1	27.7		steam		
	078:36	272.1	27.7	D0	Drying starts		
	~			D1	Drying duration completed		
EXH	080:40	271.7	2.14	END	Record ended		
	080:41	271.6	2.14				
	~						
D0	083:42	206.6	1.1				
	083:43	206.6	1.1				
	~						
D1	113:51	234.8	1.1				
END	114:52	235.1	1.1	<u> </u>			
Steri. Tem	p: 272.2 ~ 2	70.8 °F		Maximum a	nd minimum temperatures detected		
)		auring the s			
Sterl. Pres	5: 27.4 ~ 28.2	∠ psi		iviaximum a	na minimum pressures detected		
				auring the s	terilization period		

7.2.1 Description of the recorded contents

Printed output	Description
Steri. Time: 04:04	Sterilization holding time
Total time: 114:52	Time passed from the beginning to the
	completion of the process
Program complete	Completion of program execution
Signature:	Signature

7.2.2 Summary Content Description

Printed of	utput			Description	1		
MODEL: P-M10TR		Model					
Version: V0.99				The softwar	The software version installed on this sterilizer		
SN:161005204-001				Serial numb	per		
Program:	270 Unwrapp	bed		Sterilization	program		
Ster. Temp	o.: 270 ⁰F			Sterilization	temperature		
Ster. Time	: 4 m			Sterilization	holding time		
Dry Time:	30 m			Drying dura	tion		
Date: 2019	9 / 06 / 13			Sterilization	date and time		
Time: 10:4	15:57 AM						
Cycle No.:	: 24			Number of t	imes used:		
			_	Step	Action description		
Step	Time	Temp.	Pres.	Time	mmm: minute		
	mmm:ss	°C	bar	mmm:ss	ss: second		
START	00:00	78.7	0.0	Temp	Temperature of chamber		
PZ1	000:44	78.6	0.1	(°F)	(°F)		
H1	010:54	119.3	-11.8	Pres (psi)	Pressure of chamber (psi)		
PZ2	036:42	246.9	12.6	START	Activation		
H2	038:13	217.4	1.7	PZ1	1st pre-vacuum suction		
	046:52	248.0	13.3	H1	1st heating		
	048:16	218.4	1.8	PZ2	2nd pulse		
	050.13	240.1	13.4	H2	2nd heating		
	057.34	210.1	1./ 14 E	PZ3	3rd pulse		
	065:42	249.0	14.0	H3	3rd heating		
500	076.34	219.3	2.1	PZ4	4th pulse		
S00	070.34	270.0	27.4	H4	4th heating		
S02	078.34	271.3	27.0	PZ5	5th pulse		
S02	070.34	272.0	27.0	H5	5th heating		
S04	080.34	271.7	27.8	<u>S00</u>	Start sterilization		
S05	080:37	271.4	27.8	<u>S02</u>	Record the sterilization		
FXH	080.07	271.7	27.0	002	time once per minute after		
	083:42	206.6	11		" S00 ", and the final		
D1	113:51	234.8	1.1		sterilization time		
END	114:52	235.1	1.1	EXH	Exhaust of water and		
					steam		
				D0	Drying starts		
				D1	Drying duration completed		
				END	Record ended		
Steri Tem	n · 272 2 ~ 2	70.8 °F		Maximum a	nd minimum temperatures		
		detected during the sterilization period					
Steri Pres · 27 4 ~ 28 2 psi		Maximum and minimum pressures detected					
0.01.1 103 21.4 20.2 p3i		during the sterilization period					
Ster. Time: 04:04		Sterilization duration					
Total time: 114:52		Time passed from the beginning to the					
				completion of the process			
Program complete		Completion of program execution					

Printed output	Description
Signature:	Signature

7.3 Storage Medium

Only use a USB flash drive recommended by the manufacturer for the storage medium, such as a USB 2.0 flash drive.



The USB flash drive should be formatted before inserting it into the recorder for the first time. The data will only be saved in the root directory.

CAUTION: You should back up the USB flash drive to another safe medium regularly.

CAUTION: Connecting an external hard drive to the recorder is not allowed.



CAUTION: DO NOT connect the recorder to a PC, notebook computer, or other mobile equipment.



7.4 Recorder Panel Description



7.5 Recorder Function Description

Please refer to Figure 43 for the flowchart of the recorder



7.5.1 General

The recorder has 3 operation modes, which are standby mode, record mode, and adjustment mode respectively.

7.5.1.1 Standby mode

After the main power is turn on, the standby mode of the recorder will display date and time as shown in Figure 44.



Figure 44

If the low power symbol flashes, please replace the new batteries as shown in Figure 45.



CAUTION: If the low power battery symbol " [] " appears on the recorder display, please contact with local dealer for replacing a new battery with the same type (CR2032). After replacing with new batteries, you must reset the date, time, and unit.

7.5.1.2 Record mode

 a) The recorder will be activated automatically and record the temperature and pressure of the chamber after pressing the "START " button on the sterilizer, as well as the execution time. The temperature and pressure of the chamber and a flashing message "R " will be shown on the display.



CAUTION: Before starting the sterilization cycle, please insert a formatted USB flash drive.

CAUTION: If USB flash drive was not detected before the sterilization cycle starts, the warning message " E105: No USB Memory " will be displayed, and the buzzer will sound the alarm. This message will not affect the sterilization task because the data will be saved to the internal memory for a period. Please refer to " 7.5.2.4 Download " for more explanations on how to download the data to the USB flash drive.

b) After the sterilization cycle has been completed, the data will be saved to the USB flash drive and the recorder will return to standby mode. The saving steps are as shown in <u>Figure 47</u>.



CAUTION: The manufacturer strongly recommends the use of a USB flash drive as the storage medium and always back up the USB flash drive to another safe medium.

7.5.1.3 Adjustment mode

At the standby mode, press the "SET " button and the recorder will enter the adjustment mode, as shown in Figure 48.



CAUTION: After 15 seconds, if no keys are pressed in the "adjustment mode " the recorder will return to the standby mode.

7.5.2 Setting

7.5.2.1 Set the date and time

Press up (\blacktriangle) or down (∇) select "1. Date / Time " and press the "SET " button to adjust the parameters of the recorder as shown in Figure 49.

1. Date / Time

Figure 49

Press the "SET" button to enter the edited content as shown in <u>Figure 50</u>, and press the increase (\blacktriangle) or decrease (\blacktriangledown) buttons until the current date and time are displayed. The "SET" button should be pressed to enter the parameters you changed, and then switch to the next parameter.

Every time you press the "SET " button, the order will be year-month-day-hour-minute-second.

After entering the current date and time, press the "SET " button to return to " adjustment mode ", and then select "8. Exit ", and then press the "SET " button again to return to standby mode, as shown in Figure 50.



Figure 50

7.5.2.2 Setting unit (temperature and pressure)

Press up (\blacktriangle) or down (∇) select "2. Unit " and press the "SET " button to adjust the parameters of the recorder is displayed, as shown in <u>Figure 51</u>.



Press the "SET" button to edit the temperature unit or pressure unit, and then press the increase (\blacktriangle) or decrease (\blacktriangledown) buttons until the temperature unit or pressure unit needed appears, as shown in Figure 52.

(
Temp:	°F	
Pressure:	psi	
	•	

Figure 52

Every time the "SET" button is pressed, the order will be temperature-pressure. After entering the equipment, press the "SET" button to return to "adjustment mode", and then select "8. Exit", and then press the "SET" button again to return to standby mode, as shown in <u>Figure 44</u>.

7.5.2.3 Remove USB

CAUTION: If this operation is not followed to remove the USB flash drive, the record data might get damaged.

Press up (\blacktriangle) or down (\triangledown) select "3. Remove USB " and press the "SET " button to adjust the parameters of the recorder. As shown in <u>Figure 53</u>.

3. Remove USB

Figure 53

Press the "SET" button and it will prompt you to "Please remove the USB flash drive", then you can safely remove the USB memory. This message will remain until you remove the USB memory.

Please remove USB memory

Figure 54

Press the "SET " button to return to " adjustment mode ", and then select " 8. Exit ", and then press the "SET " button again to return to standby mode, as shown in Figure 44.

7.5.2.4 Download

WARNING: The recorder can operate without a USB flash drive, if the built-in memory of the recorder is full, then the data recorded will be overwritten by the next data. The manufacturer strongly recommends to use a USB flash drive as the storage medium and always back up the USB flash drive to another safe media. If sterilization must be executed without using a USB flash drive, the following steps must be followed to download the data in the recorder memory before executing next sterilization program.

Insert a formatted USB flash drive into the appropriate port. Press the "SET" button and then press up (\blacktriangle) or down (∇) select "4. Download", as shown in <u>Figure 55</u> to <u>Figure 57</u>.

4. Download	

Figure 55

Press the "SET" button and then press up (\blacktriangle) or down (∇) to select the document to download, as shown in <u>Figure 56</u>.



Figure 56

Press the "SET " button and a prompt " Please wait! Data download... " will appear, and then execute " Data download Completed " as shown in <u>Figure 57</u>.





CAUTION: If no storage medium was detected, the message "E105: No USB Memory " will be displayed and the buzzer will sound the alarm, and the recorder will return to the previous screen in 15 seconds.

7.5.2.5 Printer (optional purchase)

Press the "SET " button and then press up (\blacktriangle) or down (\triangledown) select " 5. Printer ", as shown in <u>Figure 58</u>.

5. Printer	
Figure 58	

Press the "SET " button and select Printer content, and then press the (\blacktriangle) or (∇) buttons to select, as shown in Figure 59.

Printer: ON	

Figure 59

Press the "SET " button to return to " adjustment mode ", and then select " 8. Exit ", and then press the "SET " button again to return to standby mode, as shown in <u>Figure 44</u>.

7.5.2.6 SN (serial number of the machine)

Press the "SET " button and then press up (\blacktriangle) or down (∇) select " 6. SN: ", as shown in <u>Figure 60</u>.

6. SN: 160524012-001

Figure 60

7.5.2.7 Cycle

Press the "SET" button and then press up (\blacktriangle) or down (∇) select "7. Cycle:" for the reading of the number of sterilization cycle that have been performed, as shown in <u>Figure 61</u>.

000056

Figure 61

7.5.2.8 Exit

Press the "SET " button and then press up (\blacktriangle) or down (∇) select "8. Exit ", as shown in Figure 62.

8. Exit	
Figure 62	

Press the "SET " button to return to standby mode, as shown in Figure 44.

7.6 Messages and Troubleshooting (for Recorder)

Problem	Troubleshooting
No display	- Turn on the main switch.
	- Reinsert the power cable.
	- Check whether there is poor connection.
	- Contact your local dealer for service.
E101: Temperature	- Contact your local dealer for service.
sensor fault	
E103: Pressure sensor	- Contact your local dealer for service.
fault	
E105: No USB Memory	- Insert a USB flash drive.
	- Reinsert the USB flash drive and try again.
E107: USB is full	Data stored on the USB flash drive is full. Please back up
	the contents of the USB flash drive to a safe area
	immediately, and then follow the process in " Download "
	to download the latest recorded data.
E108: USB Format Error	- Reformat the USB flash drive.
	- Replace with another USB flash drive.
	- Contact your local dealer for service.
E109: EEPROM fault	- Replace with another main board.
	- Contact your local dealer for service.
E125: Keyboard fault	Contact your local dealer for service.
E135: Abnormal of the	- Check the power of the sterilizer.
cycle	- Contact your local dealer for service.
E155: Password fail	Authorized person only. This function is reserved for the
	manufacturer for diagnostic purposes. The user is
	protected by a password. Please contact your local dealer
	or manufacturer for information.

CAUTION: Please contact your local dealer if you encountered any other problems. DO NOT try to dismantle the sterilizer or recorder by yourself. Otherwise it may result in severe physical injuries or damage to equipment.

8. PC Record Reader (for P-M10TR)

8.1 Record Reader Instructions

The text is subject to change without further notice.

Please visit the website (<u>https://healthcare.agneovo.com/us/downloadcenter/download-</u> <u>center/autoclave/louiep-series</u>) and download the latest software by clicking " P-M10TR / P-M10-PC Record Reader " software, or contact your dealer for help.

CAUTION: This software can only be operated by trained personnel. CAUTION: This software can only be used with the AG Neovo autoclave / sterilizer series.

8.2 Features

This software is used with the P-M10TR series autoclave / sterilizer.

- 1. Read the recorded files in the USB flash drive.
- 2. ID and password of administrators and users.
- 3. Administrator permissions: Open software, read, print, and back up recorded documents, modify and set the ID and password of administrators and operators.
- 4. Operator permissions: Open software, read, and print recorded documents.

8.3 Computer System Requirements

- CPU Over 1GHz
- 256MB RAM or above
- USB 2.0 port or above
- Windows© 7 service pack 2 or above (Windows© is a trademark of Microsoft Co.)

8.4 Installation and Setup

Insert the USB flash drive or download the installation file from the AG Neovo Healthcare website

(<u>https://healthcare.agneovo.com/us/downloadcenter/download-center/autoclave/louiep-</u> <u>series</u>) by clicking " P-M10TR / P-M10-PC Record Reader " to download the software. Follow the steps below when using for the first time.

- 1. Decompress the file (" recordsetup-Vx.x ") on the computer.
- 2. Double-click the " setup " file and the installation process is as shown in Figure 63.



3. Select installation folder, Please Click "Next " to "FileChecker Setup Wizard " and follow the steps below to install the program as shown in Figure 64.

률 FileChecker	-		\times
Select Installation Folder			
The installer will install FileChecker to the following folder.			
To install in this folder, click "Next". To install to a different folder, enter it be	low or c	lick "Bro	wse".
Eolder:			
C:\recoder\FileChecker\		Browse	
	[Disk Cost	
Install FileChecker for yourself, or for anyone who uses this computer:			
○ Everyone			
Just me			
Cancel < Back	[Nex	t>

Figure 64

4. Confirm installation, Please Click "Next", as shown in Figure 65.



5. Installation complete, Please Click " Close ", as shown in Figure 66.



Figure 66

6. Complete the program installation. You will see the icon (Shortcut to FileChecker) on the desktop of your computer as shown in <u>Figure 67</u>.



8.5 Operating the "PC Record Reader " Software

Insert the USB (with the recorded data) into the computer before opening the software.

1 Double-click the "Shortcut to FileChecker "icon (as shown in Figure 67). A window will pop up as shown in Figure 68.



Figure 68



Default ID and	password table
----------------	----------------

User name	Password
admin	admin
user	user

2 Enter the default " User name and password " when operating the software for the first time, as shown in <u>Figure 69</u>.

💀 File Transfer Login	
	User Name(U)
	admin
	Passwords(P)

	OK(O) Cancel(C)

Figure 69

3 Click "OK " to get Figure 70. There are 3 main areas: Menu, USB data, and Data area.



Figure 70

8.5.1 Menu Area

8.5.1.1 Log out

Click "Log out " once to exit the software.

8.5.1.2 Account management

Click once to enter this function. This function is divided into 2 areas. (1) User Accounts and (2) Admin Accounts, as shown in <u>Figure 71</u>.

User A	ccounts List		User Accounts	
userName user	password	userList use	er v	Delete
		userName user	password user	Change Passwords
			Add New Account	
		Adm	in Accounts .	
		Name	password *****	Change Passwords
	Show Passwords		Show Password	

8.5.1.2.1 Operator account (User accounts):

8.5.1.2.1.1 Add a User Account

To create new user accounts, please refer to the following steps:

- 1. Click the "Add New Account " button.
- 2. Enter the new " user name " or your desired name, as shown in ① of <u>Figure</u> <u>72</u>, and enter the password as shown in ② of <u>Figure 72</u>.
- 3. Click " OK " as shown in ③ of Figure 72, and then click " Add New Account " as shown in ④ of Figure 73, and then return to the submenu.

four Help		P
User Acc userName user	ounts List password	Add new Account userName user-1 password user-1 OK Cancel



User Accounts List	User Accounts
userName password	userList user V Delete
user-1	userName password Change user Passwords
	Add New Account
	Admin Accounts
	Name password Change

Figure 73

8.5.1.2.1.2 Delete User Account

To delete user accounts, please refer to the following steps:

- 1. Select the user to delete as shown in ① (for example user-1) of Figure 74, and then click ② of Figure 74.
- 2. Click ③ of Figure 74 to delete user-1.
- 3. After deleting user-1, please refer to ④ as shown in Figure 75, and then return to the submenu.



Figure 74

& Account Management og out Help	- 0	
User Accounts List userName password user user-2	User Accounts userList user V Delete userName password User User Passwords	
	Add New Account	
	Admin Accounts	
	Name password Change admin ***** Passwords	
C Chau Barrada	Show Password	

Figure 75

8.5.1.2.1.3 Change password

To change password, please refer to the following steps:

1. Click 0 on " userList " and select " user-2 " such as 2, as shown in Figure <u>76</u>.

out Help	
User Accounts List userName password	User Accounts
user-2 user	userName user User - 2 User Passwords
	Add New ccount
	Admin Accounts

Figure 76

2. Enter the password such as ③, and then click the " Change Passwords " button such as ④, as shown in Figure 77.

ccount Managem	ent	- o >
out Help		
User Acc	counts List	User Accounts
user	userList user-2 v Delete	
user-2		userName password Change
		user-2 user-3 Passwords
		Add New Account
		3
		Admin Accounts
		Name password
		admin ***** Passwords

Figure 77

3. A pop-up window like the one shown in <u>Figure 78</u> will be displayed, and then click OK such as ⑤.

User Ac	counts List	User Accounts
userName	password	userList user-2 V Delete
user-2		userName password Change user-3 Passwords
		Add New Account
		FileCheck X
		The user account already exist! The passwords of this account will be overwrited!
		ок - зе

Figure 78

4. Select " user-2 " to ensure that the password has already been changed like as shown in <u>Figure 79</u>.

out Help		
User Acc	ounts List	User Accounts
userName Jser	password	userList user-2 V Delete
iser-2		user-2 user-3 Change Passwords
		Add New Account 6
		Admin Accounts Name password

Figure 79

8.5.1.2.2 Administrator account (Admin account)

To change administrator's password, please refer to the following steps:

- 1. Click the frame ① once and the password will be displayed as shown in Figure 80.
- 2. Enter the new password ② as shown in Figure 80.
- 3. Press the " change password " button ③ as shown in Figure 80.

userName	password	User Accounts
user user-2 user-1		userList user-2 v Delete userName password user-2 user-3 Change Passwords
		Add New Account
		Admin Accounts Name password Change admin 1234 Passwords
	Show Passwords	Show Pessword

- 4. Click the frame ④ once and the password will be displayed as shown in Figure 81.
- 5. Enter the same password again (5) as shown in Figure 81.
- 6. Click the " confirm " button © as shown in Figure 81.

User A	ccounts List	User Accounts	
userName user	password	userList user V Delete	
user-2 user-1		userName password Change user Passwords	
		Add New Account	
		Confirm Password Again	

Figure 81

7. A pop up window will be displayed, and then click OK \odot as shown in Figure <u>82</u>.

ccount Manager	nent			
out Help				
User Accounts List			User Accounts	
user-2 user-1	pussiona	userList use	r-2 ~	Delete
		userName	password	Character
		user-2	user-3	Passwords
		FileCheck	×	1 4351101 43
		Passwords changed	New Accour	nt
		OK <	Irm Password A	gain
		Name	password	
		admin	1234	Confirm
	C Chan Brannada		Show Password	- 3

Figure 82

8. Check the password change (8) as shown in Figure 83.

User Accounts List	User Accounts
userName password	userList user
user-2 user-1	userName password Change Passwords
	Add New Account
	Admin Accounts
	Name password

Figure 83

8.5.2 USB Area

1.

Once the USB flash drive is detected, it will be displayed the file name as shown in Figure 84.



- Click the icon Griecheek once to open the software such as shown in Figure 84.
- 2. The warning sign dialog window will pop up, telling you that the USB content is incorrect. The USB flash drive might have contained certain viruses or incorrect data. Please check your USB flash drive and then click OK to continue as shown in ① of Figure 84.
- 3. Click on the "I:\" disk once as shown in ② of <u>Figure 84</u>, and then the files content of USB flash disk as shown in ③ of <u>Figure 84</u> can be displayed in the file browsing area.

₽ DataReader		- D ×
Log out AccountManagement		
Login User : admin	File Name :	File Explore
Select USB Disk USB Driver List I:\	FileCheck.	E-Ameeting E-W7200 E-Wi-10 E-WI-10 E-W
		create cev file in output Path

Figure 84
- 4. Select "folder " ① as shown in <u>Figure 85</u> to view the log files (such as I: \ 20190916_190902 \ S20190916_190902.std) ② as shown in <u>Figure 85</u>.
- 5. The log file content will be displayed in the data area ③ as shown in Figure 85.

Job DataReader		×
Login User :	File Name :	File Explore
admin		3 Directorys
Select USB Disk	MODEL:SA-8000000 Version:V0.99 SN:000000000000	Electing Electing Electrony
USB Driver List	Program: Handpieces Ster. Time: 0m., Dry Time: 0m.,	1.51000 work 1.5200 icit (cn 1990) 1.5200 i
I:\	Date::2019/09/16 Time:.19:09:02,, Cycle No.463,,	ESSystem Volume Information
	Step,Time,Temperature,Pressure, ,mmm:ss,F,bar	
	START.000:00, 57.0,-0.12 PZ1.000:41, 56.8, 0.00 E05 Low Water	Files 2
		[12/2019/09/16_19/09/23/27/019/09/16_19/09/23/ard [12/2019/09/16_19/09/22/2019/09/16_19/09/02.ard
		Print
		Create cav file in output Path
-		

Figure 85

8.5.2.1 Print

Click " Print " ④ to show the total pages, and click " Yes " ⑤ of <u>Figure 86</u> to print the recorded data, or click " No " ⑤ return to <u>Figure 85</u>.

ten mittennenge sin			
agin Uner :	File Name :	-	File Explore
ədmin	-		Directorys
Select USB Disk	MODEL-SA-R000000_ Version: V0.99_ SN:0000000000000_		Elunceting
USB Driver List	Program Handpicces, Ster. Time: Din, Dy Time: Din,	Print Document X	E.M.Home, work F.Meeving, 10, 10, 10, 10, 10, 10, 10, 10, 10, 10
Iri	Date: 201909/16 Time: 19:09:01. Cycle No. 463.	Total 103 pages	E:System Volume Information
	Step,Time,Temperature,Pressa annum: ss, 9 hur	pise Do you want to continue?	
	START.000:00, 57.0.0.12 PZ1.000:41, 56.8, 0.00 E05 Low Water_	Yee	Film
			E-(20190916_190907(200190916_190902.atd E-(20190916_190902(20190916_190902.atd
	5	Print	Create cov file in output Path

8.5.2.2 Create CSV file in output Path

Click this " create csv file in oputput Path " once to start creating file function and export the detailed data using csv format. As shown in ④ of Figure 87.



9. Test Description

9.1 Biological Indictor

It is often used for sterilization verification and regular checking of sterilization cycles. The biological indictor changes in color and / or turbidity represent the results of the sterilization process. If there are no changes, it has reached the proper sterilization condition. Otherwise the growth of the spores shows that the sterilization process has not been reached. Please refer to the data from the manufacturer of the biological indictor.

For example of biological indicator (EZ Test) is shown below:

1. Execute a sterilization program at a location where sterilization is most difficult (top of the drainpipe). Place one or multiple EZ Test biological indicator balances inside the sterilizer.

WARNING: Please handle carefully the biological indicator after sterilization.

WARNING: EZ Test is a trademark of Mesa Laboratories, Inc. biological indicator products.

WARNING: Use only FDA-cleared chemical & biological indicators designed for steam sterilization that are compatible with the particular sterilization cycle temperature and exposure time being monitored. Use sterility monitors with each sterilization load. If a sterilizing cycle is terminated prematurely, reprocess instruments (loads) to ensure sterility of the load. Follow manufacturer's instructions for proper disposal of used indicators.

- 1. Wait for the biological indicator to cool and then pass it through the side of the extruded plastic tube, or use the tool provided to crush the ampoules for the culture medium.
- 2. Place the treated unit(s) and an untreated (control) unit vertically in an incubator with a temperature of 58-62 degrees for 24 hours (Geobacillus stearothermophilus).
- 3. Start monitoring and record the cultivated units after 12-18 hours.
- 4. The untreated (control) unit should appear turbid and / or its color changed to yellow or close to yellow.
- 5. A failed sterilization cycle is turbid and / or the color changed to yellow or close to yellow. A test device retaining the original color indicates that the sterilization parameters have been reached.
- 6. For more detail information, please consult your biological indicator dealer.

9.2 Bowie-Dick Test Pack

The size of commercially available Bowie-Dick type Test Pack must be suitable for the sterilizer to test. The indicator is a type of thermal paper. It is placed in the middle of a box made of multiple layers of paper and foam rubber.

Bowie-Dick Test Pack must be inserted manually. It would be the best if it is inserted on the lowest tray with the label facing up. Verify the test immediately after the cycle execution has been completed. Be careful when treating the data pack (it is still very hot). Remove the indicator paper and evaluate the test results according to the explanations given in the package.

Bowie-Dick Test Pack monitor the temperature of the sterilizer at 132 °C-134 °C (270 °F-273 °F) every day to confirm the performance of the sterilizer.

For example Description of the Bowie-Dick Test Pack (which is the 3M™Comply™ Bowie-Dick Test Pack #1233LF) is as follows:

- 1. Place the " 3M[™]Comply[™] Bowie-Dick Test Pack #1233LF " on top of the drainpipe at the bottom of the sterilizer tray frame. (the coolest point of the chamber)
- 2. Execute a Bowie-Dick test program.
- 3. Wear heat-resistant gloves after treatment and remove the Bowie-Dick Test Pack from the sterilizer.
- 4. Open the Bowie-Dick Test Pack and check the indicator.
- 5. The indicator should display even color changed. If the color change is incomplete, it means that the sterilizer might have fault and should be reported to the supervisor immediately.
- 6. Keep it as a permanent record.
- 7. For more detail information, please consult your Bowie-Dick Test Pack dealer.

WARNING: 3M™Comply™Bowie-Dick Test Pack #1233LF is a trademark of 3M Medical Corporation.

WARNING: Use only FDA-cleared chemical & biological indicators designed for steam sterilization that are compatible with the particular sterilization cycle temperature and exposure time being monitored. Use sterility monitors with each sterilization load. If a sterilizing cycle is terminated prematurely, reprocess instruments (loads) to ensure sterility of the load. Follow manufacturer's instructions for proper disposal of used indicators.

10. Maintenance Instructions

WARNING: Not following the maintenance instructions will cause negative effects to the performance and lifespan of the sterilizer, and may void the warranty.

WARNING: Turn off the sterilizer and disconnect the power before performing maintenance. Make sure the sterilizer has cooled down to room temperature.

WARNING: Make sure the pressure gauge reading is zero (0) before opening the door.

CAUTION: Confirm that the sterilizer is empty before performing maintenance. Correct and regular maintenance is required to optimize the performance of the sterilizer.

Not following the maintenance instructions will have severe impacts to the performance and lifespan of the sterilizer.

CAUTION: Failure to change water may result in sterilizer malfunction. DO NOT use bleaching agents or any abrasive materials / substances in chamber (i.e. bleach, steel wool, wire brush, scouring powder, etc.). Failure to comply may result in damage to the chamber and / or other components.

CAUTION: Before conducting maintenance, confirm that the chamber is empty without loads.

10.1 Daily

Clean the external surface with a soft cloth.

NOTE: Use of alcohol cleaner containing substantial of alcohol in the formula may damage the faceplate.

- Wipe the chamber, door, and the inside of the gasket with a damp lint-free cloth.
- Check the water level of the water reservoir.
- Filling distilled water only.
- Make sure that the vents on the cover of the water reservoir (Figure 15 and Figure 16) are not blocked / clogged.
- Check the status of the power cable. Please call for service staff if there are ruptures.

10.2 Weekly

- Use a cloth or sponge with a non-corrosive stainless steel cleaner and water to clean the tray rack and trays.
- Change the distilled water in the water reservoir:

Drain water from the water level / drain hose (Figure 15, Figure 16 and Figure 18) located on the right side of the sterilizer and fill in clean distilled water.

Exhaust filter cleaning:

Unlock the filter nut with a wrench in a counter-clockwise direction, as shown in Figure 88 and Figure 89.

CAUTION: Place a towel at the bottom of the filter faucet to prevent leaking.



Remove the filter carefully and rinse it with water to clean it. Assemble it again as shown in Figure 90.



Install the filter in the direction indicated by the arrows. Fasten the filter nut in a clockwise direction.

Figure 90

10.3 Monthly

 Use non-corrosive cleaner and a hard brush or sponge to clean the water level sensor in front of the chamber to prevent it from being unable to detect water levels, as shown in <u>Figure</u> <u>91</u>.

NOTE: Cleaning the dirt on the side of the sensor is more important than tip of the sensor. Finally, Use a damp cloth to wipe the surface after cleaning.



Follow the instructions on the " CHAM-MATE " pouch and to clean the chamber and the piping system.

To check the safety valve:

Turn off the power and unplug the power plug of the sterilizer. As shown in <u>Figure 92</u>, remove the cover of the water reservoir. Use a screwdriver to pull the metal ring of the safety valve out for at least 3 times. Put the water reservoir cap back in place.

WARNING: If excess force is required to pull the safety valve, the safety valve needs to be replaced. Call for service staff.



Figure 92

10.4 Annually

CAUTION: Annual maintenance service must be performed by trained and experienced engineers. Contact your distributor for detailed information. The following maintenance instructions are for reference only.

- Check whether the piping is any leaking.
- Check whether the progress indicator is operating normally.
- Check the operating status of the drain valve, safety valve, and heater.
- Check whether the door gasket is ruptured or worn. The door gasket is a consumable. It is suggest to change the door gasket once a year.

10.4.1 Changing Door Gasket

How to change the door gasket:

1. Remove the old door gasket from the door, and then remove the O-shaped washer from the door gasket. Install the O-shaped washer into the new door gasket, as shown in <u>Figure</u> <u>93</u>.



Figure 93

2. Check the O-shaped washer is fully installed into the door gasket, as shown in Figure 94.



 Install the door gasket into the groove of the door. As <u>Figure 95</u> shown, press the door gasket into the groove of the door evenly. When pressing the door gasket into the trapezoidal door grove, please beware of the installation direction and refer to <u>Figure 96</u> for the correct direction.



CAUTION: The disposal of the old door gasket should comply with local regulations.

Follow the order in Figure 97, Figure 98, and Figure 99 to install the door gasket into the groove of the door.



Figure 97







CAUTION: The disposal of the old door gasket should comply with local regulations.

10.4.2 Changing Air Filter

CAUTION: Make sure that the power is turn off and no pressure in the autoclave / sterilizer before changing the air filter.

Open the door. The air filter is located at the front of the autoclave / sterilizer.

- 1. Rotate the air filter in a counter-clockwise direction until the air filter is loosened as shown in Figure 100.
- 2. Install a new air filter and tighten the air filter in a clockwise direction.



11. Troubleshooting

11.1 Symptoms

Problem	Possible Cause	Troubleshooting	
Power indicator isn't illuminated	Main cable is unplugged or the POWER switch is off	Plug in the power cord and turn on the POWER switch.	
	Forget to turn on the switch	Press the Power switch to "I (ON) " position.	
	No Fuse Breaker tripped	Wait until sterilizer cools down to room temperature. Reset all the circuit breakers located at the rear lower right hand-side of the equipment.	
Louvetor	Insufficient water inside the water reservoir	Follow " 4.3 Sterilizer Installation " to fill distilled water.	
Low water LED indicator lights ON and buzzer	Water level sensor inside chamber	Follow the maintenance in "10.3 Monthly" to clean the sensor.	
	Water filter blocked	Follow the maintenance in "10.2 Weekly " to clean the water filter.	
sounus	Water level sensor inside water reservoir	Contact local distributor for service.	
Steam leaks from the door	Door gasket is dirty or wear out	Clean the door gasket. If the door gasket has been used for over one (1) year, please replace it according to the maintenance requirements in " 10.4 Annually".	
Door cannot be opened	Pressure still exists in the chamber	Follow the steps in "6.8" and press the "VACUUM RELEASE" button to release the pressure. If problems still exist, contact your local dealer for service.	
Water inside chamber doesn't	 Exhaust filter in the pipeline system is clotted 	1. Contact local distributor for service.	
automatically return to the reservoir	2. Exhaust solenoid valve is faulty	2. Contact local distributor for service.	
Excessive force is	1. DO NOT use any tool	 Please use the tool (e.g. screw driver or pliers) to pull the ring. 	
required to pull the safety valve	2. Faulty safety valve	2. Contact local distributor for service.	
No Vacuum	1. Pipeline leakage 2.Vacuum pump fail	Contact local distributor for service.	

CAUTION: If any other problems were encountered, contact your local dealer at any time for service. DO NOT try to dismantle the sterilizer by yourself, otherwise it may result in severe personal injuries or damage to the equipment.

11.2 Error Code List (for Sterilizer)

ERROR CODE	Description
E01	K-type sensor in chamber is out of connection (EMERGENCY LED indicator is ON)
E02	Door is not closed completely (" DOOR OPEN " LED indicator is ON)
E03	Sterilization temperature is over 279 °F (137 °C) (EMERGENCY LED indicator is ON)
E04	Water reservoir is in LOW WATER level condition (LOW WATER LED indicator is ON)
E05	Water in chamber is not enough in first 5 min. during add-water stage.
E06	Sterilization temperature is under than 2 °C exceeding 5 min. during sterilization step (EMERGENCY LED indicator is ON)
E07	EMERGENCY water / pressure exhaust (EMERGENCY LED indicator is ON)
E08	No vacuum has been detected within 10 min of operation.

12. Specifications

Model	del P-M10T P-M10TR	
Capacity of chamber	6.3 Gallons (24 liters)	
Maximum instrument length	13.8 in. (35 cm)	
Maximum load (Solid item)	9.0 lbs (4082 grams)	
Maximum load (Packs)	2.9 lbs (1300 grams)	
External dimensions (D x W x H)	25.8 in. (65.5 cm) x 21 in. (5	3.3 cm) x 17.4 in. (44.2 cm)
Chamber dimensions	10.2 in. (26 cm) Diameter x ²	17.7 in. (45 cm) Depth
Net weight	127.9 lbs (58 kg)	
Gross weight	134.5 lbs (61 kg)	
Voltage / power (heater) / current	120 V ~ 60 Hz / 1400 W / 12	A
Fuse	15 A x 2	
Water reservoir capacity	1.1 Gallons (4.2 liters)	
Water consumption	0.074 Gallons (0.28 liters) - (0.0925 Gallons (0.35 liters)
Sterilization temperature	250 °F / 270 °F (121 °C / 132 Bowie Dick test: 273 °F (134	2 °C) - °C)
Working environment	 Indoor use. Under 3,280.84ft (1,000) Temperature 41 °F (5 °C) Relative humidity 80% F relative humidity 50% R Voltage fluctuation ±10% Transient overvoltage ca Pollution degree 2, in ac 	m) (altitude). C) to 104 °F (40 °C). RH @ 88 °F (31 °C) to H @ 104 °F (40 °C). 6. ategory II ccordance with IEC 60664
Transportation environment	-50 °F (10 °C) to 158 °F (70	°C), 10% RH to 90% RH
Storage condition	-50 °F (10 °C) to 122 °F (50	°C), 10% RH - 70% RH
Atmospheric pressure	7.2 psia to 15.4 psia (49.6 kF	Pa to 106.4 kPa)
Overpressure protection	Safety valve 40 psi to 41 psi	(275.8 kPa-282.7 kPa)
Overpressure indication	warning LED	
Overheat indication	warning LED	
Water level indication	 Low water level of the Chamber warning LED Low water level of the water reservoir warning LED 	
Door lock indication	Door switch with warning LED	
Pressure indication	Analog pressure gauge	
Function display	LED	
Recorder	_	Yes

Model	P-M10T	P-M10TR
Cycle Program	 Wrapped (Textile Packs) 2 Wrapped (Pouches) 270 ° Unwrapped 270 °F (132 ° Handpieces 270 °F (132 ° Bowie Dick test 273 °F (13 Pump test Re-Dry 	50 °F (121 °C) F (132 °C) C) C) 34 °C)
Other controls	 Vacuum Release Unlock Emergency 	
	ASME Boiler & Pressure Ves Division 1.	sel Code, Section VIII,
Certifications	IEC 61010-1 IEC 61010-2-040 IEC 61326-1	

13. Accessories and Spare Parts



Item 1. 424-01001 Cleanser for chamber (CHAM-MATE)

Item 2. 910-04001 Pouch holder



Item 3. 211-02002 Tray Holder



Item 4. 203-02004 Tray Rack



Item 5. 600-22151 Tray



Item 6. 411-01003 Air filter



Item 7. 409-02022 Door Gasket



Accessories and Spare parts list

ltem number	Material number	Product name
1	424-01001	Cleanser for chamber (CHAM-MATE)
2	910-04001	Pouch holder
3	211-02002	Tray Holder
4	203-02004	Tray Rack
5	600-22151	Tray
6	411-01003	Air filter
7	409-02022	Door Gasket

14. Warranty

Limited Warranty

For a period of <u>two (2) years</u> or <u>2,500 cycles</u>, whichever occurs first, AG Neovo guarantees that the LouieP series steam sterilizer, when shipped out by AG Neovo is in new and unused condition.

<u>Two (2) years or 2,500 cycles</u> warranty (according to the invoice date) will cover the performance of all components of the unit except consumable parts such as the door gasket, air filter, and Cham-Mate (chamber and pipe cleaner), provided that the unit is being used and maintained according to the instruction manual. This limited warranty is not transferable or assignable and applied to the first retail purchaser.

In the event of failure due to defects during this warranty or cycle period, the exclusive remedies shall be repaired or replaced only, at AG Neovo's option and without charge, of any defective nonconsumable part(s), provided AG Neovo is notified and confirmed such defects by receiving RMA request through <u>https://healthcare.agneovo.com</u> with complete and accurate information, and further provided that the defective part(s) or unit(s) as a whole are returned to AG Neovo designating service center packed in good well-protected or original packing material. It is retail purchaser's obligation to arrange for repair delivery of the unit to AG Neovo Service Center or any authorized dealers for warranty service at retail purchaser's expense. AG Neovo may be contacted for service inquiries by email (<u>service.usdental@agneovo.com</u>); by calling toll-free 1-866-333-3686; or by writing to AG Neovo Technology Corporation Service Center, 2362 Qume Dr. Suite A, San Jose, California 95131.

This warranty shall be considered to be validated if the product is accompanied by the original purchase invoice from the authorized AG Neovo dealer, which included a clear serial number and date of purchased. All retail purchasers must complete Product Registration form at https://healthcare.agneovo.com to keep this warranty validated within <u>60 days</u> of purchase (date on invoice). AG Neovo will not accept any other forms of validation. AG Neovo reserves the right to reject or refuse any warranty service with incomplete or inaccurate product registration.

Upon two (2) years or 2,500 cycles and after, all AG Neovo's warranties and other duties with respect to the quality of the product shall be conclusively presumed to have been satisfied. AG Neovo shall not be held liable after such termination and no action or breach of any such warranty or duty may thereafter be commenced against AG Neovo. Warranty period may differ with product and region; please check with your local branch office or sales representative for more detail. AG Neovo reserves the right to refuse any warranty for anyone tempered with the original warranty product(s) and part(s).

Warranty Exclusion

Warranty would not be honored or AG Neovo would not be held liable for damage, deterioration or malfunction resulting from:

- a. Accident, abuse, misuse, neglect, fire, water / liquids, lightning, or other acts of nature, unauthorized product modification, or failure to follow instructions supplied with the products.
- b. Repair or attempt to repair by anyone included use NON-Genuine parts for repairing not certified by AG Neovo.
- c. Any physical damage of the products due to shipping or packing.
- d. Disassembly or improper installation and improper cleaning or maintain of the unit not according to the operating guideline in instruction manual.
- e. Normal wearing out and tearing.
- f. Other causes, which does not relate to product defect or any quality of the product.

Warranty made by authorized personnel or dealers and anything not follow those terms and conditions stated above would considered to be part of Warranty Exclusion.

Name	AG Neovo Autoclave LouieP Series
Model	P-M10T / P-M10TR
Telephone	1-408-321-8210
Address	2362 Qume Dr. Suite A, San Jose, CA 95131
Website	healthcare.agneovo.com
Authorized service	
company	