

## **Technical Manual**

Models FL120 and FL135



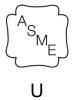


Fort Defiance Industries LLC (FDI) 2411 Maremont Parkway Loudon, TN 37774

Phone: (865) 408-0100 techsupport@fortdefianceind.com

# The FRONT-LINE Field Sterilizers comply with the applicable requirements of the following standards:

- ANSI/AAMI ST55:2016, Table-top Steam Sterilizers
- IEC 61010-1 Edition 3.1 2017-01, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 1 General Requirements
- IEC 61010-2-040:2020, Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
- IEC 61326-1:2020 Electrical equipment for measurement, control, and laboratory use EMC requirements Part 1: General Requirements
- ASME Boiler and Pressure Vessel Code, Section VIII, Division I, Current Edition, Rules for Construction of Pressure Vessels



Fort Defiance Industries (FDI) is ISO 13485:2016 certified and Food and Drug Administration compliant for the design and manufacture of sterilizers for the medical device industry.



Fort Defiance Industries LLC
Certified to ISO 13485:2016
ISO Certificate #: US19/819943310
MDSAP: United States, Canada
MDSAP Certificate #: US19/81841407

### **Continuous Improvement**

Fort Defiance Industries LLC (FDI) is committed to providing our customers with a safe and effective product that is simple and easy to operate and maintain. As an ISO 13485:2016 certified company, we have a strong desire to continually improve. If you have any feedback regarding the FRONT-LINE Field Sterilizer (FRONT-LINE) or this technical manual, please contact us. If any critical updates to the FRONT-LINE become necessary, the updates will be communicated through a Medical Device Advisory Notice. It is imperative these notices be read in full and followed.

### Feedback, Questions, and Technical Support Requests:

Address:

Fort Defiance Industries LLC 2411 Maremont Pkwy Loudon, TN 37774

Submit an online form:



https://www.fortdefianceind.com/tech-help/

**Email or phone:** 

techsupport@fortdefianceind.com +1 865-408-0100 [phone]

### **Electronic Technical Manual and Support Documents:**



- Compression Fittings Instructions
- Citrajet SDS (Alconox)
- PLC Data Sheet and Manual

https://www.fortdefianceind.com/tech-help/

### **Operation and Maintenance Videos:**



https://www.youtube.com/c/FDIvideos/playlists

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## **List of Acronyms**

AAMI Association for the Advancement of Medical Instrumentation		
ASME	American Society of Mechanical Engineers	
EN	Euro-norm	
FDI	Fort Defiance Industries, LLC	
FL	FRONT-LINE	
IFU	Instructions for use	
IQ/OQ/PQ	Installation, operational, and performance qualification	
IUSS	Immediate use steam sterilization	
PSIG	Pound per square inch gauge	
PLC	Programmable logic controller	
PM	Preventive maintenance	
PSV	Pressure safety valve	
RTD	Resistance temperature detector	
SFPP	Steam flush pressure pulse	
T/C	Thermocouple	



## Part 1 – OPERATION

## **1 General Information**

### 1.2 Safety Precautions

## **WARNINGS**

This technical manual contains critical information on the proper use of the FRONT-LINE Field Sterilizers. All operators and maintenance personnel of these sterilizers must be properly trained prior to operation or service and are urged to carefully read this manual in its entirety to become familiar with the warnings, cautions, and instructions for use.

- **Service and Maintenance** Regularly scheduled preventive maintenance is required for the safe and reliable operation of the FRONT-LINE. Reference Section 5 and 6 for details.
- Personnel Service and maintenance work must be performed by qualified personnel only.
- Authorized Parts Repair parts must be authorized for use in the FRONT-LINE and must be sourced from Fort Defiance Industries LLC (FDI). Use of unauthorized parts could reduce the safety or effectiveness of the device and will void the warranty.

#### Burn Hazards:

- Sterilizer door and chamber shelf will be hot during and after a cycle. Always wear protective gloves, safety glasses, and an apron when loading and unloading the chamber.
- o Before performing any cleaning or maintenance, allow sterilizer to cool.
- Hot steam and condensate may flow out of the chamber when the door is opened. Stay a safe distance from the door and open the door slowly to reduce steam exposure.
- **Electrical Shock and Burn Hazard** Do not service unless the sterilizer has been de-energized per the appropriate safety-related work practice standards.
- **Explosion Hazard** Do not process flammable materials in this sterilizer. Only process medical supplies and materials per the intended use as described in Section 1.9.
- Slipping Hazard Ensure any water spills are immediately wiped up.
- Efficacy Sterility could be compromised if the spore strip or biological indicator testing indicates a problem. Refer any concern to a qualified equipment technician before continuing to use the sterilizer.
- Performance Qualification Sterility could be compromised if Advancement of Medical Instrumentation (AAMI) and/or European Norm (EN) standards are not followed for cleaning, decontamination, packaging, and preparation prior to sterilization. In addition, it is critical for the user to follow AAMI or EN guidelines to conduct routine biological monitoring to verify the sterilization process.
- **IFU's** Refer to the instrument device manufacturer's instructions for use (IFU) before selecting the appropriate cycle, including exposure and dry time. The

FRONT-LINE is designed to sterilize loads per the intended use as specified in Section 1.9. If you have any question or concern about a specific material, instrument, or device, please contact the manufacturer of the device regarding the recommended IFU.

- **No Liquids** The FRONT-LINE does not include a sterilization cycle for liquids. Do not attempt to sterilize any solutions or liquids in this sterilizer.
- IQ/OQ/PQ After transport and relocation, the setup must include proper installation, operational, and performance qualification testing (IQ/OQ/PQ) per the AAMI or EN standards. Refer to Section 2.

### 1.3 Symbols

Caution! – If the sterilizer is used incorrectly, significant injury or death could occur. The front panel is marked with the caution symbol to remind that only trained personnel are approved to operate the sterilizer.

Caution! Hot Surface. – The front hinge and all metal door parts will be hot during and after a cycle. The main drain, manual drain, and chamber vent metal fittings will be hot during and after draining hot water/steam.

Protective earth (ground) – Identifies the protective earth ground pin on the incoming electrical power connector.

Shock Hazard – Caution, possibility of electric shock. Do not service unless the sterilizer has been de-energized.

#### 1.4 Included Contents

The FRONT-LINE Field Sterilizer includes the following:

- 1. QuickStart Instructions (P/N: FL-8001, shipped in box)
- 2. Chamber Shelf (*P/N: FL-9064*)
- 3. Accessory Bag (P/N: FL-9075, shipped inside chamber, see below)



### **Accessory Bag Contents:**

- 4. Power Cord, 120 VAC (P/N: FL-9002)
- 5. Power Cord, 230-240 VAC (P/N: FL-9003)
- 6. Drain Hose (P/N: FL-9053)
- 7. Standard (Flathead or Slotted) Screwdriver (P/N: FL-9043)
- 8. Technical Manual (P/N: FL-8000)
- 9. Spare PFA Tubing (*P/N: FL-9081*)
- 10. FRONT-LINE (Citrajet) Cleaning Solution (P/N: FL-9072)
- 11. Spare Door O-rings (2) (P/N: FL-9058)
- 12. Spare Fitting Gaskets (1/4" Gasket P/N: FL-9060, 1/4" O-Ring P/N: FL-9091, 3/8" O-Ring P/N: FL-9061)
- 13. SD Card, w/ adapter and PLC Program (P/N: FL-9063)



### 1.5 Optional Accessories

- 1. Table (36 x 36 x 30 in, aluminum) (P/N: FL-9076)
- 2. Distilled Water Generator (w/ Case) (P/N: FL-9077)
- 3. Sterility Assurance Startup Kit (P/N: FL-9083)
  - a. Biological indicators
  - b. Chemical indicators
  - c. Incubator
  - d. Logbook
  - e. Protective case
- 4. Consumables Kit (P/N: FL-9082)
  - a. HEPA Filter (F-2) (P/N: FL-9022)
  - b. Air inlet filter (P/N: FL-9021)
  - c. Door O-ring (Pkg of 2) (P/N: FL-9058)
  - d. FRONT-LINE (Citrajet) cleaning solution (P/N: FL-9072)
- 5. Recommended Spare Parts Kit (P/N: FL-9073)
  - a. Includes all parts with an asterisk in Section 5.3 Replacement Parts List
- 6. Transport Case, Ruggedized Hard (P/N: FL-9094)
- 7. Power Cord, Type F, 230 VAC (*P/N: FL-9105*)
- 8. Case, Soft (Model FL120) (P/N: FL120-7010)
- 9. Case, Soft (Model FL135) (P/N: FL135-7010)

Please contact FDI to purchase optional accessories:

Email: sales@fortdefianceind.com

Phone: +1(865) 408-0100

#### 1.6 Sterilizer Overview

The FRONT-LINE Field Sterilizer (FRONT-LINE) is a highly portable, dynamic air removal sterilizer that offers the highest level of sterility assurance to the field environment using steam as the sterilant. The FRONT-LINE can run on either 120 or 230-240 VAC and uses a closed-loop water recycling system that reclaims the condensate and exhausted steam, allowing it to run up to 50 cycles before the water needs to be changed.

The FRONT-LINE is fully automated and microprocessor controlled. The chamber is well insulated for increased energy efficiency. Additionally, the boiler is integrated into the bottom of the chamber and sectioned off with a partition to reduce water use. The chamber has a removable shelf that can be flipped to accommodate a variety of sterilization containers, pouches, and dental handpieces. The FRONT-LINE is constructed of a stainless-steel chamber and an aluminum door. The aluminum frame and polymer panel assembly provide integrated handles and protection for the internal components. The front transport panel protects the operator control panel and chamber door during transport. The FRONT-LINE has rubber shock absorbers on the corners of the frame for protection during shipment and handling.

During a cycle, steam is generated in the back of the chamber in the boiler section. In the conditioning stage, a process called steam flush pressure pulse (SFPP) is used to remove air through a series of pressure pulses and exhaust vents. The chamber is then fully pressurized with steam until the exposure temperature is reached. Hot condensate formed during a cycle exits the chamber through a chamber drain screen and solenoid valve. Air and steam are exhausted from the chamber through a heat exchanger that condenses the steam and water vapor; the condensed water is stored in the water tank. During a cycle, a boiler water pump and a boiler liquid level sensor are used to maintain a consistent water level in the boiler section. During drying, the air pump forces air across the heaters, through the load, and then out the front chamber drain. The drying air passes through the heat exchanger to condense any water vapor, which is then stored in the water tank.

### 1.7 Safety Features Overview

#### **Chamber Door Safety**

A mechanical lock prevents a user from unsealing the door if the FRONT-LINE is running a cycle or the chamber is pressurized above atmospheric pressure. A manual unlock toggle allows the user to unlock the door in power loss or no power situations. There are two door safety sensors: (1) the door tight sensor (DS-1) is energized when the door is closed in the door frame and completely tight and (2) the door lock sensor (DS-2) is energized when the mechanical lock is in the locked position.

#### **Heater Overtemperature Protection**

Boiler full condition (all phases of a cycle except dry):

- 1. The primary safety feature to prevent overtemperature is a boiler liquid level sensor, which controls the water level to keep the heater elements immersed.
- 2. The secondary safety circuit uses thermocouples inside each cartridge heater, which allows the heater temperature to be continuously monitored.

Boiler empty condition (during dry phase):

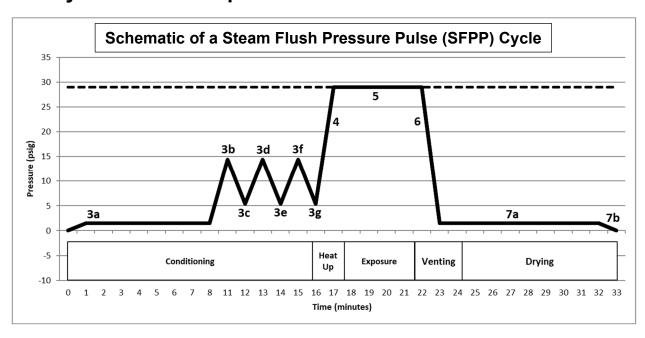
- 1. The primary safety feature to prevent overtemperature is air flowing through the chamber to carry away the heat from the heaters. The air flow is sensed through a pressure rise in the chamber measured by the chamber pressure sensor.
- 2. The secondary safety circuit uses thermocouples inside each cartridge heater, which allows the heater temperature to be continuously monitored.

#### **Overpressure Protection**

A pressure transmitter monitors the chamber pressure during operation.

The secondary safety feature is a pressure safety valve (PSV) mounted to the chamber.

### 1.8 Cycle Phases Sequence



The following is a description of the phases of a FRONT-LINE cycle:

- 1. The water pump automatically fills the boiler section in the chamber.
- 2. Water is heated to prepare for the steam flush.
- 3. Conditioning\*
  - a. Steam Flush Generated steam begins to remove air from the chamber by forcing it out the chamber drain valve.
  - b. Pressure Pulse #1 Steam is generated in the chamber to build up temperature and pressure.
  - c. Exhaust #1 The steam-air mixture is naturally vented from the chamber to remove air.
  - d. Pressure Pulse #2 Steam is generated in the chamber to build up temperature and pressure.
  - e. Exhaust #2 The steam-air mixture is naturally vented from the chamber to remove more air.
  - f. Pressure Pulse #3 Steam is generated in the chamber to build up temperature and pressure.
  - g. Exhaust #3 The steam-air mixture is naturally vented from the chamber to remove more air.
- 4. Heat Up Steam fills the chamber to build up pressure and temperature until the exposure temperature is reached.
- 5. Exposure The temperature inside the chamber is controlled to stay within a specified range during the entire exposure time selected.
- 6. Venting Steam is vented through the heat exchanger, condensed, and then stored in the water tank. Additionally, water is vented from the boiler to the water tank.
- 7. Drying
  - a. Air is pumped across the heaters and is warmed, then moves across the load, and then out the front chamber drain to be vented to the atmosphere.
  - b. The pressure in the chamber created from the air pump is vented so the chamber door can be opened by the operator.

**\*NOTE:** The handpieces cycle includes five total pressure pulses and five exhausts to increase the air removal performance, which is required for small dental handpieces.

### 1.9 Indications for Use and Sterilization Cycles

The Fort Defiance Industries FRONT-LINE Field Sterilizers are autoclaves designed for sterilizing heat- and moisture-stable medical, dental, and surgical materials, including wrapped and unwrapped, solid, porous, and hollow items (e.g., dental handpieces, suction pipes) in healthcare facilities.

Model	Cycle	Maximum Load	Exposure Temperature <sup>1</sup> (°F/°C)	Exposure Time (minutes)	Dry Time (minutes)
	Immediate Use Steam Sterilization (IUSS)	20 lbs.	270/132 275/135	3	0
FL120	Textiles	3 Textile Packs²	250/121 270/132 275/135	30 4 3	60
12120	Wrapped Instruments/ Pouches	20 lbs.	250/121 270/132 275/135	30 4 3	60
	Handpieces	12 Handpieces	270/132 275/135	4 3	60
	Immediate Use Steam Sterilization (IUSS)	25 lbs.	270/132 275/135	4 3	0
FL135	Textiles	3 Textile Packs <sup>2</sup>	250/121 270/132 275/135	30 4 3	60
	Wrapped Instruments/ Pouches	25 lbs.	250/121 270/132 275/135	30 4 3	60
	Handpieces	12 Handpieces	270/132 275/135	4 3	60

<sup>&</sup>lt;sup>1</sup> The AAMI/EN minimum temperature is listed for all cycles.

Note: The IUSS cycle is considered a type N cycle. Textiles, Wrapped, and Handpieces are considered type B cycles according to EN 13060:2014.

**WARNING**: The FRONT-LINE sterilizers do not include a sterilization cycle for liquids.

<sup>&</sup>lt;sup>2</sup> AAMI Standard Textile Pack (9 towels - ST55 Section 5.7.1.1)

<sup>\*</sup> The Bowie-Dick cycle is not included on the FRONT-LINE per guidance from AAMI ST55 Section A.4.6.1.

## 1.10 Specifications

Power Requirements:	120VAC ±10%, 1PH, 50/60 Hz, 15 AMP 230 – 240VAC ±10%, 1PH, 50/60 Hz, 15 AMP
Electrical Receptacle:	120VAC: NEMA 5-15P (IEC Type B) (US) 240VAC: NEMA L14-30P (US) WARNING: The receptacle must be properly grounded. It is recommended to use a dedicated 20 Amp circuit.
Sterilization Temperatures:	250°F (121°C) (delicates) (30-min exposure) 270°F (132°C) (default) (4-min exposure) 275°F (135°C) (3-min exposure) Note: All cycles temperature tolerance range is +6/-0°F
Steam Flush Pressure Pulse Phases:	3 pressure/exhaust pulses (5 for handpieces)
Water Tank Capacity:	1 gal (3.8 L), minimum required: 1/3 gal (1.25 L)
Water Usage:	3.4 fl oz/cycle (100 mL) Note: Based off average water use during a typical cycle.
Water Quality:	Distilled water only. See Section 1.12.
Maximum Working Pressure/Vacuum:	45 psig/full vacuum
NEMA Classification:	NEMA 3R – protection from rain, sleet, and Snow
Operating Temperature Range:	35°F to 130°F
Operating Altitude Range:	0 – 10,000 ft (approximately 10.2 psia)
Maximum Relative Humidity:	88%, noncondensing
Noise Level:	70 dBA (peak) 57 dBA (background)
Storage Temperature Range:	-65°F to 180°F

	FL120	FL135
Length:	31.5 in.	32 in.
Width:	20 in.	21.5 in.
Height:	22 in.	23.5 in.
Chamber Size:	Ø12" x 23.5" long (1.6 ft <sup>3</sup> )	Ø13.5" x 24" long (2.0 ft <sup>3</sup> )
Usable Chamber Space:	0.57 ft <sup>3</sup> (16 L)	0.85 ft <sup>3</sup> (24 L)
Weight (dry):	130 lbs.	140 lbs.
Weight (fully loaded, wet):	160 lbs.	180 lbs.
Boiler Water Capacity:	0.25 gal (0.95 L)	0.25 gal (0.95 L)
IUSS Cycle Times, 120 VAC:	40 min (w/no dry)	45 min (w/no dry)
IUSS Cycle Times, 240 VAC:	25 min (w/no dry)	30 min (w/no dry)

#### 1.11 Materials of Construction

**Table 1. Materials of Construction** 

Component	Material
Chamber	316 stainless steel (electropolished)
Door	6061-T6 aluminum
Chamber Shelf	5052 aluminum (anodized)
Water Tank	316 stainless steel (electropolished)
Heat Exchanger	Copper
Plumbing	Teflon®-based (PFA), silicone, brass, stainless
Solenoid Valves	Brass
Frame	6061-T6 aluminum
Panels	Polymer (TPO)

### 1.12 Water Supply Quality

Distilled water is required in the FRONT-LINE. The sterilizer is filled through a fill port on the front panel and stored in an internal water tank. Using distilled water protects the sterilizer from scale buildup in the plumbing and on the heaters, which keeps cycle times short and eliminates sterilizer downtime to clean the boiler surfaces. See Table 2 for recommended water quality specification.

**Table 2. Recommended Water Supply Quality Specification** 

Parameter	Value
Iron	≤ 0.1 mg/L
Cadmium	≤ 0.005 mg/L
Lead	≤ 0.05 mg/L
Rest of heavy metals except iron, cadmium, lead	≤ 0.1 mg/L
Chlorides	≤ 0.1 mg/L
Phosphates	≤ 0.1 mg/L
Conductivity	≤ 3 µS/cm
pH (20°C, 68°F) value	5 – 7
Appearance	Colorless; clean without sediment
Hardness (total)	≤ 0.2 mg/L
Total dissolved solids	≤ 1 ppm

#### NOTE:

- 1. It is the responsibility of the user to supply feedwater that meets distilled water criteria, considered ASTM Type II water.
- 2. 1 mg/L is equal to 1 parts per million (ppm)

### 1.13 Sterility Assurance Products

	3M <sup>®</sup> System	Steris <sup>®</sup> System	Crosstex <sup>®</sup> System
30-Minute Exposure 250°F	None	None	
4-Minute Exposure 270°F		aron d	SporView <sup>TM</sup> SVT- 050 Biological
3-Minute Exposure 275°F	1492V Biological Indicator P/N: FL-9044	Celerity <sup>TM</sup> 20 Biological Indicator <i>P/N: FL-</i> 9045	Indicator P/N: FL-9046

### 1.14 Consumables

Table 3 provides the consumables recommended for daily use, sterility assurance, and preparing sterilization loads. All consumables can be purchased from FDI using one of the following methods:

Email: sales@fortdefianceind.com

Phone: +1(865) 408-0100

**Table 3. Consumable Items and Part Numbers** 

Item	Description	Part Number
1.	INDICATOR, 3M 1492V BIOLOGICAL (50/BOX)	FL-9044
2.	INDICATOR, STERIS CELERITY 20 BIOLOGICAL (25/BOX)	FL-9045
3.	INDICATOR, CROSSTEX SPORVIEW SVT-050 BIOLOGICAL (50/BOX)	FL-9046
4.	CLEANING SOLUTION, FRONT-LINE (CITRAJET)	FL-9072
5.	POUCH, STERILIZATION, 3.5" X 10" (200/BOX)	FL-9087
6.	WRAP, STERILIZATION, 48" X 48", 2-PLY (50/BOX)	FL-9088

## 2 Installation, Setup, and Qualification

1. Install the sterilizer in a suitable location:

**CAUTION:** Two people are required to lift the FRONT-LINE. Use the front and rear handles as shown below.

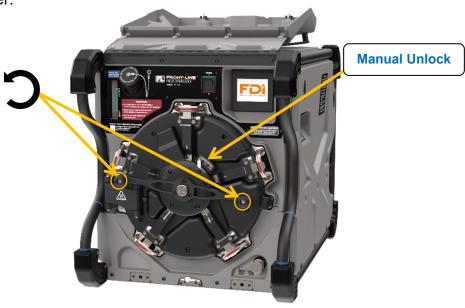


- **A.** Place the sterilizer on a level surface capable of safely supporting 180 lbs. (82 kg). It is recommended to install the FRONT-LINE so all sides, including the top and back, are accessible for maintenance.
- **B.** Place the sterilizer in a room with a minimum of 10 air changes per hour.
- **C.** Open the front transport panel by unlocking the front latch, pulling the panel open, and rotating the panel to sit on the top of the sterilizer.

#### 2. Open the Chamber Door and remove the Accessory Bag:

A. Ensure the door is unlocked by turning the Manual Unlock toggle, located at the top of the door hub, to the position.

**B.** Open the Chamber Door by rotating the door handles fully counterclockwise and then pulling the door open. Remove the Accessory Bag stored in the chamber.



- **C.** Check that the heat shield inside the chamber is securely fastened.
- **D.** Check that the chamber drain screen is installed hand tight.



#### 3. Connect to Power:

**A.** Open the Accessory Bag and select the <u>correct</u> power cord (there are two cord options) by checking the plug end and verifying the voltage on the labeled tag on the cable.



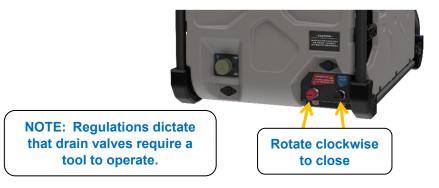
**B.** Remove the receptacle cap on the back of the FRONT-LINE. Connect the green metal end of the power cord to the back of the FRONT-LINE by lining up the key on the connector and then twisting the collar clockwise to lock in place.



**C.** Connect the plug end of the power cord to a verified 20 Amp power source.

**CAUTION:** The power source must be connected to a properly grounded outlet. It is recommended to (1) use a dedicated 20 Amp circuit for the FRONT-LINE and (2) install the FRONT-LINE close to the electrical disconnect.

4. Using the supplied standard screwdriver from the Accessory Bag, close the manual valves labeled Chamber Vent and Manual Drain. These are located on the back of the FRONT-LINE. (setup continued on next page)



5. **Fill the sterilizer with 1 gal or 3.8L of <u>distilled water</u>,** using the front water fill port. Do not overfill. Replace the cap after filling. See Section 1.12 on the importance of supply water quality.

**NOTE:** It is normal to see a small amount of water in the fill port tube at full capacity.



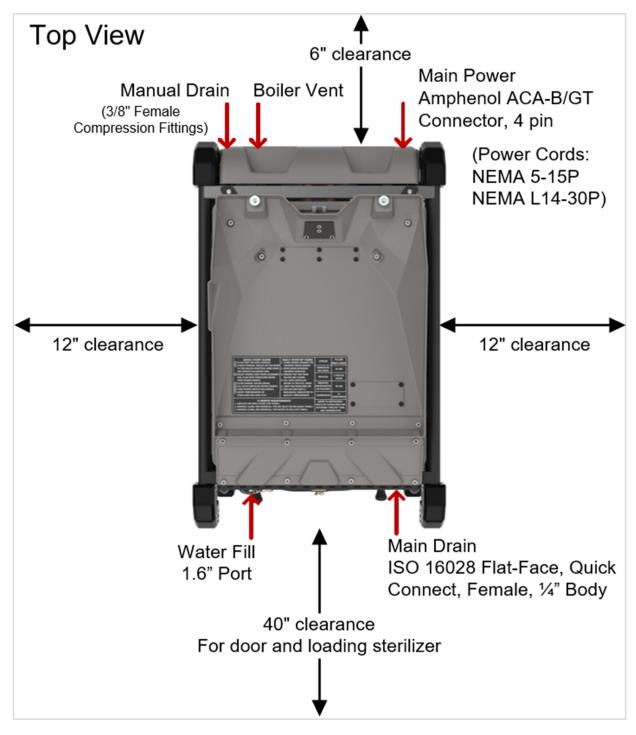
- 6. **Turn the sterilizer ON** using the front power switch. You should hear a fan turn on and then the touchscreen controller will take a few seconds to boot up.
- 7. Qualify the sterilizer before placing in service:
  - **A.** Run an immediate use steam sterilization (IUSS) cycle to verify the sterilizer is fully operational. This is important if the sterilizer has recently been transported or stored. Monitor the sterilizer to check for any issues such as steam leaks.
  - **B.** Check for water left in the bottom of the chamber after the cycle. If necessary, shim the back of the sterilizer to allow the water to drain towards the front.
  - **C.** Verify performance of the sterilizer per AAMI ST79 standards before placing the sterilizer into service.

**NOTE:** FDI recommends completing three consecutive sterilization cycles with biological indicators in the load. Always follow the BI manufacturer's instructions. For information on biological indicators, see Section 1.13.

8. **The sterilizer is now ready for use.** See Section 4 for more information on operating the sterilizer.

WARNING: When not in use for an extended period, the sterilizer should be drained completely (see Section 4.13) to prevent biological growth and protect the sterilizer from freezing conditions.

### 2.1 Installation Diagram

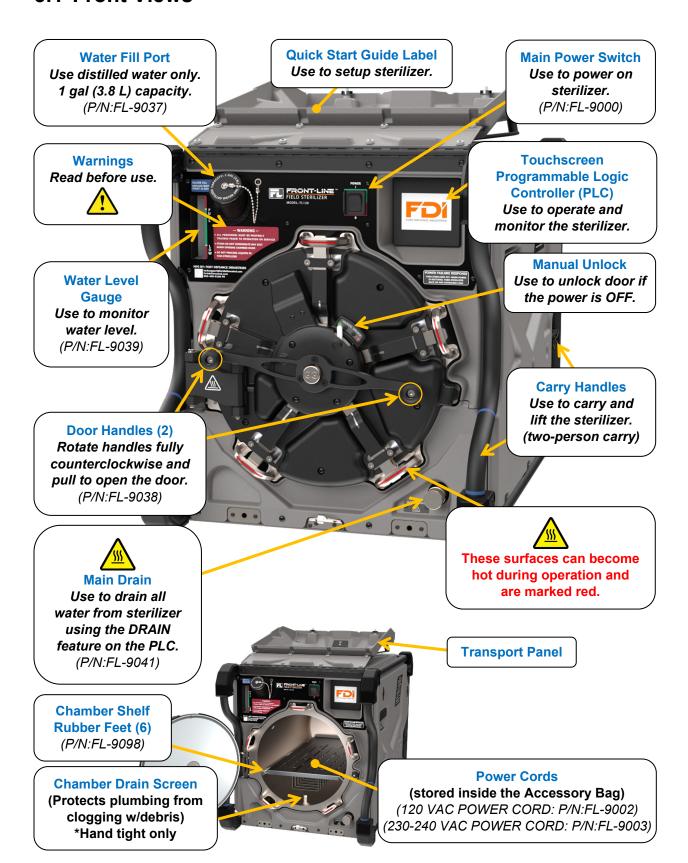


Recommended room ventilation: 10 air changes / hour Max heat transmitted to room: 3450 Watts

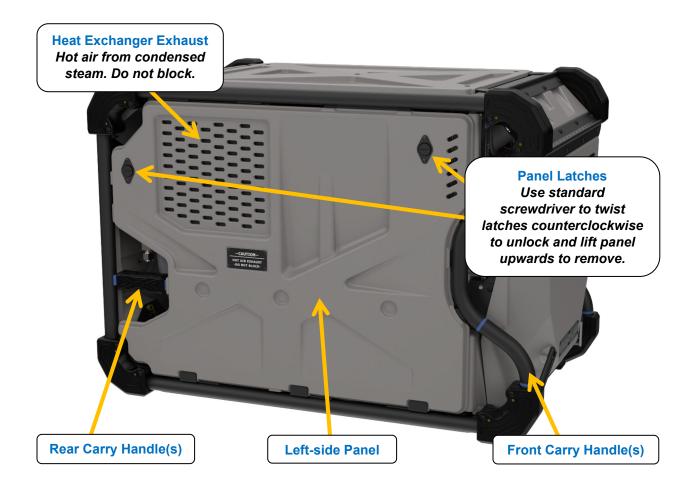
	FL120	FL135
Length:	31.5 in.	32 in.
Width:	20 in.	21.5 in.
Height (transport panel open):	22 in.	23.5 in.
Weight (fully loaded, wet):	160 lbs.	180 lbs.

### 3 Controls and Indicators

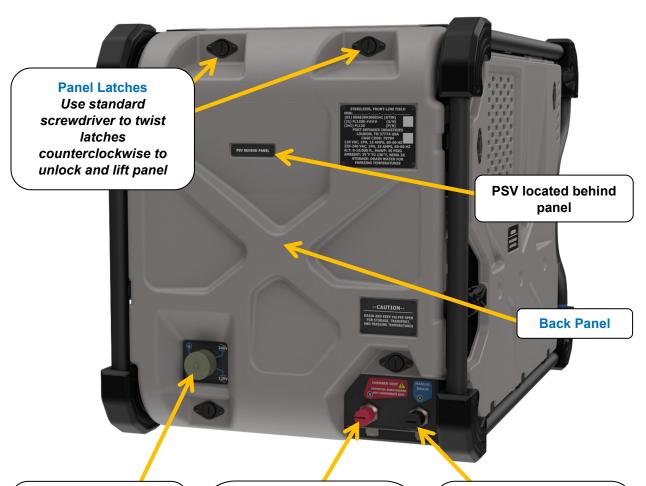
#### 3.1 Front Views



### 3.2 Left-side View



### 3.3 Back View



Main Power Connector (P/N:FL-9001)

Use to connect either 120 VAC or 230-240 VAC power cord.



Chamber Vent (P/N:FL-9040)

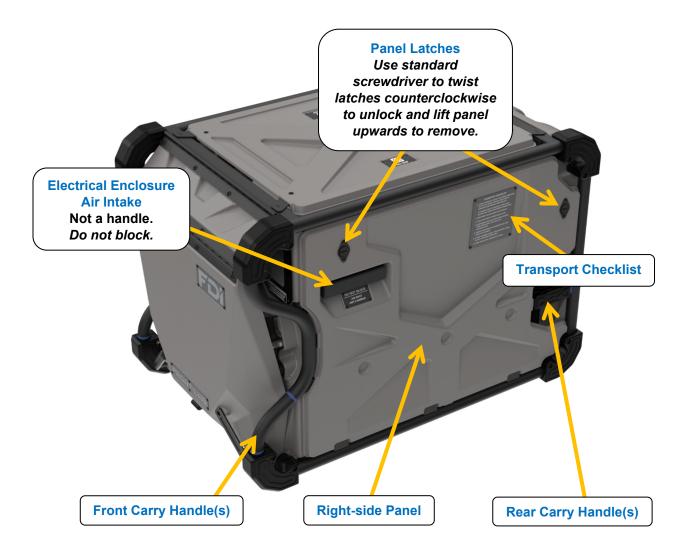
Use to vent chamber steam or relieve vacuum if there is loss of power. Use standard screwdriver to operate.

NOTE: Regulations dictate that drain valves require a tool to operate.

Manual Drain (P/N:FL-9041)

Use to drain the system if no power is available and the Main Drain cannot be used. Use standard screwdriver to operate.

## 3.4 Right-side View



## **4 Operating Procedure**

**NOTE:** The following instructions assume the FRONT-LINE is set up, qualified for use, and distilled water has been added. Reference Section 2.

### 4.1 Preparing Sterilizer Loads

#### WARNING:

Aways use AAMI ST79 or EN equivalent for directions on loading the sterilizer, wrapping instruments, preparing instruments, verifying performance, and any other load-related questions. The information presented below is for reference and recommendation only.

- All instruments must be dry and free from any residual debris, blood, organic tissue, or any mineral deposits.
- Always consult the instrument manufacturer's instructions for use (IFU) for information on cleaning and sterilizing instruments.
- **Textiles:** Do not use bleach to wash any textile load. Chlorine bleach can harm the stainless-steel chamber.

#### • Pouches or Handpieces:

- o Flip the chamber shelf for dental handpieces and pouched loads
- Do not stack pouches
- Place only one pouch per slot in the pouch rack. Maintain 1/4-in. gap.
- All pouches should face the same direction

#### Wrapped Instruments Guidance:

- Do not overload trays or sterilization containers. Overloading can cause incomplete sterilization and poor drying performance. Distribute instruments evenly throughout the container or tray.
- It is recommended to use a commercially available woven textile wrap such as the KIMGUARD® ONE-STEP Sequential Sterilization Wrap for all wrapped instrument loads.
- For efficient dry performance, ensure that the sterilization wraps are wrapped tightly and that the top of the wrap does not have any low areas where condensate could collect.

### 4.2 Turning the Sterilizer ON

- 1. Verify the sterilizer is plugged in.
- 2. Turn the front power switch ON.
- 3. The touchscreen controller will boot up and go to the HOME screen.
- 4. The sterilizer is ready for use. There is no warmup required.

### 4.3 Door Operation



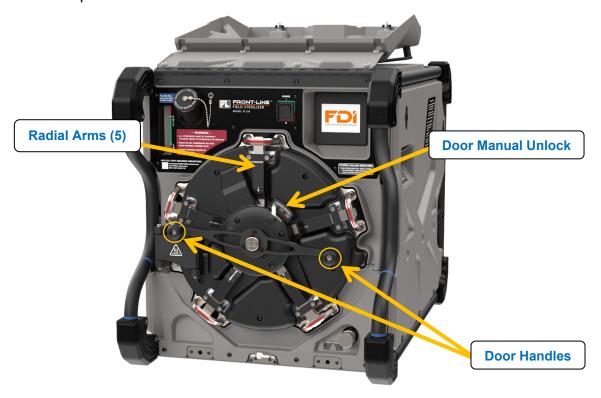
CAUTION: Hot steam and condensate may flow out of the chamber when

the door is opened. Stay a safe distance from the door and open

the door slowly to reduce the risk of steam exposure.

**NOTE:** If the door needs to be opened with the machine off, verify the chamber has been vented to atmospheric pressure by <u>slowly</u> opening the Chamber Vent at the rear of the sterilizer. Then, flip the door Manual Unlock to the

position. <u>Slowly</u> loosen the door handles. If any pressure remains in the chamber, the operator will hear a hissing sound as the chamber is opened.



1. If pressure or vacuum in the chamber is not equalized, a VENT button will appear on the touchscreen controller. Press VENT to equalize the pressure.

### 2. To open the door:

- a. Rotate the door handles counterclockwise until they stop
- b. Pull on the door handles to swing open the door

#### 3. To close the door:

- a. Ensure the handles are rotated fully counterclockwise to retract radial arms
- b. Push the door closed
- c. To tighten the door, rotate the handles clockwise until they stop

**CAUTION:** Do not overtighten the door. Once the door handles stop, the door is tight.

**NOTE:** If the door does not successfully unlock after a completed cycle or a fault, a screen as shown below will prompt the user to rotate the door handles slightly clockwise to unlock the door. Then, rotate the handles counterclockwise to loosen and open the door as normal. This condition can be prevented by ensuring the user does not attempt to loosen the door handles while the door is locked.



#### **Door Manual Unlock**

The manual unlock is not used when the sterilizer is ON. The manual unlock should only be used to access the chamber when the power is OFF and the chamber is VENTED.

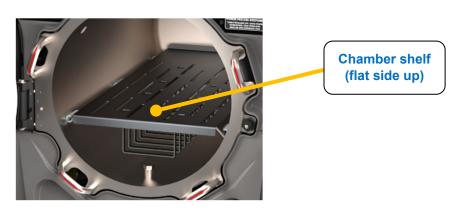
#### **Door Lock Reset Feature**

If the user tries to manually unlock the door at any time when the door should be locked (i.e., pressure in the chamber), the sterilizer will automatically re-lock the door. This feature is only active when the sterilizer is powered ON.

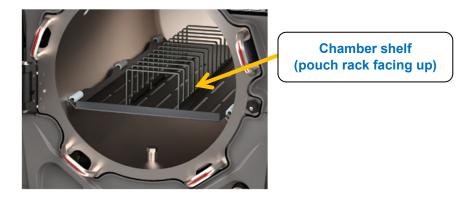
### 4.4 Loading and Unloading the Sterilizer

**CAUTION:** It is recommended to wear protective gloves, safety glasses, and an apron when loading and unloading the chamber.

- 1. Reference the maximum load limits on the Sterilization Cycles table on the inside of the transport panel (also found in Section 1.9).
- 2. If a tray or sterilization container is being used, use the flat side of the chamber shelf. Insert the load until it is centered in the chamber.



3. If pouches or other handpieces are being sterilized, flip the chamber shelf so the pouch rack is facing up.



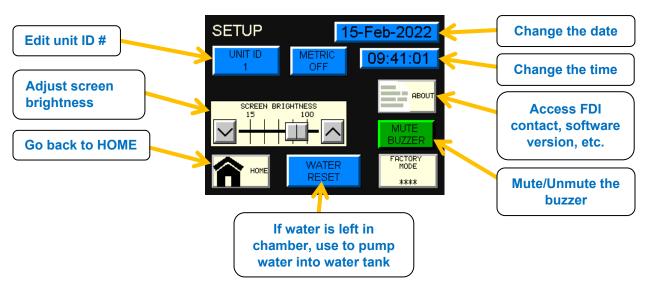
### 4.5 Setup and Basic Functions

To navigate to the SETUP screen, press SETUP from the HOME screen. The SETUP screen is used to change time, date, unit ID, etc., as shown below.

**Unit ID # –** provides a unique identifier for the sterilizer. This number is displayed in the LOG for each cycle.

**Metric ON/OFF** – toggles displayed units to metric or U.S. standard. Defaults to U.S. standard.

**Water Reset –** pumps water left in the chamber/boiler back into the water tank. Typically used after a Fault.



**NOTE:** The Factory Mode is password protected and can only be used by FDI factory-trained personnel.

### 4.6 Running a Sterilization Cycle

The FRONT-LINE is automatically controlled with a touchscreen controller (PLC) that performs pre-programmed sterilization cycles.

#### **Cancelling a Sterilization Cycle:**

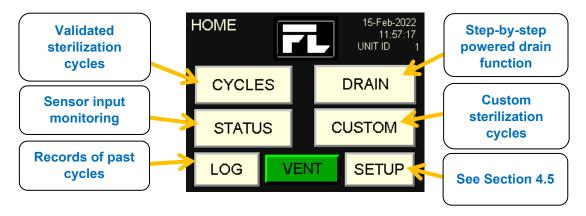
If the cycle needs to be cancelled for any reason, the operator can press CANCEL on the PLC. Once venting is complete, the screen will display CYCLE CANCELLED, notifying the operator that the load is not sterile. The load must be reprocessed if the cycle is cancelled.

WARNING:

Use a biological indicator per ST79 standards in each load to ensure proper sterilization. A negative biological indicator is the only guarantee of complete sterilization. The CYCLE COMPLETE screen should never be used as load validation.

#### To Run a Sterilization Cycle:

- 1. Place the load to be sterilized in the chamber. Close and tighten the door.
- 2. From HOME on the touchscreen controller, press CYCLES.



3. Select the correct cycle for the instrument load.



4. Select the appropriate cycle temperature, exposure time, and dry time. Then press CONFIRM.

**NOTE:** The dry time defaults to 60 minutes but can be manually increased based on the instrument manufacturer's recommendations.

**WARNING**: Always follow the instrument manufacturer's instructions when selecting the cycle temperature and dry time.



- 5. Verify the cycle parameters are correct on CONFIRM screen as shown below.
- 6. Verify the door is tight and press CYCLE START.

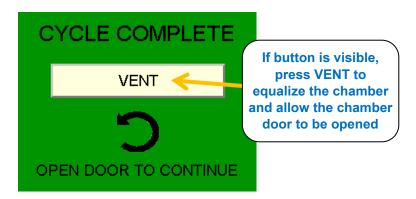


7. The sterilizer will automatically complete the cycle phases sequence as described in Section 1.8. The cycle running screen shown below displays all process monitoring information.



8. At the end of a successful cycle, a green CYCLE COMPLETE screen will display as shown below.

**CAUTION:** Hot steam and condensate may flow out of the chamber when the door is opened. Stay a safe distance from the door and open the door slowly to reduce steam exposure.



**NOTE:** If the load is left to cool, a VENT button will automatically display that allows the user to vent any vacuum that may have formed before the door is opened.

- 9. Inspect the load:
  - **A.** The door can now be opened, and the load removed.
  - **B.** Check for load dryness (i.e., visible condensation). Use Extra Dry feature if more dry time is needed. See Section 4.16.
  - **C.** Check sterilization indicators (e.g., tape).

### 4.7 Log (Cycle Records)

- 1. From the HOME screen, press LOG to access cycle records.
- 2. Use the arrow buttons or press the CYCLE button to navigate.
- 3. The LOG holds up to 200 records. Once 200 records are reached, the oldest record is deleted to allow each new cycle to be recorded. The MAIN screen displays a summary of the cycle results. The DETAIL screen displays information about the conditioning pulse pressures, temperatures, and times.
- 4. All cycle parameters can be read from the log screen to allow the user to verify cycle parameters such as minimum and maximum temperature, exposure time, etc.



S. FLUSH 09: CYCLE Example Pulses 4 and 5 EXH 1 PRESS 2 **DETAIL** screen are only used UNIT ID for handpieces. EXH 2 PRESS 3 EXH 3 PRESS 4 Values will be All time zero on all stamps in the other cycles EXH 4 **DETAIL** screen are for the end of each phase Go back to main MAIN. LOG screen

**NOTE:** If metric units are chosen, unused pulses will display "-17.8°C" due to the unit conversion.

### Main Log Screen Acceptable Value Ranges:

Value Title	Description	Acceptable Range	
Start Date	Date cycle was started	Any	
Start Time	Time cycle was started	Any	
Cycle Time	Total cycle time	Any	
Real Exp. Time	Total exposure time	Chosen exposure time ± 2 sec	
Max Temp	Maximum Temperature	Chosen exposure temperature	
	during exposure	+6°F	
Min Temp	Minimum Temperature	Chosen exposure temperature	
	during exposure	-0°F	
Max Press	Maximum Pressure	43.4 psig	
	during exposure		
Min Press	Minimum Pressure	15 psig	
	during exposure		

### **Detail Log Screen Acceptable Value Ranges:**

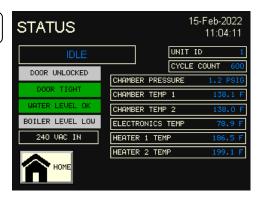
Phase Title	Description	Temperature Range (°F)	Pressure Range (psig)		
S. FLUSH	Steam Flush	Any	Any		
PRESS 1	Pressure Pulse 1	240 – 255	14 – 19		
EXH 1	Exhaust 1	215 – 245	5 – 10		
PRESS 2	Pressure Pulse 2	240 – 255	14 – 19		
EXH 2	Exhaust 2	215 – 245	5 – 10		
PRESS 3	Pressure Pulse 3	240 – 255	14 – 19		
EXH 3	Exhaust 3	215 – 245	5 – 10		
NOTE: Pulses 4 and 5 are only used on the Handpieces cycles.					
PRESS 4	Pressure Pulse 4	240 – 255	14 – 19		
EXH 4	Exhaust 4	215 – 245	5 – 10		
PRESS 5	Pressure Pulse 5	240 – 255	14 – 19		
EXH 5	Exhaust 5	215 – 245	5 – 10		

#### 4.8 Status Screen

To access, select STATUS from the HOME screen. The STATUS screen monitors all sensor inputs for troubleshooting and installation qualification. The STATUS screen displays:

- Door Lock Sensor displays the status of the door lock, either LOCKED or UNLOCKED
- Door Tight Sensor displays the status of the door tight switch, TIGHT or NOT TIGHT
- Water Tank Level Sensor displays the status of the sensor, either OK or LOW
- Boiler Level Sensor displays the status of the sensor, either OK or LOW
- Voltage Input Indicator displays the input voltage (120 or 230-240 VAC) to the sterilizer
- Unit ID displays a user selectable ID number of the sterilizer. Can be changed in SETUP
- Cycle Count number of total sterilization cycles run on the sterilizer
- Chamber Pressure pressure of chamber displayed in psig or kPa gauge
- Chamber Temperature 1 and 2 temperature of chamber displayed in °F or °C
- Electrical Enclosure Temperature electrical enclosure temperature in °F or °C
- Heater Temperature 1 and 2 internal temperature of heaters in °F or °C

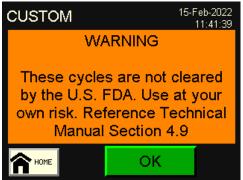
Example status screen



### 4.9 Custom Cycles

From the HOME screen, select CUSTOM. This feature allows the user to run custom temperature, exposure time, and dry time combinations at the user's own risk. Please see Table 4 for the options on a custom cycle.

WARNING: Only the standard AAMI cycles listed in Section 1.9 have been validated. Custom cycles have not been validated. The user accepts all risks associated with sterilizing any load using a custom cycle.



**WARNING:** Custom cycles use three pressure pulses/exhausts and are not suitable for handpieces. Handpieces must be processed using the Handpieces validated cycle.

**Table 4. Custom Cycle Options** 

Cycle	Maximum Load	Exposure Temperature (°F/°C)	Exposure Time (minutes)	Dry Time (minutes)
		250/121	30-90	0-90
Custom	N/A	270/132	5-90	0-90
		275/135	5-90	0-90

# 4.10 Daily Startup Procedure

Check	Operation
	Clean any lint or debris found around the chamber drain screen. The drain screen prevents lint from clogging the plumbing.
	Clean interior chamber surfaces using a cleaner approved for stainless-steel surfaces (e.g., Citrajet) and a soft, microfiber cloth. <a href="Do">Do</a> not use bleach as it will prematurely corrode the stainless chamber.
	3. Ensure the two rear valves are closed.
	4. Fill sterilizer with distilled water to the FULL mark.
	5. Turn the sterilizer ON using the front power switch.
	6. Run a sterilization cycle with a biological indicator (BI) in the load to ensure the sterilizer is functioning correctly. Always follow the BI manufacturer's instructions. Listen and inspect for any steam leaks or unexpected sounds.
	7. Proceed with normal sterilization cycles as needed.

# 4.11 Daily Shutdown Procedure

WARNING: If freezing temperatures are possible around the sterilizer, all water must be drained to prevent possible freezing and damage to the water pump or other components. Reference Section 4.13 for information on draining water.

Check	Operation
	Add distilled water to the FULL mark.
	<ol> <li>Leave the chamber door closed but not fully tightened to prevent a vacuum from being created in the chamber during cooldown. To break a vacuum in the chamber and open the door, press the VENT button on the touchscreen controller.</li> </ol>
	3. Turn the front power switch to OFF.

### 4.12 Operator and Maintenance Reminders

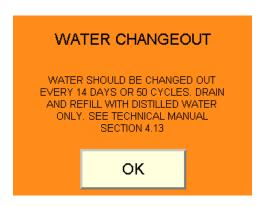
**WARNING:** 

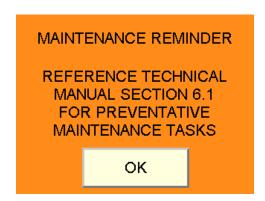
The following <u>Operator procedures</u> are critical to the reliable operation of the sterilizer. These procedures must be followed at the frequencies given.

- 1. Water Changeout Procedure (Section 4.13)
- 2. Chamber and Boiler Cleaning Procedure (Section 4.14)

#### 50 Cycles or 14 Days (whichever comes first): Water Changeout Required

The WATER CHANGEOUT screen reminds the operator that the water in the sterilizer must be drained and refilled with fresh distilled water. This procedure is critical to protect the stainless-steel chamber. See Section 4.13 for the Water Changeout Procedure.





#### **Every 300 Cycles: Maintenance Reminder**

The MAINTENANCE REMINDER screen reminds maintenance technicians to check and follow the recommended preventive maintenance (PM) schedule (see Section 6.1). This maintenance is critical for the continued reliable operation of the sterilizer. All maintenance must be performed by qualified personnel.

# **4.13 Water Changeout Procedure**

# **REQUIRED FREQUENCY: 50 CYCLES OR 14 CALENDAR DAYS**

Check	Task
	Cool: Allow the sterilizer to cool to room temperature by opening the chamber door and leaving the sterilizer ON.
	2. <b>Drain:</b> Drain the water by using the DRAIN function on the HOME screen of the touchscreen controller. Follow the on-screen instructions. Use the drain hose from the Accessory Bag for this step.
	DRAIN  Follow on-screen instructions  1. ENSURE CHAMBER DOOR IS TIGHT  Insert drain hose here
	2. PRESS START BUTTON  DOOR TIGHT  START
	NOTE: The sterilizer can be manually drained by using the two valves at the back of the sterilizer if power is not available.
	CAUTION: Allow the sterilizer to cool to reduce any burn hazard that may result from draining hot water. Hazardous liquids should never be drained to a municipal water supply. Temperature of water can exceed 200°F if it is drained immediately following a cycle. Max flow rate of the Main Drain is 0.62 gal/min.
	3. Remove the drain hose:
	<ul><li>A. Line up the coupling sleeve and push back on the sleeve.</li><li>B. Store the hose in the Accessory Bag.</li></ul>
	C. Ensure the two valves are closed at the rear of the sterilizer.
	4. <b>Refill:</b> Refill the sterilizer with distilled water using the water fill port. The sterilizer holds approximately 1 gal (3.8L) of water. See Section 1.12 on the importance of water supply quality.

# **4.14 Chamber and Boiler Cleaning Procedure**

## **REQUIRED FREQUENCY: 3 MONTHS**

Check	Task		
	This procedure provides instructions on how to deep clean and descale the chamber by using FRONT-LINE Cleaning Solution supplied in the Accessory Bag. It is important to follow the steps carefully to keep the FRONT-LINE properly maintained.		
	CAUTION: It is important to keep the chamber clean. Contaminant buildup can cause premature corrosion of the stainless-steel chamber.		
	<b>CAUTION:</b> Never use bleach or an abrasive material such as a steel brush to clean the chamber.		
	Materials needed:		
	FRONT-LINE Cleaning Solution (Citrajet, stored in the Accessory Bag)		
	CAUTION: Eye and skin irritant. Wash hands well after touching the solution. In case of eye contact, flush with water for 15 min. If irritation persists, seek medical attention. If large quantities are swallowed, seek medical attention immediately. See Support Documents link on page 3 for the safety data sheet (SDS).		
	Drain hose (stored in the Accessory Bag)		
	Soft, lint-free cloth		
	Bucket for capturing drain water		
	Rubber gloves and safety glasses		
	Distilled water		
	Procedure:		
	CAUTION: Use rubber gloves and safety glasses when handling the FRONT-LINE Cleaning Solution.		
	Start with the sterilizer ON and fully drained.		
	2. With the black cap tight, slightly loosen the white cap on the FRONT-LINE Cleaning Solution bottle. Squeeze the bottle until cleaning fluid fills to the top line (1/2 oz) in the smaller reservoir. Remove the white cap and pour measured solution through the front water fill port.		
	3. On the touchscreen controller, select STATUS and add distilled water to the water tank until water is visible at the bottom of the sight glass. "Water Level OK" is illuminated green on the screen.		

Check	Task		
	4. Return to the HOME screen and complete an IUSS cycle at 275°F.		
	5. Drain the sterilizer using the DRAIN function on the HOME screen.		
	<b>CAUTION:</b> Temperature of water can exceed 200°F if it is drained immediately following a cycle. Max flow rate of the Main Drain is 0.62 gal/min.		
	6. Refill the sterilizer with fresh distilled water and perform a second IUSS cycle using steps 3 through 5 to rinse the system.		
	<ul> <li>7. Wipe down interior surfaces:</li> <li>A. De-energize the sterilizer by unplugging the supply power.</li> <li>B. Open the chamber door and allow the sterilizer to cool.</li> <li>C. Remove the chamber shelf and rear heat shield and wipe down all surfaces using a clean cloth.</li> <li>D. Be sure to wipe the entire chamber, including behind the chamber partition near the heaters. Failure to wipe down the rear of the chamber could result in premature corrosion or reduced heater life.</li> </ul>		
	Reinstall the heat shield and ensure the wing nuts are fully tight.  Replace the chamber shelf. Reconnect supply power.		
	<ol><li>Refill with fresh distilled water. The sterilizer is now ready to be placed back into service.</li></ol>		

# **4.15 Transport and Storage Procedure**

Check	Task		
	CAUTION: Cool the sterilizer to reduce any burn hazard that may result from draining hot water. Hazardous liquids should never be drained to a municipal water supply.  Temperature of water can exceed 200°F if it is drained immediately following a cycle. Max flow rate of the Main Drain is 0.62 gal/min.		
	Drain: Drain water by using the DRAIN function on the touchscreen HOME screen.		
	If power is not available, open the rear manual valves and drain the sterilizer completely. Using the standard screwdriver from the Accessory Bag, open the valves slowly to verify that no pressure remains in the chamber.		
	<ol> <li>Valves Open: Keep rear valves open for transport and storage. Note that some remaining water/steam can exit when these valves are opened. Tilt the unit backwards and forwards and side to side to ensure all water is drained.</li> </ol>		

Check	Task
	3. <b>Power OFF:</b> Turn the sterilizer OFF using the front power switch.
	4. <b>Disconnect Power:</b> Disconnect the power cord from the <u>supply</u> <u>source first</u> , then from the sterilizer. Store in the Accessory Bag. Replace the main power connector cap.
	<ol> <li>Store Bag: Verify all contents of the Accessory Bag and store the bag inside the chamber. Ensure the shelf is in the chamber. Reference Section 1.4 for contents.</li> </ol>
	6. Close Chamber Door: Close the door and rotate the handles clockwise until the five radial arms are fully extended. Tighten handles until snug but do not fully compress the door O-ring. NOTE: Do not fully tighten the door for transport or storage.
	7. Close and Latch the Transport Panel.



#### **Handling during Transport or Storage:**

**Stability:** Use strap points to secure

Orientation: As shown

**Temperature:** -65° to 180°F

**Humidity:** 88% non-condensing (max)

**Pressure:** Leave rear valves open

Water: Fully drained

### 4.16 Extra Dry

After a <u>completed</u> sterilization cycle, if the user notices visual condensation and the need for additional dry time, use this feature to run the sterilizer dry function. To access, select EXTRA DRY from the CYCLES screen.

**WARNING:** This feature <u>does not include conditioning or exposure</u> phases. This feature can only be used to dry a load if more dry time is needed.



### 4.17 Faults, Alerts, and Warnings

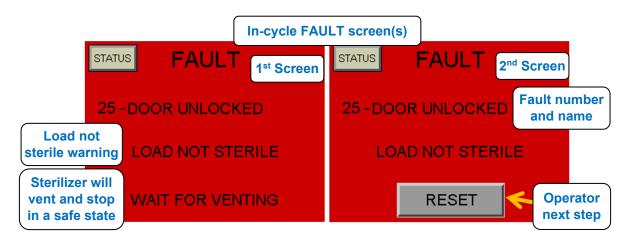
#### **Faults**

Faults occur when the FRONT-LINE detects an issue with the normal operating conditions or with one of its sensors or components. The FRONT-LINE will not start or complete a cycle until the issue is addressed and fixed.

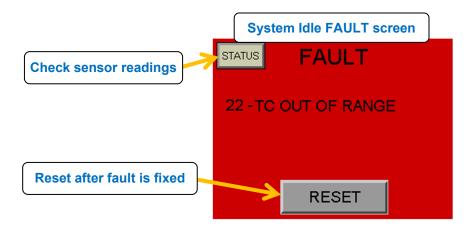
Sterilizers with faults should be serviced by qualified maintenance technicians. When a fault occurs, the buzzer beeps three times. In addition, the sterilizer will vent and stop the cycle in a safe condition. A red FAULT screen will show the fault number and name of the fault. The screen has a RESET button the user can press once the condition that caused the fault has been fixed. Choosing to RESET the fault will either (1) switch the display to the LOG screen to show the record of the fault or (2) repeat the FAULT screen if the fault condition is still present. After the issue is addressed, the LOG screen will display the fault in the cycle result line if the fault occurred during a cycle.

#### Water Reset Feature

If a fault occurs during a cycle, water could be left in the boiler. After a fault occurs during a cycle, navigate to SETUP and press WATER RESET to pump any remaining water out of the boiler.



If a fault occurs outside a cycle during system idle, the FAULT screens show the fault number and name but will not display "load not sterile" since the fault did not occur during a cycle. A STATUS button is available on FAULT screens to allow maintenance personnel to troubleshoot the sterilizer by observing the sensor data. See Section 9 for information on troubleshooting faults. Only qualified maintenance personnel should troubleshoot faults.



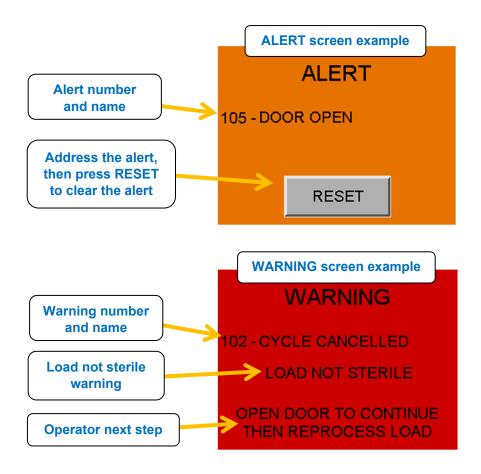
### **Alerts and Warnings**

**Alerts** are notices that remind the operator of certain tasks such as tightening the door.

**Warnings** are notices to the operator that a sterilization cycle did not complete properly, but the sterilizer is functioning correctly (such as cancelling a cycle).

Alerts and warnings can typically be addressed by the operator. For example, "Tank Low Water" means the operator needs to add water before starting the cycle, or "Door Open" means the operator needs to close and tighten the door before starting the cycle.

Alerts and warnings can be reset by (1) addressing the condition and then pressing RESET or (2) opening the door if the warning occurred during a cycle. See Table 5 for information on troubleshooting alerts and warnings.



**Table 5. Alerts/Warnings and Corrective Actions** 

#	Alert/Warning	Description	Corrective Action
ALERT 101	Tank Low Water	Water tank low water level warning. Cycle start is prevented until distilled water is added to the water tank.	Navigate to the SETUP screen and select WATER RESET to pump any water left in the boiler section to the water tank.  If level is still low, add distilled water via the front water fill port to the FULL mark.  If problem persists, contact a qualified maintenance technician to troubleshoot and clean the tip of the Water Tank Level Sensor.
WARNING 102	Cycle Cancelled	User manually aborted a cycle.	Open door and remove the load. Repackage and prepare the load per AAMI ST79. Re-run the cycle.
WARNING 103	In-Cycle Power Loss	Sterilizer experienced a power loss during a cycle.	Check incoming power connections and supply power. Repackage and prepare the load per AAMI ST79. Re-run the cycle.

#	Alert/Warning	Description	Corrective Action
ALERT 104	Water Changeout Required	Time since last reminder has reached 14 days or 50 cycles.	See Section 4.13 - Water Changeout Procedure to drain the entire system and refill the sterilizer with distilled water.
ALERT 105	Door Open	User attempted to start a cycle when the door is not closed and tight. Cycle start is prevented until door is closed/tight.	Close and tighten the door completely to start a cycle.  If problem persists, have a qualified maintenance technician review Section 8.4 to recalibrate the door sensors.
ALERT 106	Maintenance Reminder	Maintenance reminder every 300 cycles.	Refer a qualified maintenance technician to Section 6.1 for scheduled preventive maintenance activities.
ALERT 107	Water Reset Incomplete	Water reset watchdog timer. Either the air pump ran >2 min or the water pump took >3 min to drain the water out of the water tank.	Re-run the water reset function and monitor for issues.  Contact a qualified maintenance technician to check the Chamber and Boiler Drain Valves (SOLV-1&2).  Check the Air In Valve (SOLV-3).  Check that the heat exchanger is not clogged.  Check that the Air Pump (P-2) is functioning correctly.
ALERT 108	Drain Incomplete	Water Tank Level Sensor still detects water in tank after step 2 of the powered drain function. (See Section 4.13)	Check that the drain hose is installed to the front quick-connect (Main Drain).  Contact a qualified maintenance technician to check the Water Filter (F-1).  Troubleshoot the water tank level sensor and clean the tip as necessary.
ALERT 109	Door Unlocked	Door interlock could not be verified locked within 1 second of cycle start attempt.	Contact a qualified maintenance technician to check the (1) door lock mechanism for operation, (2) door solenoid, and (3) door lock proximity sensor for calibration using Section 8.4.

# 4.18 Operational Situations and Responses

**Cycle and Touchscreen Controller-related Situations** 

What do you do if	Response
You experience a power failure during operation?	Flip the control power switch to the OFF position. When the power returns, flip the control power switch ON. If the power outage was short, there will still be pressure in the chamber. The sterilizer will automatically vent and return to a safe state. After venting, open the door and reprocess the load per AAMI ST79 standards.
You want to stop a cycle?	Press CANCEL on the touchscreen controller.
The touch screen will not accept a command or seems to be "lost" and not functioning correctly?	Flip the control power switch to OFF, wait 5 seconds, and then flip it back ON. Restart the cycle.
The cycles are taking a lot longer than usual?	Check for steam leaks that may be causing long pulse and heat-up times. Check incoming power for proper voltage.
You forgot to record a previous cycle?	From the HOME screen, press LOG. On the LOG screen view previous results by using the arrow buttons.
You turn ON the sterilizer and get a low battery error while the PLC is booting up.	Contact a qualified maintenance technician to have the PLC battery replaced according to the Battery Replacement Procedure in Section 8.9.
The PLC screen responds slowly when the screen is pressed.	Contact a qualified maintenance technician to have the PLC battery replaced according to the Battery Replacement Procedure in Section 8.9.
You turn ON the sterilizer and nothing turns on.	Contact a qualified maintenance technician to remove the top panel and electrical enclosure cover and check the 20 Amp circuit breaker.
You turn ON the sterilizer and the fans turn ON, but the PLC screen does not.	Contact a qualified maintenance technician to remove the top panel and electrical enclosure and check the 1-Amp fuse on the terminal PCB.

# **Water and Steam-related Situations**

What do you do if	Response
You hear or see a steam	If it is safe to do so, CANCEL the cycle. Alternatively,
leak somewhere other	turn the front power switch OFF and allow the sterilizer
than the door?	to cool and depressurize. Contact a qualified
	maintenance technician to locate the leak by running a
	cycle and looking for condensate or water vapor.

What do you do if	Response
You hear or see a steam leak at the door?	If it is safe to do so, wait for the cycle to finish and then inspect the door frame and door gasket for any debris that could prevent a good seal. Closely inspect the gasket for any damage such as nicks or cuts. Contact a qualified maintenance technician to replace it if needed.
The sterilizer seems to be using more water than normal during each cycle?	Verify the Heat Exchanger Fan is working by checking for warm air exiting the left side of the sterilizer (Section 3.2) during a cycle.  Contact a qualified maintenance technician to troubleshoot if needed.
The PSV opens and releases steam?	Contact a qualified maintenance technician to troubleshoot the chamber pressure sensor, the chamber temperature sensor, and the PSV.  If it is safe, turn the sterilizer OFF and disconnect the incoming power.
There is a lot of water around the sterilizer?	Identify the source of the water immediately. Remove the panels and using a flashlight, inspect and locate the leak. If needed, de-energize and de-pressurize the sterilizer, remove the side panels, and inspect all fittings closely.

# **General Situations**

What do you do if	Response
There is algae in the sterilizer sight glass?	No response needed. Algae forms due to heat and light. It is normal and will not affect sterilization. To clean the sight glass, follow the procedure in Section 8.1.
The chamber door will not open due to vacuum on the chamber?	Press "VENT" on the HOME screen. If the door still will not open, open the chamber vent valve on the back of the sterilizer to vent the chamber.  CAUTION: This valve can be hot.
A biological indicator fails but the cycle completed w/ no alarms?	Reprocess per latest edition of AAMI ST79.



# Part 2 – MAINTENANCE

# **5 General Maintenance Information**

#### **Maintenance Videos**

Please visit the FDI video channel for step-by-step videos on the maintenance of the FRONT-LINE. Scan the QR code below, click on the hyperlink, or enter the Web address listed to access these videos.

**NOTE:** This channel is updated frequently, so check periodically to view new content.

https://www.youtube.com/c/FDIvideos/playlists



WARNING:

Ensure that AAMI standards are followed for qualification testing after maintenance or repairs. Reference Section 5.4 Post-maintenance Checklist for checkout procedure.

**WARNING:** 

When not in use, the FRONT-LINE should be drained completely to prevent potential growth of biological matter. To drain water, use the DRAIN function on the touchscreen controller.

**WARNING:** 

The FRONT-LINE has a pressure vessel that has been ASME boiler and pressure vessel code stamped. It is a violation of federal code to replace the main door plate or make any repairs to the pressure vessel. All repairs to the pressure vessel, including the door plate, must be made by FDI.

**WARNING:** 

Replacement parts should be sourced from FDI. Unauthorized parts could be of inferior quality, configuration, or specification and could compromise the safety and/or efficacy of the sterilizer and will void the warranty.

# **5.1 Maintenance Log**

Date	Cycle Count	Task(s) Performed	Technician Initials	Notes

# 5.2 Tools and Materials Required for Maintenance

The items listed below are less readily available than standard tools (e.g., standard or flathead screwdriver, open-ended wrenches) used to maintain the FRONT-LINE. These tools are not provided with the FRONT-LINE but are available for purchase from FDI using the contact information below.

Item	Description	Part Number
1.	WRENCH, TORQUE (3/8" SQUARE DRIVE, UP TO 150 INCH-LBS.)	FL-9047
2.	GREASE, HIGH TEMPERATURE (275°F), NLGI #2	FL-9048
3.	GLOVES, HEAT RESISTANT	FL-9049
4.	DRIVER SET, HEX KEY	FL-9078

Please contact FDI to purchase tools:

Email: <a href="mailto:sales@fortdefianceind.com">sales@fortdefianceind.com</a>

Phone: +1(865) 408-0100

## 5.3 Replacement Parts and Material List

**WARNING:** 

Replacement parts should be sourced from FDI. Unauthorized parts could be of inferior quality, configuration, or specification and could compromise the safety and/or efficacy of the sterilizer and will void the warranty.

Email: sales@fortdefianceind.com

Phone: +1(865) 408-0100

NOTE:

Nomenclature within parentheses (e.g., F-2) references the labeling in the piping and instrument diagram and electrical wiring diagrams in Sections 7.8 and 7.9, respectively.

Parts marked with an \* are FDI recommended spare parts to stock.

All parts, unless otherwise noted, are replacement only and cannot be serviced separately.

Item	Description	Part
4	·	Number
1.	BAG, ACCESSORY (WITH CONTENTS)	FL-9075
	BAG, ACCESSORY (W/O CONTENTS)	FL-9080
3.	BATTERY, TOUCHSCREEN CONTROLLER	FL-9050*
4.	BREATHER, WATER TANK	FL-9020
5.	CAP, WATER FILL PORT	FL-9037
6.	CASE, RUGGEDIZED HARD (BOTH MODELS)	FL-9094
7.	CASE, SOFT (MODEL FL120)	FL120-7010
8.	CASE, SOFT (MODEL FL135)	FL135-7010
9.	CIRCUIT BOARD ASSEMBLY, AC FILTER	FL-9034
10.	CIRCUIT BOARD ASSEMBLY, RELAY	FL-9036
11.	CIRCUIT BOARD ASSEMBLY, TERMINAL	FL-9035
12.	BREAKER, 20AMP CIRCUIT	FL-9032
13.	CLEANING SOLUTION, FRONT-LINE (CITRAJET)	FL-9072
14.	CONTROLLER, AIR PUMP, ASSEMBLY	FL-9074
15.	CONTROLLER, TOUCHSCREEN (PLC)	FL-9029*
16.	CORNER ISOLATOR, RUBBER	FL-9084
17.	DISTILLED WATER GENERATOR (W/ CASE)	FL-9077
18.	DRIVER SET, HEX KEY	FL-9078
19.	ELECTRICAL ENCLOSURE, W/ COMPONENTS	FL-9013
20.	FAN, ELECTRICAL ENCLOSURE (EF-2)	FL-9069
21.	FAN, HEAT EXCHANGER (EF-1)	FL-9068
22.	FAN, HEATSINK LARGE (EF-4)	FL-9071
23.	FAN, HEATSINK SMALL (EF-3)	FL-9070
24.	FEET, CHAMBER SHELF, RUBBER (PKG OF 6)	FL-9098
25.	FILTER, HEPA (F-2)	FL-9022*
26.	FILTER, WATER (F-1) - WASHABLE	FL-9005
27.	FILTER, AIR INLET - WASHABLE	FL-9021
28.	FUSE, 1 AMP (PKG OF 5)	FL-9051
29.	GASKET, 1/4" FITTING (PKG OF 20)	FL-9060
30.	GAUGE, SIGHT - WASHABLE	FL-9039

32. GRI 33. HAN	DVES, HEAT RESISTANT	Number FL-9049
32. GRI 33. HAN	·	FI -0040
33. HAN	TACE LUCITEMP (275°E)	1 6-3043
	EASE, HIGH TEMP (275°F)	FL-9048
34 HF/	NDLES, DOOR	FL-9038
UT.   1 1 L /	AT EXCHANGER	FL-9065
35. HEA	ATER, 1650W (H-1&2)	FL-9006*
36. HOS	SE, DRAIN	FL-9053
37. IND	ICATOR, 3M 1492V BIOLOGICAL	FL-9044
1 3X I	ICATOR, CROSSTEX SPORVIEW SVT-050 LOGICAL	FL-9046
39. IND	ICATOR, STERIS CELERITY 20 BIOLOGICAL	FL-9045
40. KIT.	CONSUMABLES	FL-9082
41. KIT.	RECOMMENDED SPARE PARTS	FL-9073*
42. KIT.	STERILITY ASSURANCE STARTUP	FL-9083
	VALVE MAINTENANCE	FL-9095*
44. LAT	CH, TRANSPORT	FL-9089
45. O-R	ING, 1/4" FITTING (PKG OF 5)	FL-9091
	ING, 3/8" FITTING (PKG OF 5)	FL-9061
	ING, DOOR (PKG OF 2)	FL-9058*
	ING, DOOR POST (PKG OF 2)	FL-9059
	ING, SIGHTGLASS (PKG OF 5)	FL-9092
	IEL, FL120, BACK	FL-9054
	IEL, FL120, TRANSPORT	FL-9055
	IEL, FL135, BACK	FL-9096
	IEL, FL135, TRANSPORT	FL-9097
	JCH, STERILIZATION, 3.5" X 10" (200/BOX)	FL-9087
55. PO\	VER CONNECTOR, MAIN	FL-9001
56. PO\	VER CORD, 120VAC	FL-9002
57. PO\	VER CORD, 230-240VAC	FL-9003
58. PO\	VER CORD, TYPE F, 230VAC	FL-9105
59. PO\	VER SUPPLY, DC (PS-1)	FL-9028*
60. PUN	MP, AIR (P-2)	FL-9016*
	MP, WATER (P-1)	FL-9008*
62. REL	AY, HEATER CONTROL (SSR-H1)	FL-9023
<b></b>	AY, HEATER MODE SELECT (K4)	FL-9030
	AY, MAIN (K1)	FL-9026
65. REL	AY, MASTER (K2)	FL-9025
	REEN, CHAMBER DRAIN	FL-9062
	REWDRIVER, STANDARD (FLATHEAD)	FL-9043
<b></b>	CARD (WITH ADAPTER AND PLC PROGRAM)	FL-9063
<b></b>	ISOR, BOILER/WATER TANK LEVEL (LS-1&2)	FL-9014*
	ISOR, CHAMBER PRESSURE (PT-1)	FL-9019
	ISOR, CHAMBER TEMPERATURE (RTD-1&2)	FL-9015
	ISOR, DOOR LOCK (DS-2)	FL-9056
	ISOR, DOOR TIGHT (DS-1)	FL-9057
<b></b>	ISOR, ENCLOSURE TEMPERATURE (RTD-3)	FL-9027
	ELF, CHAMBER	FL-9064
<b></b>	ENOID, DOOR (SOLA-1)	FL-9086
	TCH, MAIN POWER	FL-9000

Item	Description	Part Number
78.	TABLE, ALUMINUM, 36 X 36 X 30 IN	FL-9076
79.	TUBING, SPARE PFA	FL-9081*
80.	VALVE, AIR IN (SOLV-3)	FL-9012
81.	VALVE, AIR OUT (SOLV-4)	FL-9011
82.	VALVE, BOILER DRAIN (SOLV-1)	FL-9009
83.	VALVE, CHAMBER DRAIN (SOLV-2)	FL-9010*
84.	VALVE, CHAMBER VENT (DV-3)	FL-9040
85.	VALVE, CHECK (CV-1, 0.5 PSI)	FL-9066
86.	VALVE, CHECK (CV-2, 1.5 PSI)	FL-9067*
87.	VALVE, MAIN DRAIN (DV-2)	FL-9041
88.	VALVE, MANUAL DRAIN (DV-1)	FL-9042
89.	VALVE, PRESSURE SAFETY (PSV-1)	FL-9017
90.	WIRING HARNESS, MAIN CABLE, FL120	FL-9052
91.	WIRING HARNESS, MAIN CABLE, FL135	FL-9106
92.	WRAP, STERILIZATION, 48" X 48", 2-PLY (48/BOX)	FL-9088
93.	WRENCH, TORQUE, 3/8"	FL-9047

## **5.4 Post-maintenance Checklist**

FDI recommends inspecting all work and using the following checklist after any intrusive maintenance (e.g., replacing a solenoid valve) to ensure the sterilizer is ready to be returned to service.

Check	Task
	All internal hoses are re-connected and tight.
	All electrical cables are re-connected.
	No loose parts or tools in the electrical enclosure.
	All panels are reinstalled.
	5. The two valves are closed on the back of the sterilizer.
	6. The water level is correct.
	7. All faults, repairs, and cycle count (found in STATUS screen) are documented in a maintenance log (see Section 5.1).
	8. During a cycle, there are no steam leaks or water leaks.
	Cycle times are normal. See Section 1.10 for average cycle times at room temperature and pressure.
	10.Follow all applicable requirements in AAMI ST79 for post-maintenance performance qualification.

NOTE:	FDI recommends completing three consecutive sterilization
	cycles with biological indicators in the load. Always follow the
	BI manufacturer's instructions.

## **5.5 Torque Specifications**

Follow the torque specifications below when performing any maintenance task on the FRONT-LINE:

4-40 Screw: 5-6 inch-lbs.
6-32 Screw: 8-10 inch-lbs.
8-32 Screw: 20 inch-lbs.
10-32 Screw: 31-35 inch-lbs.

1/4-20 Screw: 75-80 inch-lbs.

• Plumbing compression fittings: finger-tight, then 1/4 turn

Boiler/Water Tank Level Sensor (LS-1&2): hand-tight to compress gasket

# **6 Preventive Maintenance**

### 6.1 Preventive Maintenance (PM) Schedule

The following PM schedule should be followed for all in-service sterilizers. These procedures only apply to sterilizers that are in use. Perform the outlined maintenance procedures only when the sterilizer is operational.

**Table 6. Preventive Maintenance Schedule** 

Frequency	Task	Section
6 Months of use, or 300 Cycles	<ol> <li>HEPA Filter Replacement</li> <li>Air Inlet Filter Inspection/Cleaning</li> <li>Water Filter Cleaning</li> </ol>	6.2
12 Months of use, or 600 Cycles	<ol> <li>PSV Test</li> <li>Chamber Doorpost Threads Lubrication</li> <li>Heat Exchanger Inspection</li> <li>Heat Exchanger Fan Inspection</li> <li>Electrical Wiring Inspection</li> <li>Doorpost Screws Re-torque</li> <li>Replacement Parts Stock Check</li> </ol>	6.3

#### **WARNING:**

The following <u>operator procedures</u> are critical to the reliable operation of the sterilizer. These procedures must be followed at the frequencies shown.

- 1. Water Changeout Procedure (Section 4.13)
- 2. Chamber and Boiler Cleaning Procedure (Section 4.14)

#### 6.2 Six-month Preventive Maintenance

**WARNING:** 

To avoid a potential electrical shock or burn hazard, be sure the sterilizer has been de-energized and depressurized prior to performing these tasks.

# EVERY 6 MONTHS OR 300 CYCLES

(whichever occurs first)

Check	Task
	Replace the HEPA Filter. See Section 8.3.
	2. <b>Inspect/Clean the air inlet filter</b> on right-hand side of the sterilizer. The filter is located behind the right-side panel underneath the electrical enclosure. If dirty, rinse with water, dry, and reinstall.
	<ul> <li>3. Inspect the water filter:</li> <li>a) Drain the sterilizer.</li> <li>b) Remove the left-side panel and locate the water filter.</li> <li>c) Disconnect the water filter from the water tank and outlet hose.</li> <li>d) Loosen the filter housing using two wrenches.</li> <li>e) Inspect the filter element and clean with water or compressed air as necessary.</li> <li>f) Re-install the filter element (check for orientation) into the filter body.</li> <li>g) Re-install the filter body onto the sterilizer (flow arrow should be down).</li> <li>h) Replace the left-side panel.</li> </ul>

### **6.3 Twelve-month Preventive Maintenance**

**WARNING:** 

To avoid a potential electrical shock or burn hazard, be sure the sterilizer has been de-energized and depressurized prior to performing these tasks.

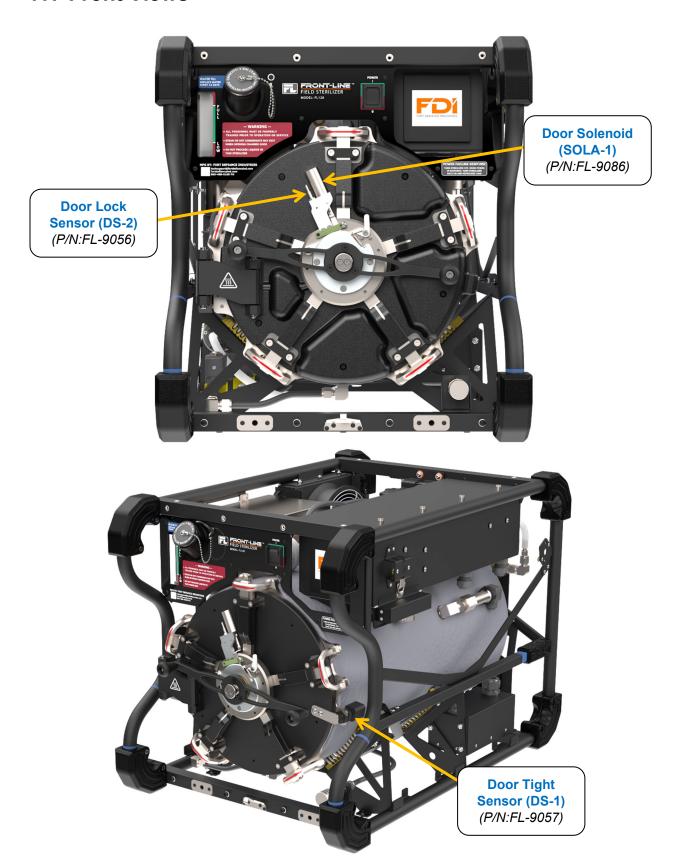
### **EVERY 12 MONTHS (approximately 600 cycles)**

Check	Task	
	1. PSV test:	
	<b>CAUTION:</b> Ensure the sterilizer is depressurized and OFF before pulling the PSV.	
	<ul><li>a) Remove the back panel.</li><li>b) Gently pull the ring on the top of the PSV to ensure the PSV moves freely and re-seats.</li></ul>	
	c) Run an IUSS cycle and inspect the PSV for leaks.	

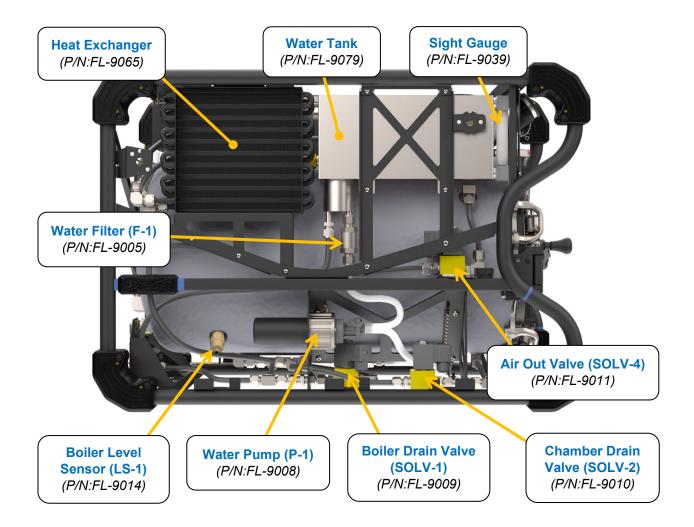
Check	Task
	d) Replace the back panel.
	2. Lightly lubricate the chamber doorpost threads using high temperature (275°F) NLGI #2 grease.
	<ol> <li>Inspect the heat exchanger behind the left-side panel and, if dirty, clean by blowing out with compressed air or spraying down with water. Use safety glasses when using compressed air.</li> </ol>
	<ol> <li>During a cycle, check to ensure warm air flows out of the left-side panel to verify the Heat Exchanger Fan is operational.</li> </ol>
	<ol> <li>Inspect wiring in the electrical enclosure for loose wires, corrosion, loose connections, or other concerns. Access the electrical enclosure by removing the top panel and the electrical enclosure top panel.</li> </ol>
	6. Verify the three doorpost screws on the inside of the door are torqued to <u>35 inch-lbs.</u>
	<ol> <li>Ensure adequate replacement parts are in stock to ensure mean- time-to-repair objectives can be met. Reference Section 5.3 for recommended spare parts marked with an * and order parts as needed.</li> </ol>

# 7 Interior Component Diagrams

# 7.1 Front Views

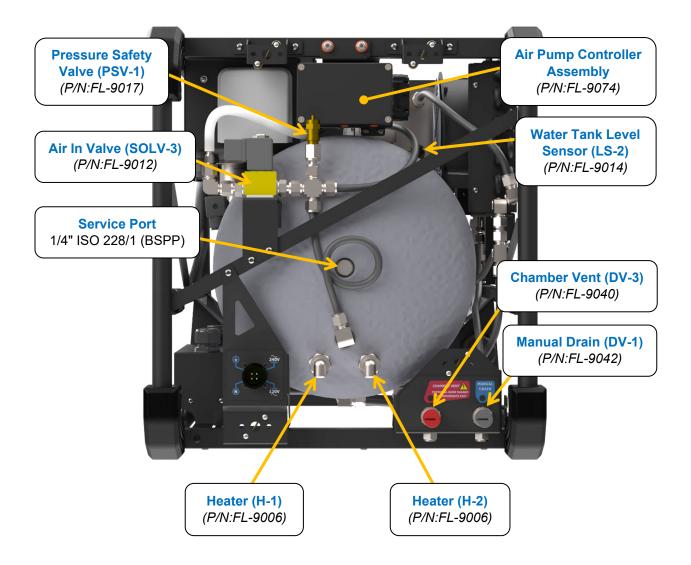


#### 7.2 Left-side View

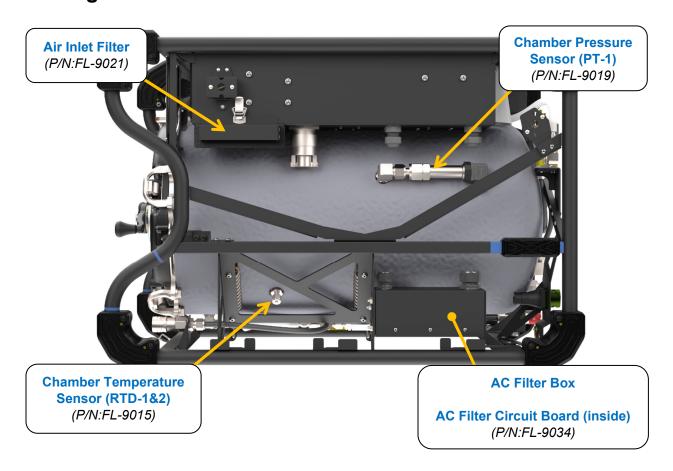


**NOTE:** On S/N's FL120S-0001 through 0006, the Boiler Level Sensor is located on the right side of the sterilizer.

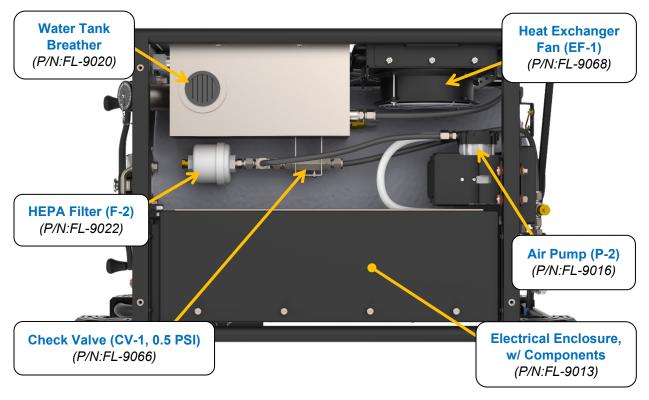
#### 7.3 Back View



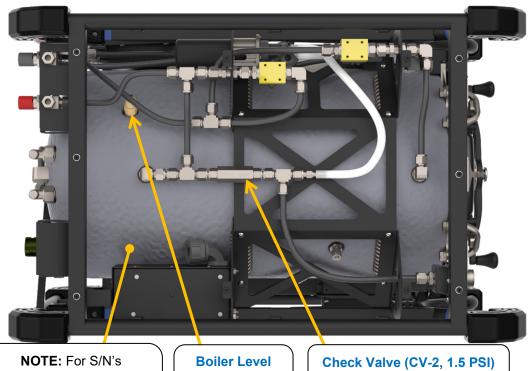
# 7.4 Right-side View



# 7.5 Top View



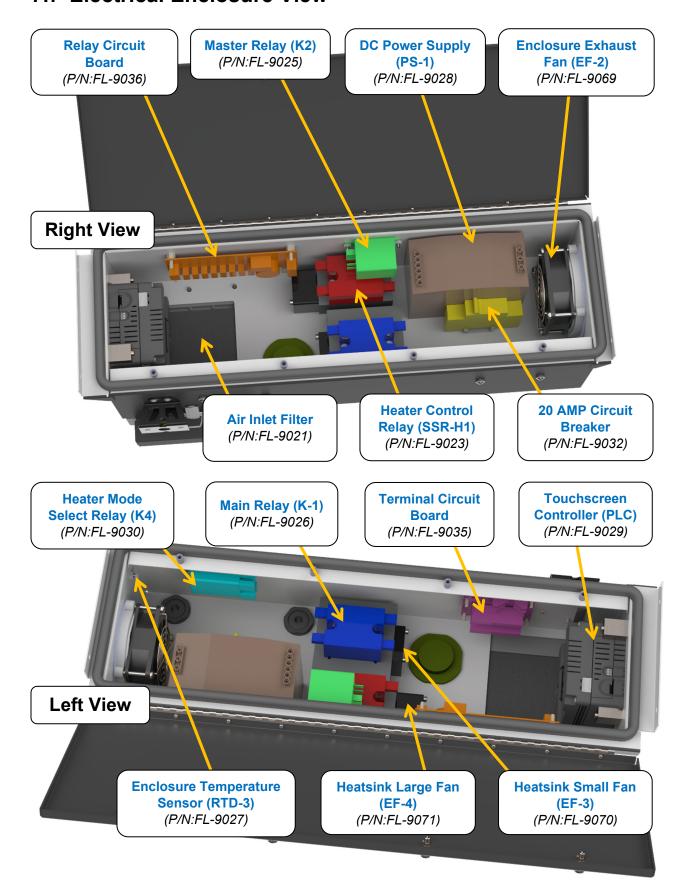
# 7.6 Bottom View



FL120S-0001 through 0006, the Boiler Level Sensor is located here Sensor (LS-1) (P/N:FL-9014)

Check Valve (CV-2, 1.5 PSI) (P/N:FL-9067)

#### 7.7 Electrical Enclosure View

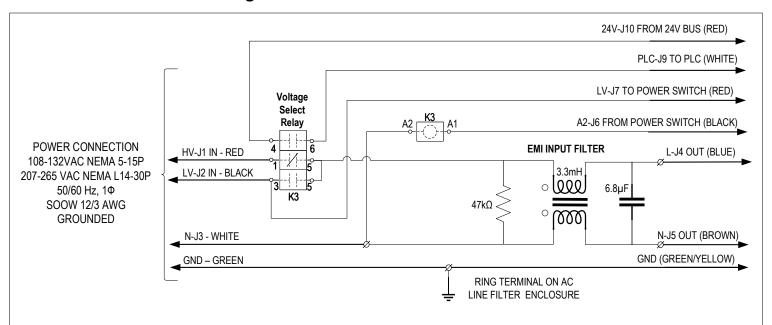


7.8 Piping and Instrument Diagram

#### **FRONT-LINE Piping and Instrument Diagram** REV A | 8 MAR 2022 \_Distilled Water Fill Sight Gauge [Manual Drain] DV-1 Drain Water Tank Water Tank Breather LS-2 [Water Tank Level Sensor] ļ F-1 [Water Filter] [Heat Exchanger SOLV-2 [Chbr. Drain] Heat Exchanger P-1 [Water Pump] SOLV-4 [Air Out] DV-2 [Main Drain] Drain SOLV-1 [Boiler Drain] **₩** $\mathbb{W}$ 72 Door CV-2 [1.5 psi break] RTD-1&2 [Chbr. Temp Sensor] Drain Hose Water Fill / Drain Chamber T3 [Chbr. Pressure Sensor] 44 Boiler Section PT-1 DV-3 [Chbr. Vent] Drain Service Coupling [¼" BSPP] □ TC-1&2 **Q**—[Heater Thermocouples] H-1&2 [Heaters] PSV-1 [Pressure Safety Valve, 45 psi] LS-1 [Boiler Level Sensor] SOLV-3 [Air In] RTD - resistance temp. detector PSV - pressure safety valve PT – pressure transmitter SOLA-1 [Door Solenoid] $^{\circ}$ SOLV - solenoid valve P-2 [Air Pump] — DS-2 [Door Lock Sensor] DS-1 [Door Tight Sensor] TC - thermocouple LS – level Sensor CV - check valve DS - door switch DV - drain valve EF – electric fan H – heaters P – pump C – cross $\mathbb{W}$ F – filter CV-1 [0.5 psi break] Acronyms: [HEPA Filter, 0.3 micron]

7.9 Electrical Wiring Diagram

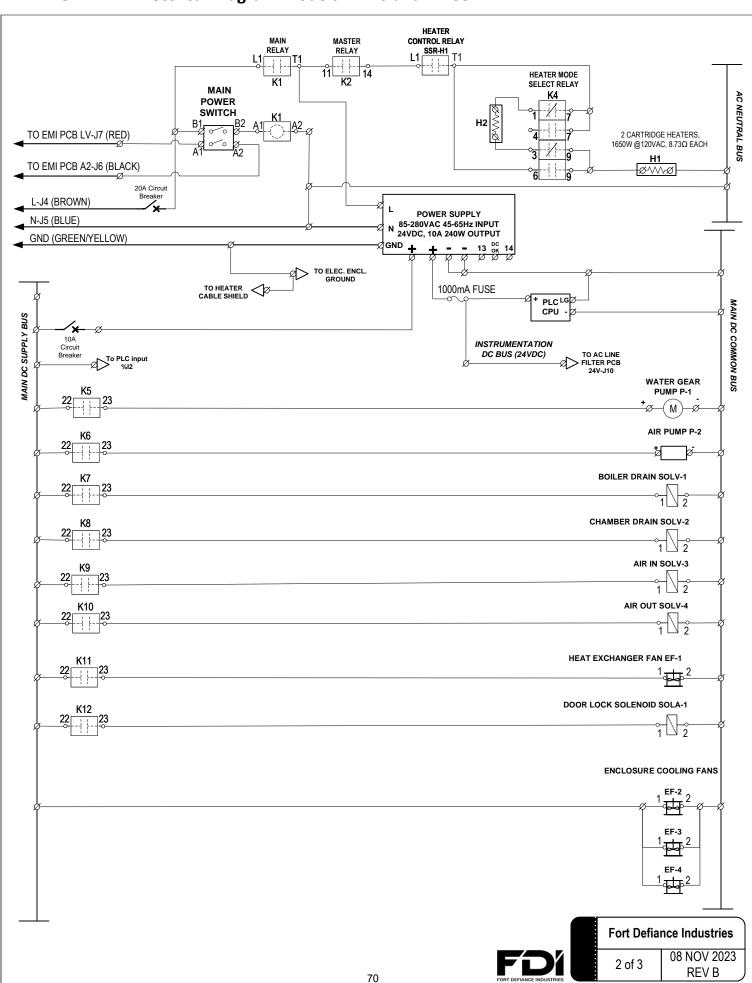
### **FRONT-LINE Electrical Diagram Models FL120 and FL135**



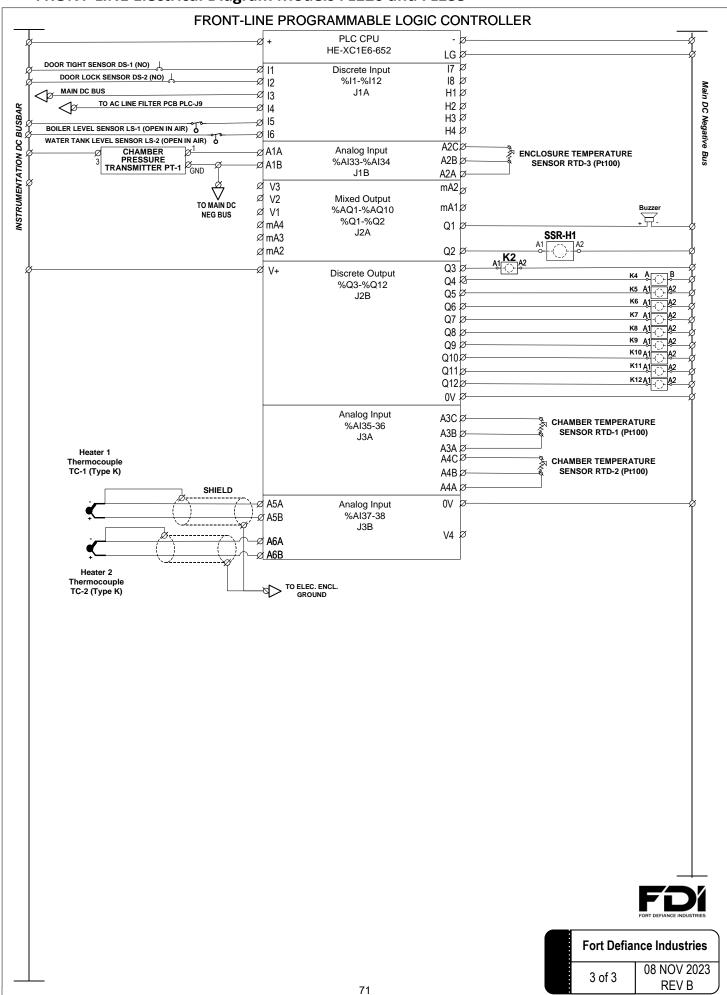


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1 of 3	08 NOV 2023 REV B		

#### **FRONT-LINE Electrical Diagram Models FL120 and FL135**



### **FRONT-LINE Electrical Diagram Models FL120 and FL135**



# **8 Maintenance Procedures**

WARNING: Maintenance work must be performed by qualified maintenance

technicians.

#### **Maintenance Videos**

Please visit the FDI video channel for helpful and informative videos on the maintenance of the FRONT-LINE. Scan the QR code below, click on the hyperlink, or enter the Web address listed to access these videos.

**NOTE:** This channel is updated frequently, so check periodically to view new content.

https://www.youtube.com/c/FDIvideos/playlists

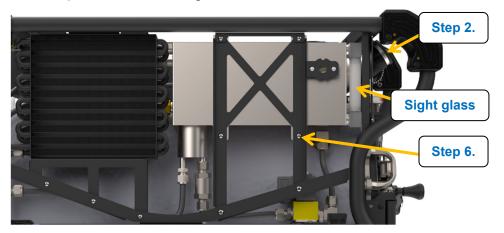


### **Procedures Summary List**

Section	Procedure
8.1	Sight Glass Cleaning
8.2	Chamber Door O-ring Replacement
8.3	HEPA Filter Replacement
8.4	Door Sensor Calibration
8.5	Solenoid Valve Maintenance
8.6	Heater Element Cleaning/Replacement
8.7	Chamber Temperature Sensor Replacement
8.8	Chamber Pressure Sensor Replacement
8.9	Touchscreen Controller (PLC) Battery Replacement
8.10	Software Update
8.11	PLC Replacement
8.12	Pressure and Temperature Sensor Check

#### 8.1 Sight Glass Cleaning

**NOTE:** Algae may form in the sight glass due to heat and light. It is a normal occurrence and does not affect sterilization. This procedure does not need to be performed on a regular basis.



- 1. Using the DRAIN feature on the HOME screen of the touchscreen controller, drain the sterilizer and remove the left side and top panels.
- 2. Remove the water fill port cap and the rubber grommet.
- 3. Disconnect all hoses from the water tank, including the HEPA filter hoses.
- 4. Disconnect the Water Tank Level Sensor connector.
- 5. Remove the four screws that secure the water tank to the bracket and remove the water tank from the frame.
- 6. Remove the two sight glass bolts w/ 9/16 wrench and disassemble the sight glass.
- 7. Use a <u>plastic</u> bottle brush to clean the sight glass and rinse it with distilled water.
- 8. Reinstall the sight glass to water tank and torque the bolts to **20 in.-lbs.**, using a 1" wrench to counter-torque. Verify the gaskets and O-rings are reinstalled.
- 9. Reinstall the water tank, rubber grommet, and fill port cap. Hoses are torqued finger-tight, then 1/4 turn.
- 10. Check that all hose fittings are torqued correctly, and the level sensor is connected.
- 11. Fill the water tank with distilled water and run an IUSS cycle to check for leaks.
- 12. Reinstall the left side and top panels.
- 13. Follow Section 5.4 for post-maintenance checklist.

### 8.2 Chamber Door O-ring Replacement



- 1. Starting at the removal hole at the 12 o'clock position and being careful not to scratch/damage the groove, use a small pick or standard screwdriver to pick the O-ring out of the groove.
- 2. Inspect and clean the O-ring groove as needed with a clean, damp rag.
- 3. Install the new O-ring by pressing in the O-ring at 3 and 9 o'clock first. Make sure there are equal amounts of the O-ring at top and bottom. Then, press the O-ring in at 12 and 6 o'clock.
- 4. Finish the insertion by pressing the O-ring in between these locations in a symmetrical motion until the O-ring is fully inserted. The O-ring should be seated completely when finished.
- 5. Run an IUSS cycle and check for steam leaks.
- 6. Follow Section 5.4 for post-maintenance checklist.

## 8.3 HEPA Filter Replacement



- 1. Remove the top panel by locating and removing the four slotted screws attached to the frame. Note that the top panel is permanently attached to the X-brace.
- Locate the HEPA Filter as shown above.
- 3. Loosen the 11/16" nut used to secure the HEPA Filter to the check valve. Counter torque the tee fitting to prevent twisting/damaging the hose.
- 4. Discard the old HEPA Filter.
- 5. Insert new HEPA Filter. Tighten the nut finger-tight, then one-quarter turn.
- 6. Check that all fittings are tight and then re-install the top panel.
- 7. Follow Section 5.4 for post-maintenance checklist.

#### 8.4 Door Sensor Calibration

- 1. Determine which sensor is out of adjustment:
  - a. If the operator has experienced the following faults or alerts, the Door Lock Sensor may need to be adjusted, cleaned, or replaced:
    - i. 25 Door Unlocked
    - ii. 26 Door Interlock
    - iii. 109 Door Unlocked
  - b. Navigate to the STATUS screen. If the DOOR TIGHT indicator does not turn green once the door is fully tightened, the Door Tight Sensor may need to be adjusted or replaced.

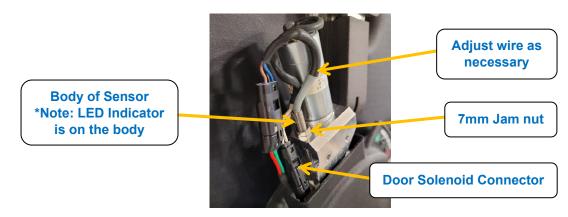
#### 2. Adjusting the Door Lock Sensor:

a. The Door Lock Sensor is located near the center of the door on the door hub. With the door closed, remove the solenoid cover.





b. Using a 7 mm wrench, loosen the jam nut on the sensor.



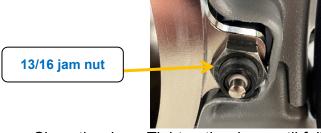
- c. Verify the sterilizer is ON and the door solenoid is retracted.
- d. Unplug the door solenoid connector by lifting the tab on the connector. An alarm will occur. Do not reset the alarm.
- e. Switch the Manual Unlock to the UNLOCKED position.

- f. If the sensor LED is ON, disconnect the sensor by lifting the tab on the connector and twist the body of the sensor out 3-5 turns and then reconnect. Then, proceed with (g).
- g. If the sensor LED is blinking or not ON, disconnect the sensor by lifting the tab on the connector, and twist the body of the sensor in 1 full turn. Reconnect the sensor and check that the LED indicator is ON and does not blink. Repeat as necessary until the LED does not blink.
- h. Tighten the jam nut on the sensor, verifying the LED indicator is still ON and not blinking.
- Switch the Manual Unlock to the LOCKED position and verify the LED indicator turns OFF.
- i. Reconnect the door solenoid connector.
- k. START and CANCEL a few cycles to verify functionality.
- During a cycle, flip the MANUAL UNLOCK to the UNLOCKED position.
   Verify the alarm trips.
- m. Re-install the solenoid cover. **Ensure the connectors and wires get** tucked into the solenoid cover.

#### 3. Adjusting the Door Tight Sensor:



- a. The sensor is located at the 4 o'clock position on the door frame. Remove the right-side panel.
- b. Using a 13/16 wrench, loosen the jam nut on the sensor to allow the sensor to be adjusted.

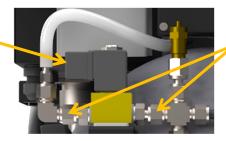


- c. Close the door. Tighten the door until fully tight and the hub stops on the door (there will be a discernable stop of the door handles). Then, rotate the handles 1.5 turns counterclockwise. This will add margin to the system.
- d. Watching the STATUS screen on the PLC, adjust the location of the DOOR TIGHT sensor by twisting it until the STATUS screen reads DOOR TIGHT.
- e. Tighten the jam nut on the sensor, being careful to counter-torque the sensor so that it does not move. Verify the STATUS screen still reads DOOR TIGHT.

- f. Operate the door multiple times to verify functionality. The indicator on the STATUS screen should change to DOOR TIGHT when the door handles are about 1.5 turns from fully tight (there is a discernable stop at fully tight).
- g. Reinstall all panels.
- 4. Follow Section 5.4 for post-maintenance checklist.

#### 8.5 Solenoid Valve Maintenance

**DIN Connector** 



Loosen these 11/16 nuts

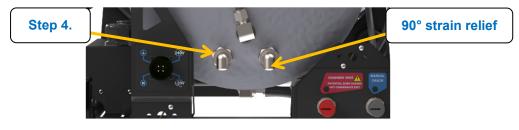
SOLV-3, back view shown

- 1. Drain the sterilizer, turn the sterilizer OFF, and disconnect power.
- 2. If a solenoid valve is leaking or will not actuate, remove the valve from the sterilizer by disconnecting the electrical DIN connector with a Phillips screwdriver, disconnecting the two plumbing fittings with 11/16 wrenches, and if necessary, removing the two mounting screws from underneath the valve.
- 3. Use a 3/4 wrench to remove the hex nut on the top of the valve. Remove the coil from the top of the valve.
- 4. Remove the stem from the top of the valve using a 7/8 wrench. The stem houses the poppet, which opens and closes the valve.
- 5. Inspect the valve seat for debris buildup or damage. Clean or replace the valve as needed.
- 6. Inspect the poppet EPDM rubber seal for buildup or damage. Clean or replace the valve as needed.
- 7. Inspect the poppet shaft, spring, and washer for buildup or damage. Clean or replace components as needed. It is normal to see small amounts of corrosion.
- 8. Reinstall the valve (ensure the flow arrow is facing the correct direction) and connect the DIN connector and associated plumbing .
- 9. Ensure all plumbing is installed finger-tight, then 1/4 turn. Reinstall the panels.
- 10. Follow Section 5.4 for post-maintenance checklist.

## 8.6 Heater Element Cleaning/Replacement

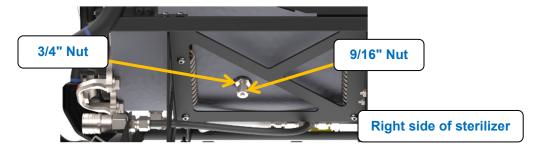
**WARNING:** 

To avoid a potential electrical shock or burn hazard, be sure the sterilizer has been de-energized and depressurized prior to performing these tasks.



- 1. Remove the back panel and right-side panel.
- 2. Locate the two heaters at the back of the chamber near the bottom side.
- 3. Disconnect the two electrical connectors and the two yellow thermocouple (T/C) connectors. NOTE: It does not matter which T/C is connected to which connector.
- 4. Using a 1" wrench, loosen the nut on each heater and slide the heaters out.
- 5. Clean the heaters as needed with a stiff <u>stainless-bristled</u> brush or a Scotch-Brite<sup>®</sup> Pad. Do not use steel brushes. Rinse the heaters with distilled water after they have been brushed and wipe them with a lint-free rag.
- 6. Discard the heaters if they need to be replaced.
- 7. Re-install the heaters by inserting and positioning the 90-degree strain relief at approximately 6 o'clock as shown above.
- 8. Tighten the nuts finger-tight, then 1/4 turn using the 1" wrench.
- 9. Connect the two electrical connectors and the two yellow T/C connectors.
- 10. Reconnect power to the sterilizer and turn the sterilizer on.
- 11. Navigate to the STATUS screen and check the Heater 1 and 2 Temperature to verify they read approximately ambient temperature.
- 12. Run an IUSS cycle and check for steam leaks and verify normal cycle times.
- 13. Reinstall the back panel and right-side panel.
- 14. Follow Section 5.4 for post-maintenance checks and tasks.

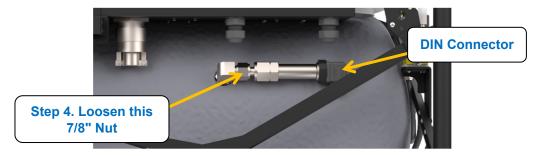
# 8.7 Chamber Temperature Sensor Replacement



- 1. Turn the sterilizer OFF, allow the chamber to cool, and disconnect power.
- 2. Using the provided standard screwdriver, remove the right-side panel, and locate the resistance temperature detector (RTD) underneath the chamber.
- 3. Using a 3/4" wrench to counter torque the fitting, loosen the RTD probe with a 9/16" wrench. Then, loosen the fitting with the 3/4" wrench.
- 4. Disconnect the RTD connector and remove the <u>fitting and the RTD probe</u> from the chamber.
- 5. Discard the old RTD.
- 6. Insert the new RTD probe into the fitting and tighten the nut finger-tight, then a final 1/4 turn to tighten the probe to the fitting. Reinstall the fitting and gasket to the chamber. Tighten the fitting with 3/4" wrench until snug.
- 7. Connect the RTD connector, reinstall the panels, and verify the input is reading correctly by navigating to the STATUS screen.
- 8. Follow Section 5.4 for post-maintenance activities. FDI recommends completing three consecutive sterilization cycles with biological indicators in the load.

**NOTE:** Temperature sensors are factory checked for accuracy and cannot be adjusted in the field. Contact FDI Technical Support for more information.

### 8.8 Chamber Pressure Sensor Replacement



**CAUTION:** Do not touch the diaphragm on the tip of the chamber pressure sensor as it could damage the sensor. The diaphragm is protected by the fitting on the end of the sensor and is not normally accessible.

- 1. Turn the sterilizer OFF, allow the chamber to cool, and disconnect power.
- 2. Remove right-side panel with provided standard screwdriver and locate the pressure sensor.
- 3. Use a Phillips screwdriver to disconnect the DIN connector on the back of the sensor. Take note of the orientation of the DIN connector.
- 4. Use a 7/8" wrench to remove the fitting and the pressure sensor. The 90° fitting can remain installed to the chamber.
- 5. Position the new sensor so the DIN connector is oriented as before. Tighten the fitting finger-tight and then 1/4 turn with a 7/8" wrench.
- 6. Re-connect the DIN connector to the back of the sensor and tighten with a Phillips screwdriver. Do not overtighten the DIN connector.
- 7. Turn the sterilizer ON, navigate to the STATUS screen, and verify the Chamber Pressure is reading close to 0.0 psig with the door open.
- 8. Run an IUSS cycle and check for steam leaks.
- 9. Re-install the panels.
- 10. Follow Section 5.4 for post-maintenance activities. FDI recommends completing three consecutive sterilization cycles with biological indicators in the load.

### 8.9 Touchscreen Controller (PLC) Battery Replacement

**WARNING:** Lithium batteries can explode or catch fire if damaged. Do not recharge, disassemble, heat above 100°C (212°F), incinerate, or puncture.

**NOTE:** Disposal of lithium batteries must be done in accordance with federal, state, and local regulations. Be sure to consult with the appropriate regulatory agencies before disposing of batteries.

**NOTE:** Do not make substitutions for the battery. The Horner XL4 PLC uses a rechargeable lithium battery (*P/N: FL-9050*).



- 1. Turn sterilizer OFF and then back ON. Record the software version as it flashes on the screen for approximately 2 seconds.
- Record the number of CYCLES from the STATUS screen in the maintenance log.
- 3. Turn the sterilizer OFF and disconnect incoming power.
- 4. Remove the right-side and top panel to access the electrical enclosure. Open the electrical enclosure access panel by loosening the four panel fasteners on top of the electrical enclosure.
- 5. Unplug the output connector of the Relay PCB board and set aside. Unplug the bottom Terminal PCB connector and set aside.
- 6. Remove the four screws on the back of the PLC and remove the cover.
- Gently pull the Input/Output (I/O) board straight out, being careful not to damage the pins.
- 8. Remove the old battery by pulling it straight out of the holder.
- 9. Dispose of the battery properly per the above note on disposal regulations.
- 10. Place new battery into the holder. Make sure the battery is inserted with the correct polarity.

**CAUTION:** Be extremely careful that all pins are aligned to the connector before sliding the I/O board back onto the PLC.

- 11. Gently place the I/O board back onto the PLC by aligning the connector to the pins and carefully press straight in.
- 12. Reinstall the back cover on the PLC with the memory card symbol at the top and tighten all four screws.
- 13. Reconnect the two connectors to the PCB boards.
- 14. Record the battery replacement in the maintenance log with the cycle count.
- 15. See Section 5.4 for post-maintenance activities. FDI recommends completing three consecutive sterilization cycles with biological indicators in the load to verify performance.

### 8.10 Software Update

Use the following procedure to update the software in the FRONT-LINE, using the Micro SD card shipped with each sterilizer. Additionally, critical software updates can be distributed to users via email and then saved to the Micro SD card.

- 1. If the software update is a new update distributed via email, save the file onto the Micro SD card with your computer. The Micro SD card stored in the Accessory Bag comes pre-formatted and ready for new software distributions.
- 2. Turn the sterilizer OFF and remove the top panel.
- 3. Loosen the four panel screws on the electrical enclosure to access the top of the PLC.
- 4. Insert the Micro SD card into the top of the PLC. The exposed pins should face toward the front of the sterilizer.
- Turn the sterilizer ON and note the firmware version number in the upper lefthand corner of the second screen. Compare the firmware version to the version on the SD card or the emailed software update. If these versions do not match, please contact FDI Technical Support.
- 6. From the SETUP screen, press the GEAR icon button on the PLC. (This button is only active on this screen.)
- 7. Arrow down to REMOVABLE MEDIA and choose ENTER (←).
- 8. Arrow down to the program (example: V1003) and choose ENTER (←).
- 9. Choose OK and wait for the program to load.
- 10. When you see "PLACE IN RUN MODE?" choose OK.
- 11. The PLC will restart, show the splash screens, and then the HOME screen will appear.
- 12. Turn the sterilizer OFF and remove the Micro SD card.
- 13. See Section 5.4 for post-maintenance activities. FDI recommends completing three consecutive sterilization cycles with biological indicators in the load to verify performance.
- 14. The new software is now installed, and the sterilizer is ready to operate.

# 8.11 PLC Replacement

**NOTE:** Please reference the Horner XL4 manual found at the link below for more information.

https://www.fortdefianceind.com/tech-help/



- 1. Turn the sterilizer OFF and then back ON. Record the software version as it flashes on the screen for approximately 2 seconds.
- Record the number of CYCLES from the STATUS screen in the maintenance log.
- 3. Turn the sterilizer OFF and disconnect incoming power.
- 4. Using the provided standard screwdriver, remove the right-side and top panel to access the electrical enclosure. Open the electrical enclosure access panel by loosening the four panel fasteners on top of the electrical enclosure.
- 5. Open the air inlet filter housing on the right side of the sterilizer by unlatching the front latch. Remove the filter element. This will allow access to the bottom PLC clip and connectors.
- 6. Carefully remove all connectors. A small, standard screwdriver can help pry the connectors off. Take note of where each connector goes.
- 7. Using a Phillips screwdriver, loosen and remove the four mounting clamps from the slots in the PLC case. There is one clamp underneath the PLC that can be seen by peering through the air inlet opening.
- 8. Pull the old PLC out through the front of the sterilizer.
- Document the serial numbers of the old and new PLCs in the maintenance log (Section 5.1).
- 10. Make sure the gasket is installed on the new PLC and is free from dust and debris.
- 11. Insert the new PLC into the electrical enclosure.
- 12. Insert the four mounting clamps into the slots on the PLC case. One clip should be installed on each corner. To install the bottom clamp, peer through the air inlet filter opening to locate it correctly.
- 13. Lightly tighten each screw so the clip is held in place.
- 14. Tighten the screws on the clamps such that the gasket is compressed against the panel. <u>Do not overtighten the clamps</u> or the PLC housing may crack.
- 15. Reinstall all connectors to the PLC.
- 16. Reinstall the air inlet filter and latch the air inlet closed.
- 17. Connect the incoming power to the sterilizer.
- 18. Turn the sterilizer ON.
- 19. As the PLC boots up, take note of the software version as it flashes on the screen for approximately 2 seconds. If the software version in the newly installed PLC is older than what was noted in Step 1, the software should be updated from the Micro SD card. See Section 8.10 on updating the software.
- 20. Close and fasten the electrical enclosure access panel.
- 21. Reinstall all panels.
- 22. Set all desired settings such as time, date, and UNIT ID on the SETUP screen.
- 23. Navigate to the STATUS screen and verify all inputs are reading correctly.
- 24. See Section 5.4 for post-maintenance activities. FDI recommends completing three consecutive sterilization cycles with biological indicators in the load to verify performance.

### 8.12 Pressure and Temperature Sensor Check

The pressure and temperature sensors should be checked for calibration as required by the operator's standard operating procedures. These sensors are factory set and cannot be adjusted in the field (but can be checked). The pressure and temperature sensors can only be calibrated with an offset by factory-trained personnel. If either sensor is out of the specified accuracy range, it should be replaced.

This procedure requires a calibrated pressure and temperature measurement device.

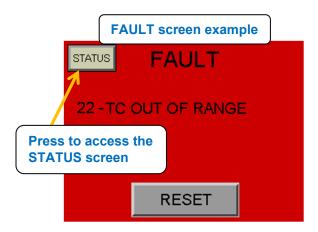
- 1. Turn the sterilizer OFF with the front control power switch.
- 2. Disconnect power from the source, then disconnect the power connector from the rear of the sterilizer.
- 3. Remove the back panel and set aside.
- 4. Locate the chamber service port in the center of the rear of the chamber.
- 5. Use a wrench to remove the service port plug and be careful to remove the gasket as well. Set aside for re-use.
- 6. Connect the calibrated instrument to the service port. The threads are 1/4" X ISO 228/1 straight threads, also known as British Standard Pipe Parallel (BSPP) or "G" threads.
- 7. Connect the sterilizer to power. Turn the sterilizer ON.
- 8. With the calibrated instrument ready, run a CUSTOM cycle at 270°F with a 15-minute exposure and 5-minute dry. The touchscreen controller will be monitored for both pressure and temperature in the next step.
- 9. During the 15-minute exposure, the chamber will equalize. At the start of exposure, start the log on the calibrated instrument device. Additionally, every 30 seconds, manually record a reading of temperature and pressure from the touchscreen display.
- 10. After exposure is complete, the sterilizer can be allowed to finish the cycle.
- 11. Average the manually recorded pressure and temperature readings and compare them to the average logged readings from the calibrated instrument device.
  - a. The temperature difference should be ≤1.8°F
  - b. The pressure difference should  $\leq 1.8$  psi.
  - c. If the accuracy check fails, re-run the procedure to verify the results. Replacement sensors can be sourced from FDI. See Section 5.3 for the replacement parts list.
- 12. Finish the calibration check by turning the sterilizer OFF, disconnecting power, and then following steps a) through e) in reverse order to remove the calibration device and return the sterilizer to its service-ready state.

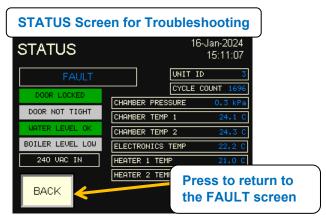
# 9 Troubleshooting

**WARNING:** Service and maintenance work must be performed by qualified

personnel only.

The FAULT screens will display a fault number and title that corresponds to Table 7. This table can be used to diagnose and perform necessary corrective actions to address the fault. A STATUS button is available on FAULT screens to allow maintenance personnel to evaluate sensor data to help troubleshoot the fault.





**Table 7. Faults and Corrective Actions** 

#	Fault	Description	Corrective Action
1	Boiler Water Fill	During boiler filling, boiler water level does not reach level sensor setpoint in <120 sec.	Check that the Chamber Vent is closed (DV-3).  Clean the water filter (F-1) located behind the left side panel.  Check the operation of the Water Pump (P-1) and associated plumbing.  Check the CV-2 Check Valve, located behind the bottom panel.  Check the Boiler and Water Tank Level Sensors (LS-1 and LS-2).
2	Boiler Water Level	Boiler water level is below boiler level sensor for >45 sec during a cycle.	Clean the water filter (F-1) located behind the left side panel.  Check the operation of the Water Pump (P-1) and associated plumbing.

#	Fault	Description	Corrective Action					
			Check the CV-2 Check Valve, located behind the bottom panel.  Check the Boiler Drain Valve (SOLV-1)					
			Check the Boiler and Water Tank Level Sensors (LS-1 and LS-2).					
3	Heaters Overtemperature	One or both boiler heaters exceed normal operating temperature	Allow sterilizer to cool. Navigate to the STATUS screen on the touchscreen controller. Check Heater 1 and 2 temperatures to verify they are reading as expected (e.g., if a cycle was just run, they read about 200-800°F). Replace heaters as needed.  Check Boiler Level Sensor (LS-1) operation by observing the STATUS screen while manually filling the boiler section in the back of the chamber with distilled water. Clean LS-1 or replace as needed if it does not detect the water touching the tip of the sensor.					
4	Low Exposure Temperature	Chamber temperature dropped below setpoint minimum for too long during exposure state (setpoint -3°F).	Check RTD-1&2 by navigating to the STATUS screen and comparing Chamber Temperature 1 to 2. Troubleshoot and replace as needed.  Check for steam leaks.  Check solenoid valves for leaks.  Inspect check valves for leaks.  Have a qualified maintenance technician verify the heaters (H-1&2) and heater control relay (SSR-H1) are working correctly.					
5	High Exposure Temperature	Chamber temperature exceeded maximum setpoint during exposure state (setpoint +3°F).	Check RTD-1&2 by navigating to the STATUS screen and comparing Chamber Temperature 1 to 2. Troubleshoot and replace as needed.  Have a qualified maintenance					

#	Fault	Description	Corrective Action					
			technician verify the heaters (H- 1&2) and heater control relay (SSR-H1) are working correctly.					
			Excessive electromagnetic interference. Relocate sterilizer if possible.					
6	Chamber Pressure High	High chamber pressure fault (>52.5 psia or >43.5 psig).	Check RTD-1&2 by navigating to the STATUS screen and comparing Chamber Temperature 1 to 2. Troubleshoot and replace as needed.  Have a qualified maintenance technician verify the heaters (H-1&2) and heater control relay (SSR-H1) are working correctly.					
7	Chamber Overtemperature	High chamber temperature alarm (>295°F).	Check RTD-1&2 by navigating to the STATUS screen and comparing Chamber Temperature 1 to 2. Troubleshoot and replace as needed.  Have a qualified maintenance technician verify the heaters (H-1&2) and heater control relay (SSR-H1) are working correctly.					
8	Exhaust Time Long	Watchdog timer monitoring each exhaust stage during Conditioning. (>5 min)	Check and clean the chamber drain screen (hand tight only).  Check the Chamber Drain Valve (SOLV-2) and Boiler Drain Valve (SOLV-1).  Heat exchanger could be clogged. Check operation by navigating to SETUP and performing the WATER RESET. Air pressure should increase and then be vented through heat exchanger if it is working correctly.					
9	Pulse Time Long	Pressure pulse watchdog timeout monitoring conditioning phase. (>10 min for boiler warmup and >20 min for Pressure Pulse 1 through 5).	Check for chamber steam leaks.  Check the wiring in the electrical enclosure. Is anything disconnected? Is anything loose?  Check solenoid valves for leaks.					

#	Fault	Description	Corrective Action					
			Have a qualified maintenance technician verify the heaters (H-1&2) and heater control relay (SSR-H1) are working correctly.					
10	Exposure Time Long	Heat up, stabilizing, and exposure watchdog timer (2*Exposure Timer + 20 min).	Check RTD-1&2 by navigating to the STATUS screen and comparing Chamber Temperature 1 to 2. Troubleshoot and replace as needed.  Check for chamber steam leaks.  Check the Chamber Drain Valve (SOLV-2).  Have a qualified maintenance technician verify the heaters (H-1&2) and heater control relay (SSR-H1) are working correctly.					
11	Vent Time Long	The chamber took too long to vent after exposure (>5 min).	Check and clean the chamber drain screen.  Check the Chamber Drain Valve (SOLV-2) and Boiler Drain Valve (SOLV-1).  Heat exchanger could be clogged. Check operation by navigating to SETUP and performing the WATER RESET. Air pressure should rise and then be vented through heat exchanger if it is working correctly.					
12	Drying Pressure Low	The sterilizer did not reach the expected chamber pressure during drying. (<0.4 psig)	Check that the HEPA Filter (F-2) is not clogged.  Check that the Air Pump (P-2) is working correctly.  Check for chamber leaks.  Check Boiler and Chamber Drain Valve (SOLV-1 and 2).  Check Air In Valve (SOLV-3).  Check the manual valves at the back of the sterilizer.					

#	Fault	Description	Corrective Action					
			Inspect the check valves for leaks.					
13	Drying Pressure High	The sterilizer exceeded expected chamber pressure during drying. (>7.5 psig)	Check the Air Out Valve (SOLV-4) and associated plumbing.  Heat exchanger could be clogged. Check operation by navigating to SETUP and performing the WATER RESET. Air pressure should increase and then be vented through heat exchanger if it is working correctly.					
14	DC Breaker Trip	10 AMP DC Breaker has tripped inside the electrical enclosure.	First, reset breaker on relay PCB. Then diagnose the root cause by checking the following: (1) the HEPA Filter (F-2) is not clogged and (2) Air In Valve (SOLV-3) and (3) Air Out Valve (SOLV-4) to verify they are working correctly.  If the problem persists, check all DC components (e.g., fans, pumps, and valves) to determine which component is tripping the breaker.					
15	Door Opened	Door Safety sensor opened during a sterilization cycle.	Verify the chamber door was tightened completely before starting the cycle.  Check tightness of door sensor hardware (e.g., mounting bracket, strike plate).  Troubleshoot and adjust door tight sensor (DS-1) per Section 8.4					
16	Sterility Assurance	Exposure measured vs. theoretical temperature (calculated from pressure transmitter) comparison requirement out of range (>3.6°F or 2°C). Cycle aborts automatically.	Attempt to run three consecutive sterilization cycles with biological indicators in the load.  Was the chamber overloaded?  Is the chamber level?  If the problem persists, replace the Chamber Temperature Sensor (RTD-1&2) or Chamber Pressure Sensor (PT-1).					

#	Fault	Description	Corrective Action			
17	RTD Deviation	Chamber temperature sensor contains a 2nd sensing element to check the control sensor. Readings differed by more than	Inspect the RTD wire connectors to the PLC. These are the red and white three-wire connections to the bottom of the PLC. Is anything loose?  Check RTD-1&2 by navigating to			
		1.8°F (1°C) during the exposure time.	the STATUS screen and comparing Chamber Temperature 1 to 2. Troubleshoot and replace as needed.			
			Inspect the thermocouple wiring and yellow connectors. Is anything damaged or loose?			
18	T/C Deviation	Heater 1 temperature sensor T/C is compared to Heater 2 T/C. Readings differed by >250°F.	These sensors are mounted inside the heaters. Check Heater 1&2 temperatures readings by navigating to the STATUS screen. Troubleshoot and replace as needed.			
			Check the resistance of the heaters with a multi-meter. The nominal resistance is $8.73~\Omega$ . The tolerance for resistance is $7.46-9.70~\Omega$ .			
19	Pressure Sensor Input Low	Chamber pressure sensor input is <1.0 psia.	Remove the right-side panel and inspect the Chamber Pressure Sensor (PT-1), wiring, and connectors.  Troubleshoot and replace the			
			Chamber Pressure Sensor (PT-1) as needed.			
20	Pressure Sensor Input High	Chamber pressure sensor input is >59.0 psia.	Remove the right-side panel and inspect the Chamber Pressure Sensor (PT-1), wiring, and connectors.			
		pola.	Troubleshoot and replace the Chamber Pressure Sensor (PT-1) as needed.			

#	Fault	Description	Corrective Action					
21	RTD Out of Range	RTD reading is <15°F.	Ensure ambient temperature > 35°F (1.7°C).  Remove the right-side panel and inspect RTD-1&2 wiring for loose wires, physical damage, disconnections, etc.  Remove the top panel and electrical enclosure and inspect the electronics enclosure RTD-3. Troubleshoot and replace as needed.					
22	T/C Out of Range	T/C sensor reading is <15°F.	Ensure the ambient temperature > 35°F (1.7°C).  Remove the right-side panel and inspect for a disconnected yellow T/C connector from the heaters to the electrical enclosure. Is anything loose or disconnected?  These sensors are mounted inside the heaters. Check Heater 1&2 temperatures readings by navigating to the STATUS screen. Troubleshoot and replace as needed.					
23	Electronics Overtemperature	Temperature in the electrical enclosure is >160°F.	Remove the top panel and open the electrical enclosure to allow it to cool. Inspect the electrical enclosure.  Check the electrical enclosure air filter behind the right-side panel and clean as needed.  Check that the electrical enclosure inlet/outlet is unobstructed.  Check ambient conditions. Max operating temperature is 130°F.  If problem persists, replace the electrical enclosure temperature sensor (RTD-3).					

#	Fault	Description	Corrective Action
24	Steam Flush Pressure High	Chamber pressure rises above (>7.5 psig low voltage, >10 psig high voltage) during steam the flush	Check and clean the chamber drain screen (hand tight only).  Check the Chamber Drain Valve (SOLV-2).  Heat exchanger could be clogged. Check operation by navigating to SETUP and performing the WATER RESET. Air pressure should increase and then be vented through heat exchanger if it is working correctly.
25	Door Unlocked	PLC detected that door was unlocked during a sterilization cycle. Cycle will be aborted, and chamber vented.	Was the door manually unlocked or tightened during a cycle?  Inspect and clean the door lock mechanism as necessary.  NOTE: Take careful note of small parts when disassembling the door lock mechanism.  Check the door lock proximity sensor for operation and calibration using Section 8.4.
26	Door Interlock	Door interlock cannot be verified "unlocked" by PLC on startup. Interlock mechanism could be jammed.	NOTE: Take careful note of small parts when disassembling the door lock mechanism.  Check the: (1) door lock mechanism for operation and clean as necessary. (2) door solenoid and clean or replace as necessary. (3) door lock proximity sensor for calibration using Section 8.4 (4) door electrical cable for damage

# **APPENDIX**

A.1 Logbook Example

	Comments									
	Biological Indicators (+/-)									
	Indicator Color Change (Y/N)									
Location:	Min Press.									
	Max Press.									
	Min Temp.									
Unit ID:	Max Temp.									
	Exposure Time									
	Cycle Time									
Month/Year:	Date (dd/mm/yy)									

### A.2 Limited Warranty

Fort Defiance Industries LLC ("FDI") warrants to the original retail purchaser that it will repair or replace components of the FRONT-LINE Field Sterilizer (FL120 or FL135) manufactured by FDI (except for components not warranted under "Exclusions") that are defective in material or workmanship under normal use and service. FDI's obligation under this warranty is limited to the repair or replacement, at FDI's option, of the applicable components.

In cases where return for repair of the FRONT-LINE Field Sterilizer is not practical, FDI may, at its sole discretion, authorize in writing repair of the unit by trained and qualified technicians. In such circumstances, FDI will furnish at the place of delivery the material or parts, and the instructions required to successfully accomplish the repair.

This limited warranty shall only apply to defects that are reported to FDI within the applicable warranty period and which, upon assessment by FDI, prove to be defective. This warranty extends only to the first retail purchaser of a FRONT-LINE Field Sterilizer and is not transferable or assignable.

This warranty shall not limit the Customer's rights under any inspection clauses in relation to latent defects, fraud, or gross mistakes that amount to fraud. This warranty applies notwithstanding inspection and acceptance or other clauses or terms of this contract.

#### APPLICABLE WARRANTY PERIOD

The applicable warranty period measured from the date of delivery to the original purchaser (whether wholesale/resale or retail) shall be three (3) years. The stainless-steel sterilization chamber is warranted for ten (10) years.

#### **OBTAINING WARRANTY SERVICE**

FDI may be contacted for warranty service inquiries or issues via phone at 865-408-0100 or by email at techsupport@fortdefianceind.com.

#### **EXCLUSIONS**

This warranty does not cover, and FDI shall not be liable for, the following:

- 1. Defects, damage or other conditions caused, in whole or in part, by misuse, abuse, negligence, tampering, alteration, accident, damage during transport, or failure to seek and obtain repair or replacement in a timely manner;
- 2. FRONT-LINE Field Sterilizers which are not installed, qualified, used, and properly cleaned and maintained as specified in the FRONT-LINE "Technical Manual";
- 3. Components considered to be of a consumable nature (e.g., O-rings, filters) or components that will require replacement per the service and preventive maintenance schedule/procedures;
- 4. Parts and accessories not purchased from FDI, nor product failure or damage associated with parts not purchased from FDI;
- Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing in advance by FDI;
- 6. Costs and expenses of routine maintenance and cleaning; and
- 7. Representations and warranties made by any person or entity other than FDI.

#### EXCLUSIVE REMEDY; CONSEQUENTIAL DAMAGES DISCLAIMER

FDI'S ONLY OBLIGATION UNDER THIS WARRANTY IS THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS. FDI SHALL NOT BE LIABLE FOR AND HEREBY DISCLAIMS ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OR DELAYS, INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS OR INCOME, LOSS OF USE, DOWNTIME, COVERAGE OF AN EMPLOYEE OR INDEPENDENT CONTRACTOR WAGES, PAYMENTS AND BENEFITS.

#### WARRANTY DISCLAIMER

THIS WARRANTY IS FDI'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. FDI MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS. ANY LIABILITY IS EXPRESSLY LIMITED TO AN AMOUNT EQUAL TO THE PURCHASE PRICE PAID, AND ALL CLAIMS FOR SPECIAL, INCIDENTAL AND CONSEQUENTIAL DAMAGES ARE HEREBY EXCLUDED. SOME STATES OR COUNTRIES DO NOT ALLOW EXCLUSIONS OF INCIDENTAL OR CONSEQUENTIAL DAMAGES AND/OR LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE EXCLUSIONS AND LIMITATIONS MAY NOT APPLY TO YOU. THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS THAT VARY FROM STATE TO STATE OR COUNTRY TO COUNTRY.

#### STATUTE OF LIMITATIONS

No action may be brought against FDI for breach of this limited warranty, an implied warranty, if any, or for any other claim arising out of or relating to the FRONT-LINE Field Sterilizer, more than ninety (90) days following expiration of the limited warranty period.