
Operating Manual

"Mark II"

Solid-State Digital Automatic
Controlled Sterilizers



Consolidated Stills & Sterilizers

Rev. 070129

**PLEASE READ CAREFULLY BEFORE
ATTEMPTING TO OPERATE YOUR STERILIZER.**

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1. Introduction

The fully automatic Consolidated SSR and SR series of sterilizers are intended for use by facilities to sterilize heat and moisture stable materials by means of pressurized steam. These sterilizers are available in several different chamber sizes.

The Mark II control system continuously monitors and visually displays the relevant temperature and pressures in the sterilizer. It also automatically initiates and controls each phase of the sterilization cycle -- condition, sterilize, and exhaust -- for greater assurance of sterilization.

Our sterilizers can either be supplied for connection to direct building steam supply of 50-80 PSI of pressure, or come equipped with an integral, electrically heated steam generator. The Mark II controls are identical for both types.

Consolidated sterilizers have been on the market since 1948 and enjoy an excellent reputation for quality and reliability. One of our design goals is to use off-the-shelf components on our machines whenever possible to minimize down time and service costs to our valued customers. Most of the solenoids, valves, and steam-traps used in our machines are available from your local service representative.

Many optional items, such as automatic jacket and generator blow-down are available with the Mark II control system. Specialized sterilization cycles, such as low-temperature sterilization are also available.

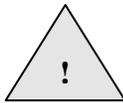
1.1 Safety Instructions

The following safety instructions appear in this manual. Please read them carefully before operating the sterilizer.

WARNING

If this sterilizer's chamber is constructed of Stainless Steel, **NEVER** use **CHLORIDE** based cleaners to clean this sterilizer. **NEVER** sterilize items containing **CHLORIDES** or producing **CHLORIDE GASES** in this sterilizer. **CHLORIDES** have proven to damage the Stainless Steel material **causing cracks and pin holes**, which will lead to steam leaks.

1.1.1 Aborting a Cycle

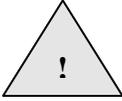


WARNING: RISK OF NON-STERILE DEVICE

Please note that if a cycle is aborted prior to successful termination, it must be considered incomplete and the load must be reprocessed (unwrapped goods or liquids) or repacked and reprocessed (wrapped goods).

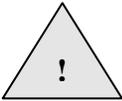
To abort a cycle in progress, press the red **POWER** key on the keypad assembly. This will shut off power to the unit. You will then need to open the green-handled manual exhaust valve (labeled Manual Steam Exhaust Valve) visible by removing the access panel below the chamber door. Wait for the pressure inside the chamber to reach atmosphere before carefully opening the door.

1.1.2 Starting a Cycle

	WARNING: BURN HAZARD
The operator MUST wear protective clothing including face shield, thermal gloves, and proper lab attire, when attempting to load and unload the chamber materials.	
Steam released from the sterilizer chamber can cause serious burns. Stand away while opening the door.	
If water leaks from the front of the sterilizer, DO NOT open the door . Contact service personnel.	

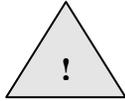
To start a cycle, make sure the door is hand-tight. Press the appropriate selector switch for the type of cycle you are running (Fast, Dry, or Fluids), then press the red power button on the selector switch to start the cycle. See section 6 for a complete tutorial before you start operating the machine.

1.1.3 Preparing the Load

	WARNING: RISK OF INFECTION
Please note that airborne microbial and particulate contamination is likely to be high in the decontamination area of the sterile processing department. Users MUST wear protective clothing and equipment when preparing goods for sterilization or when in the decontamination area.	

Please see section 7.2 on load preparation before you start operating the machine.

1.1.4 Sterilizing Fluids



WARNING: INJURY HAZARD

If the wrong cycle is selected to sterilize liquids, the containers may burst or crack during the processing.

After completion of a FLUIDS cycle, take care that you do not agitate the fluids during removal from the chamber. Otherwise the containers may burst or crack.

2. Overview of the Mark II Controller

The Mark II is a simple, easy-to-operate sterilizer control system. It allows selection of sterilizer cycles, setting of temperature, and times for Sterilization and Dry. It displays status of the machine in sterilize or exhaust modes, executes selected cycles, and prints a chart of sterilizer temperature vs. time. Figure 2.1 shows a typical Mark II controller with a chart recorder.

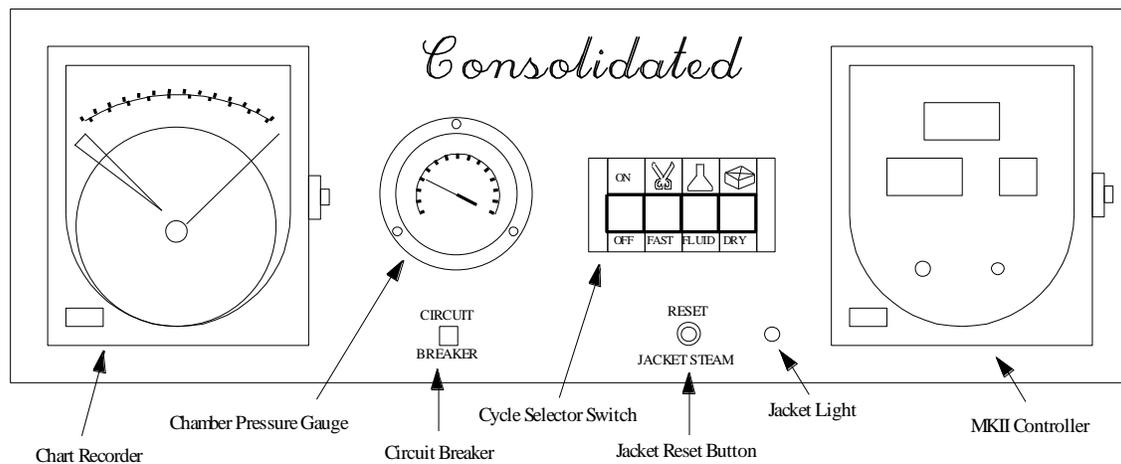


Figure 2.1 The Mark II Controller & Chart Recorder

2.1 Description

The Mark II controller was designed with simplicity of operation in mind. The controller allows setting of sterilization time and dry time (for a Dry cycle only). LEDs on the controller show when the machine is in the sterilize mode and when it is in the exhaust mode. A selector switch (see Figure 2.1) allows user to select one of three types of cycles: Fast, Fluid, & Dry. A pressure gauge shows the current steam pressure inside the chamber of the sterilizer. A chart recorder records a graph of time vs. temperature during the cycle. For Low-Temp equipped sterilizers, please see section 4.3.

2.2 Chamber Pressure Gauge

The chamber pressure gauge shows the steam pressure in the chamber at all times. Make sure this gauge registers zero before you attempt to open the door.

2.3 Circuit Breaker

The circuit breaker's purpose is to protect the electronics. If the circuit breaker cuts off the power to the sterilizer, a qualified technician needs to troubleshoot the source of the problem before resetting it.

2.4 Cycle Selector Switch

You can choose the type of cycle you want to run with the cycle selector switch. The cycle selector switch also acts as the ON/OFF button for the sterilizer. See section 3 on Selector Switch operation.

2.5 Jacket Reset Button and Light

When the green Jacket Light (see Figure 2.1) comes on, you need to press the Jacket Reset Button and wait for the jacket pressure to build up before you can start a new cycle.

2.6 MKII Controller

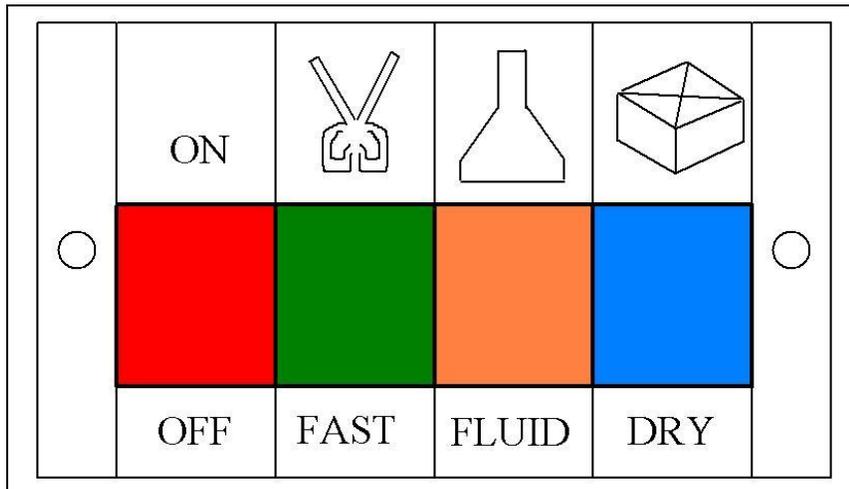
You can set the sterilizer and exhaust (in case of a Dry cycle) time and view the remaining time on the MKII controller. See section 4 for more information.

2.7 Chart Recorder

The chart recorder offers a chart of time vs. temperature for your sterilization cycle. You can also set the temperature for your sterilization cycle on the chart recorder. See section 5 for more information.

3. Cycle Selector Switch Operation

The cycle selector switch is used to select the type of cycle to run and to start a cycle. The cycle selector switch is located on the front of the sterilizer near the controller (See Figure 2.1). The cycle selector switch is depicted in Figure 3.1 below. For Low-Temp equipped sterilizers, please see section 4.3.



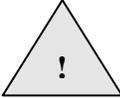
3.1 ON/OFF

With the ON/OFF switch in the OFF position, select the type of cycle you want to run by pressing the FAST, FLUID, or DRY button as in Figure 3.1 above. After you have chosen which type of cycle you want to run, depress the ON/OFF switch to start a cycle.

3.2 FAST

Choose a FAST cycle if you are sterilizing instruments or other items that do not require a drying phase or are not liquids. At the conclusion of the sterilization phase of the FAST cycle, the steam pressure in the chamber will be reduced to atmosphere as quickly as possible and the end-of-cycle buzzer will sound.

3.3 FLUID

	WARNING!
Sterilized liquids are not intended for direct patient contact.	

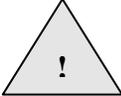
Choose a FLUID cycle if you are sterilizing liquids or media. At the conclusion of the sterilization phase of the FLUID cycle, the steam pressure in the chamber will be reduced to atmosphere very slowly in order to minimize boil-over. When the chamber pressure reaches atmosphere, the end-of-cycle buzzer will sound.

Liquid Quantity (mL)	Time Setting (Minutes)
75	25
250	30
500	40
1000	45
1500	50
2000	55

Minimum Recommended Exposure Times at 250°F (121°C) for
Liquids (Solutions, Water, Media, etc.)

Note:

1. These are suggested minimum exposure times. Additional time may be required if flasks are placed in plastic container.
2. Utilize smaller volumes whenever possible. Larger volumes of liquid will take longer to come up to temperature.

	WARNING: INJURY HAZARD
If the wrong cycle is selected to sterilize liquids, the containers may burst or crack during the processing.	
After completion of a FLUIDS cycle, take care that you do not agitate the fluids during removal from the chamber. Otherwise the containers may burst or crack.	

3.4 DRY

Choose a DRY cycle if you are sterilizing packs, instruments, or other items that require a drying phase. At the conclusion of the sterilization phase of the DRY cycle, the steam pressure in the chamber will be reduced to atmosphere as quickly as possible, then the end-of-cycle buzzer will sound after the required number of minutes in DRY time.

4. MKII Controller

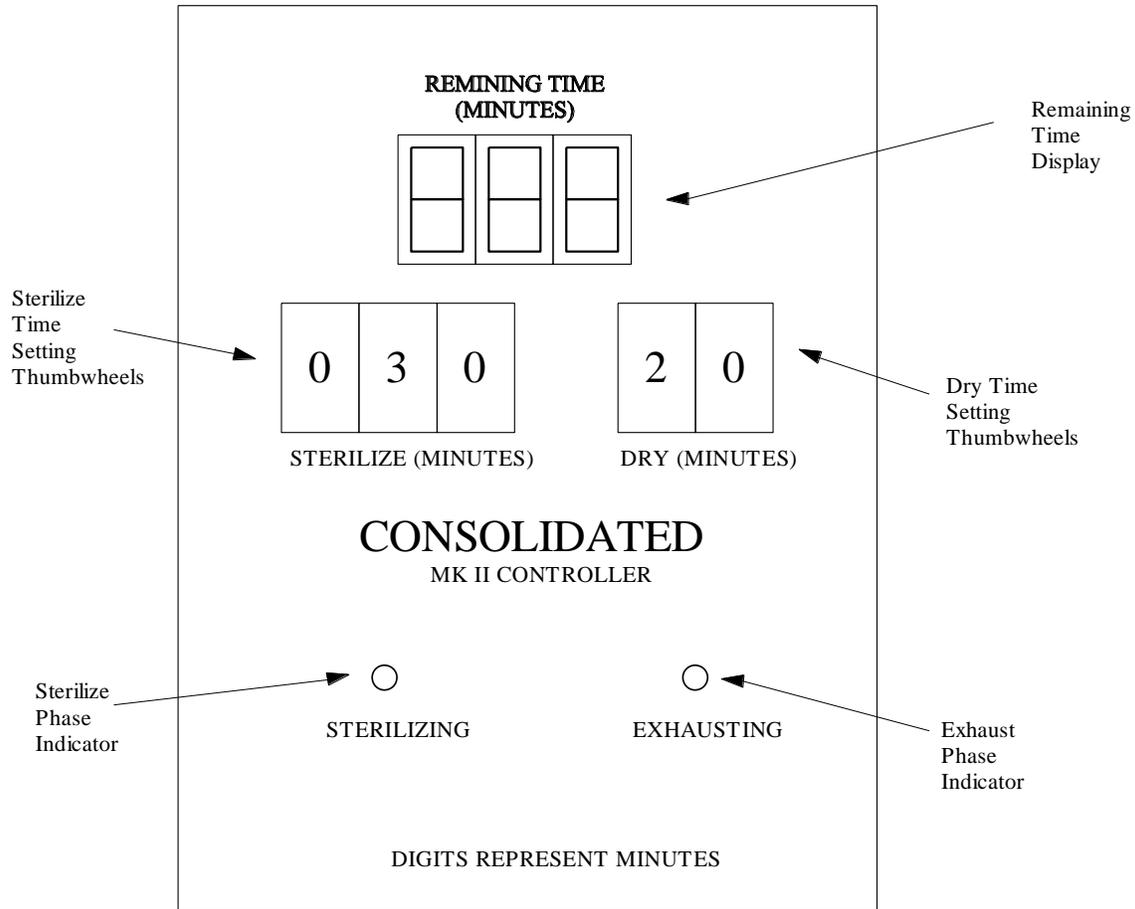


Figure 4.1
MK II Controller Face Plate

The MK II controller allows you to set the Sterilize and Dry times (if necessary). It uses two LED lights to indicate if the cycle is in the Sterilize or Exhaust phase. Using the thumbwheels on the top of the controller, set your Sterilize and Dry times in minutes. Then select FAST, DRY, or FLUID exhaust phases using the selector switches (See section 3). Once the sterilizer reaches the set sterilization temperature, the sterilize light will come on and stay on for the duration of the set Sterilize Time period. If the temperature inside the chamber goes below your Sterilization Temperature set point, the controller will re-start the sterilization phase. After a successful sterilization phase, the Exhaust indicator light will come on and stay on for the duration of the Exhaust phase of the cycle. At the end of the Exhaust phase, the buzzer will sound. You may now open the sterilizer door after checking the pressure gauge to make sure that the pressure has reached zero atmospheres inside the chamber. For Low-Temp equipped sterilizers, please see section 4.3.

4.1 Setting Sterilization Time

Turn the Sterilize Time Setting thumbwheels (see Figure 4.1) to the desired number of minutes for your sterilization phase.

Note that if the selected cycle on the cycle selector switch (see Figure 3.1) is FAST or FLUID, the controller will ignore the time set on the Dry Time Setting thumbwheels (see Figure 4.1).

4.2 Setting Dry Time

Turn the Dry Time Setting thumbwheels (see Figure 4.1) to the desired number of minutes for the Dry phase.

Note that the Dry Time is only in effect if the selected cycle on the cycle selector switch (see Figure 3.1) is DRY. At the end of the exhaust phase of the cycle, the controller will wait this many minutes before it sounds the end-of cycle buzzer.

5. Chart Recorder & Controller

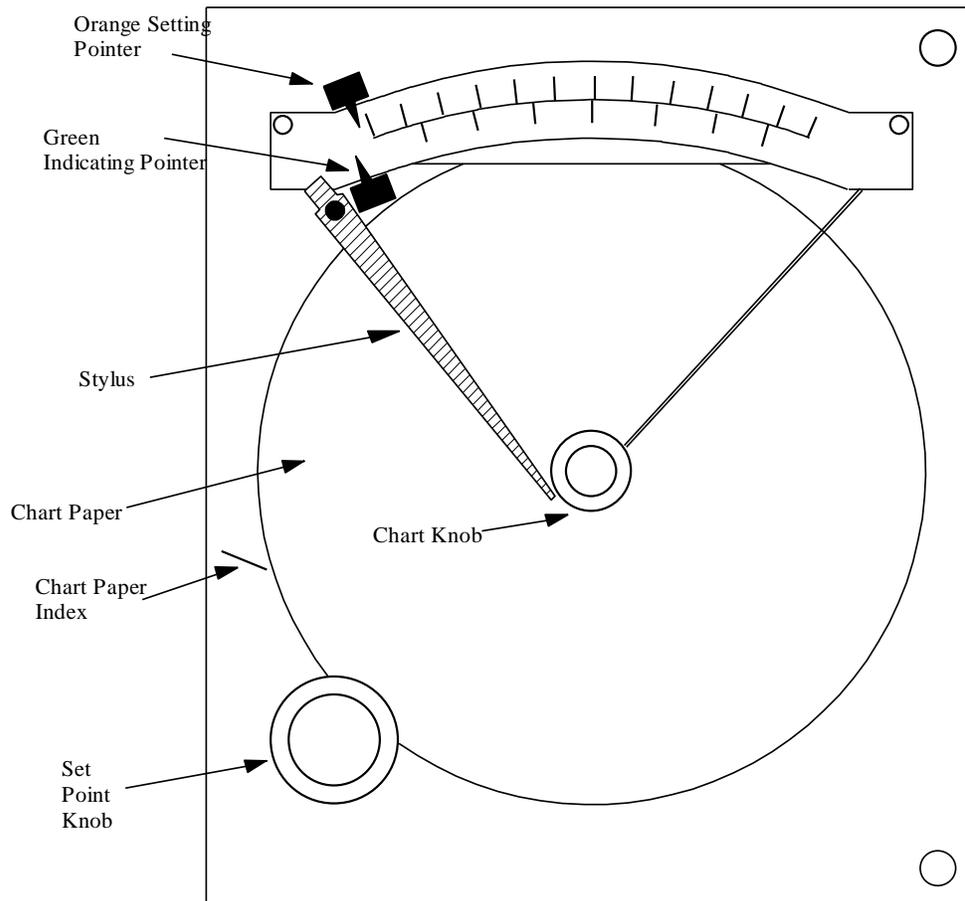
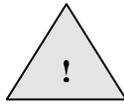


Figure 5.1
Chart Recorder/Controller

The chart recorder (see Figure 5.1) records a chart of time vs. sterilization temperature. It also allows you to set the sterilization temperature.



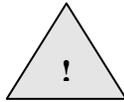
WARNING: Damage to the Chart Recorder

The Chart Recorder/Controller's Green Indicating Pointer and Orange Set Pointer (see Figure 5.1) must not be manipulated by hand or any tools in an attempt to swing them up or down the scale. This can result in serious damage to the recorder's linkage. This damage is **not** covered under your sterilizer's warranty.

5.1 Setting Sterilization Temperature

Use the set-point knob (see Figure 5.1) to set the sterilization temperature.

5.2 Changing Chart Recorder Paper



WARNING: Damage to the Chart Recorder

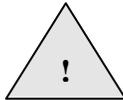
The Chart Recorder/Controller should never operate without chart paper. This will damage the stylus' sapphire tip (see Figure 5.1). This damage is **not** covered under your sterilizer's warranty.

To remove the old chart, unscrew the chart knob (see Figure 5.1) and swing the chart knob arm counter-clockwise out of the way. Raise the stylus pen by pressing on the tab at the uppermost end of the arm. List the old Chart forward off the hub and slide down and away. Do not release the stylus pen arm. Install the new chart paper. Align the proper chart time with the chart plate index (see Figure 5.1).

6. Operating Instructions Tutorial

THIS IS A TUTORIAL FOR THE FIRST OPERATION. FOLLOWING THE STEPS IN THIS SECTION WILL HELP THE OPERATOR BECOME FAMILIAR WITH RUNNING THE MACHINE.

6.1 Direct Steam Sterilizers



WARNING: BURN HAZARD

The operator **MUST** wear protective clothing including face shield, thermal gloves, and proper lab attire, when attempting to load and unload the chamber materials.

Steam released from the sterilizer chamber can cause serious burns. Stand away while opening the door.

If water leaks from the front of the sterilizer, **DO NOT open the door**. Contact service personnel.

To start your sterilizer:

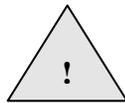
Note: If your sterilizer is equipped with Low-Temp cycle, please read section 4.3 before you proceed.

1. Check with proper installation and maintenance personnel to make sure that:
 - A) building steam supply of 45-80 PSI is piped and connected to the sterilizer
 - B) steam return line is piped and connected to the sterilizer
 - C) the 110 volt supply cord to the machine is plugged in
2. Make sure that the sterilizer chamber as well as the chamber drain strainer (inside the drain hole near the sterilizer door) is free of any debris. **THIS SHOULD BE DONE BEFORE EVERY CYCLE, EVERY DAY. A CLEAN DRAIN STRAINER IS ESSENTIAL FOR SMOOTH OPERATION OF THE MACHINE.**
3. Check to make sure that the ON/OFF key on the cycle selector switch (see Figure 3.1) is in the OFF position. Load sterilizer chamber (optional for this test run) and close the door. **MAKE SURE THE DOOR HANDLES ARE HAND TIGHT. IT IS THE OPERATOR'S RESPONSIBILITY TO ENSURE THAT THE DOOR HANDLES ARE TIGHTENED SECURELY BEFORE STARTING A CYCLE.**

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4. Check to make sure the chart recorder (see Figure 2.1) is set to the correct sterilization temperature. Check to make sure the correct sterilization and dry (if applicable) times are on the MK II controller (see Figure 2.1). Select the correct cycle by pressing the appropriate button on the cycle selector switch (see Figure 3.1). If you have a double-door unit, there are warning lights on both ends of the unit that are ON when either door is open. Make sure both doors are securely tightened before attempting to run the machine. Otherwise, the control system will not allow a cycle to begin.
 5. Press the ON/OFF button on the cycle selector switch to start the cycle.

The sterilizer will start the cycle. The chart recorder will record the chamber temperature vs. time throughout the cycle. At the end of the cycle, a buzzer will sound. Make sure the Chamber pressure gauge reads zero PSI, and then turn off the ON/OFF switch. After that, opening the door will terminate the cycle and reset the machine for next operation.

To abort a cycle in progress, turn OFF the red ON/OFF button on the cycle selector switch (see Figure 3.1). Reach underneath the chamber and open the green-handled Manual Exhaust valve, located below the sterilizer chamber next to the drain piping, to release the steam pressure inside the chamber. Wait till the chamber steam gauge reads zero PSI before attempting to open the sterilizer door.



WARNING: RISK OF NON-STERILE DEVICE

Please note that if a cycle is aborted prior to successful termination, it must be considered incomplete and the load must be reprocessed (unwrapped goods or liquids) or repacked and reprocessed (wrapped goods).

6.3 Sterilizers with Automatic Jacket Blow-down

If your sterilizer is equipped with Auto Jacket Blow-down, then during the exhaust phase of the Fluid cycle the sterilizer allows the jacket and chamber to cool at the same time. The steam supply is shut off to the sterilizer's jacket and the jacket exhaust relay is energized.

The above process occurs automatically every time you run a Fluid cycle with your machine. Because of this, you need to reset the Jacket pressure by pressing the Jacket Reset Button (see figure 2.1) after you run a Fluid cycle in order to allow the steam pressure to build back up in the Jacket. The green Jacket Light (see figure 2.1) will be on to indicate that the red Reset Jacket Button needs to be pressed in order to pressurize the Jacket for your next cycle.

6.4 Double Door Sterilizers

If your double-door sterilizer is equipped with Alarm Warning System, a loud siren and a flashing warning light will warn users of cross contamination danger. If the DOOR OPEN indicator light above the door is ON and the door on your side of the sterilizer is closed, it means that the door at the opposite end is open – **DO NOT OPEN DOOR**. If you attempt to open the door, the Alarm Warning System will initiate both flashing lights and a loud siren. This can be triggered by just a few turns of the door handle.

If the door at the “dirty” (or “load”) end of the sterilizer is opened, thus contaminating the chamber, the Alarm Warning System will flash at the unload/clean end of the sterilizer. This light will flash until a sterilization cycle is initiated.

In order for the sterilization cycle to begin, both doors must be closed and locked. Sterilizer will not operate with either door open.

	PLEASE NOTE:
When the Controls are initially powered up, the Alarm Warning System will sound for a few seconds. This is normal.	

6.4.1 Double Door Sterilizers with Remote Start

If a double door sterilizer is equipped with a Remote Start button, there is a switch (labeled “Remote Start”) on the non-control end that will start the sterilizer, if one of the buttons Fast, Fluid, or Dry is pushed on the cycle selector switch (see figure 2.1 & 3.1). If a cycle has not been selected on the cycle selector switch, then you will hear the buzzer when trying to start the sterilizer.

When the “Power On” light at either end of the sterilizer is ON, a cycle has been initiated from one end of the sterilizer.

6.5 Sterilizers with Post-Vac System

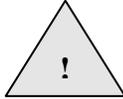
If your sterilizer is equipped with a Post-Vac system, then during the exhaust phase of both the Fast and Dry cycles a vacuum will be drawn.

Following cycle completion of a Fast cycle, the buzzer will sound and the chamber will draw down to a 28" vacuum and hold until either the "On-Off" switch is pressed or the door is opened.

Following the Dry cycle, the chamber will draw down to a 28" vacuum. This vacuum will be held for the amount of time set on the Dry Timer. After the Dry Timer counts down to zero, the end of cycle buzzer will sound. At this point, press the "On-Off" switch to release the vacuum. Before attempting to open door, wait a few minutes to give chamber enough time to release the vacuum and return to atmospheric pressure. You can observe the chamber pressure on the chamber pressure gauge.

7. Load Preparation

Clean, package and load items according to established procedures for your facility. Refer to AAMI Standard ST46 Good Hospital Practice: Steam Sterilization and Sterility Assurance.



WARNING: RISK OF INFECTION

Please note that airborne microbial and particulate contamination is likely to be high in the decontamination area of the sterile processing department. Users **MUST** wear protective clothing and equipment when preparing goods for sterilization or when in the decontamination area.

- All packages must be positioned in the chamber to allow free circulation and penetration of steam, enhance air elimination, and prevent entrapment of air or water.
- Items capable of holding water, such as basins and trays, should be oriented in the same direction and arranged so that any condensation will drain out. Wicking material should be used to absorb condensate.
- Large or heavy metal items should be placed on the lowest shelf to enable the condensate to drain out without wetting any other items in the load.
- When using non-woven wrap, ensure there are no low spots that might hold condensate.
- Instruments, such as forceps, must be sterilized in the open position.