

Sterilemax Table Top Steam Sterilizer

Operation Manual Series 1277

Model Numbers ST75925 ST75920-33 Voltage 120V 220V

LT1277X1 • 5/23/07

Serial Number_

Sterilemax Table Top Sterilizer

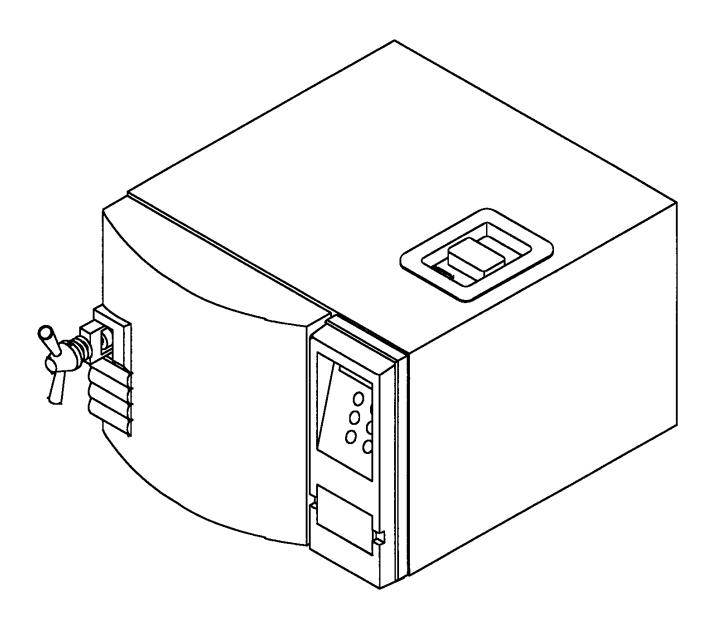


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Introduction



Warning

Do not use this equipment for any purpose other than its intended use, described in this manual.

Do not use the sterilizer to process volatile substances or materials which could release toxic or explosive substances.

This Thermo Scientific Sterilemax Table Top steam sterilizer has been designed for use in medical and dental offices, university laboratories, clinics, hospitals and other locations where a variety of materials require sterilizing.

Your sterilizer can be used for wrapped or unwrapped instruments, packs, liquids, test tubes, petri dishes and media.

The optional Impact printer provides a permanent record of actual exposure times and temperatures.

General Usage
Do not use this equipment for any purpose other than its intended use, described in this manual.

Safety Information

Alert Signals



Warning

Warnings alert you to a possibility of personal injury.



Caution

Cautions alert you to a possibility of damage to the equipment.



Note

Notes alert you to pertinent facts and conditions.



Hot Surface

Hot surfaces alert you to a possibility of personal injury if you come in contact with a surface during use or for a period of time after use.



Consult Instructions for Use

This symbol appears on the product to refer you to the instruction manual for further information.

Warnings

- 1. Do not use this equipment for any purpose other than its intended use, described in this manual.
- Use only self-venting, automatic sealing stoppers when processing liquids or media. Use of other stoppers or seals, or lack of stoppers, will create the possibility of burns or injury from boiling liquids and exploding flasks.
- 3. Refer servicing to qualified personnel.
- Use caution when opening the sterilizer door. Stand to the side behind the door and open door slowly and partially to protect yourself from escaping steam or boiling liquids and exploding flasks.
- Sterilizer and trays will be hot after cycle is run.
 Always wear protective gloves and apron when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.
- 6. Do not attempt to open sterilizer door until the display reads "Cycle Complete". Pressure within the chamber could cause the door to open with extreme force, possibly causing personal injury.
- Ensure that the sterilizer is cool before cleaning to avoid burns.
- 8. Pressurized steam will be discharged when the relief valve is opened. To prevent burns, place a steam barrier (such as a rolled towel) around the opening in the back of the unit. To prevent burns, wear gloves or use an extension device if it becomes necessary to operate the pull ring.

SAFETY INFORMATION

- Do not use the sterilizer to process volatile substances or materials which could release toxic or explosive substances.
- 10. Connect only to an electrical circuit of the appropriate voltage and load rating.
- Do not overfill reservoir. To avoid slippery conditions and possible load recontamination, immediately wipe up all spillage resulting from overfilling chamber or reservoir.
- 12. Do not add water to reservoir while a sterilization cycle is in process. When the cycle ends and steam vents back into the reservoir, a sudden overflow of hot water could occur, possibly resulting in burns to personnel.
- To prevent collection of mineral deposits and corrosion of chamber components, use distilled or low quality deionized water only. Clean chamber after each use if sterilizing saline solutions.
- 14. Processing goods at less than recommended time/temperature could result in unsterile goods.
- Reprocess your load when the sterilizing cycle has been terminated prematurely. The load may not be sterile when the sterilizing cycle has been terminated prematurely.
- 16. Open door slowly at the end of a liquid sterilization cycle. Do not allow hot bottles to be jolted. This can cause bottle explosions. Do not move bottles if any boiling or bubbling is present.
- 17. Allow bottles to cool before attempting to move them from sterilizer shelf or tray(s) to the storage area.
- If media is processed, bottles and tubes should contain no more than 3/4 the total volume of the container. When processing water bottles and test

SAFETY INFORMATION

tubes, the bottles and tubes should contain no more than 3/4 the total volume of the container. Chamber should be cleaned **daily** when processing media.

- 19. Keep patients at least six (6) feet away from the sterilizer when it is in use.
- 20. Do not operate this sterilizer in the presence of flammable or explosive substances (such as anesthetics). A fire or explosion could occur.
- 21. Never use a wire brush, steel wool, abrasive material, or chloride-containing products to clean door and chamber assembly.
- 22. Use a process monitor in every cycle to ensure exposure to minimum sterilizing conditions. Use a biological indicator once a week to verify your sterilization process.
- 23. Dental handpieces should be run only on optional cycle at 132°C for 10 minutes. Check manufacturer's recommendations for sterilization parameters.

Specifications

Trays

Tray Dimensions

Large - 15 1/2" x 9 3/16" (39.4 x 23.3 cm) Small - 15 1/2" x 6" (39.4 x 15.2 cm)

Number of Trays

The sterilizer is supplied with two trays, 1 large and 1 small, and one rack.

Dimensions

Capacity

34 Liters (Vessel) (1.2 cubic feet) 7.0 Liters (Reservoir)

Overall Dimensions

W x D x H Inches(cm) 22 7/16" x 24 1/2" x 17" (57.0 x 62.2 x 43.2) Chamber (Dia. x Depth) 12" X 18" (30.5 x 45.7)

Shipping Weight

85 lbs. (38.5 kg)

Electrical

Heater Power 1500 W

Power requirements 120V, 50/60 Hz, 12.5 Amps 220V, 50/60 Hz, 6.5 Amps

Standards ASME UL/cUL to UL3101-1

Reservoir Water Distilled or low quality deionized

Max. 1.5 Megohm/cm Min. .5 Megohm/cm

Mounting Benchtop only

Controls

Fixed Cycles

- Liquid
- Packs
- Wrapped
- Unwrapped

Optional Cycle



Note

You can examine the pressure vessel rating plate for the sterilizer chamber by opening the panel on the back cover of the sterilizer, then removing the small plug of insulation on the back of the sterilizer chamber.

SPECIFICATIONS

Environmental Conditions



Operating: 4°C - 40°C; 20% - 80% relative humidity, noncondensing. Installation Category II (overvoltage) in accordance with IEC 664. Pollution Degree 2 in accordance with IEC 664. Altitude limit: 3,650 meters.

Storage: -25°C - 65°C; 20% - 80% relative humidity.

Declaration of Conformity



(for 230 volt, CE models only)

We hereby declare under our sole responsibility that this product conforms with the technical requirements of the following standards:

EMC: EN 61000-3-2 Limits for harmonic current emissions

> EN 61000-3-3 Limits for voltage fluctuations and flicker EN 61326-1 Electrical equipment for measurement, control, and laboratory use; Part I: General

Requirements.

Safety: EN 61010-1 Safety requirements for electrical equipment

> for measurement, control, and laboratory use; Part I: General Requirements.

Part II: Particular requirements for EN/EIC 61610-2-010

laboratory equipment for the heating of materials.

Part II: Particular requirements for autoclaves using steam EN61010-2-041

for the treatment of medical materials, and for laboratory

processes.

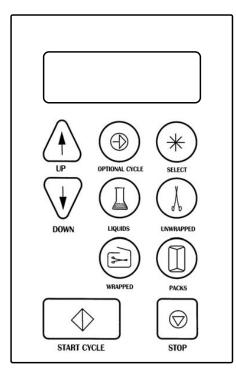
and meets the requirements of the Medical Device Directive 93/42/EEC, and its relevant transition into the national laws of the member states into which we place the device(s).

The authorized representative located within the European Community is:

Thermo Fisher Scientific 419 Sutton Road Southend On Sea Essex SS2 5PH United Kingdom

Copies of the Declaration of Conformity are available upon request

Description





Note

The liquid cycle is not designed for sterilization of liquids in a clinical application. Do not prepare sterile liquids for in vivo applications with the Sterilemax system.

Dental handpieces should be run in the optional cycle at 132°C for 10 minutes. Refer to manufacturer's recommendations for contra indication of sterilization parameters.

When sterilizing handpieces, refer to the manufacturer's specifications on handpieces for contra indication of sterilization parameters.

Operational Programs The sterilizer has four preset cycles which have been opti-

The sterilizer has four preset cycles which have been optimized to provide excellent results for most applications. In addition, there is one optional cycle that allows you to set your own sterilization parameters. You access the pre-programmed cycles by pushing one of the four green fixed-cycle buttons. The four preset sterilization programs are:

Unwrapped Goods

For unwrapped instruments and items made of metal, glass or plastic. Parameters: 3 minutes at 135°C.

Wrapped Goods

For wrapped packs of clothes, bandages, pads, fabrics, rubber tubing and metal instruments. Parameters: 10 minutes at 135°C.

Liquids

For distilled water, media solutions and other liquid prepared in closed bottles or flasks. Parameters: 15 minutes at 121°C.

Packs

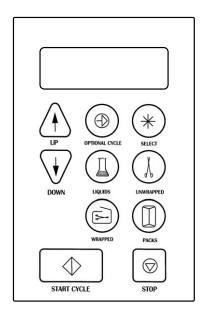
For packs of instruments and towels and other packed goods. Parameters: 30 minutes at 121°C.

DESCRIPTION



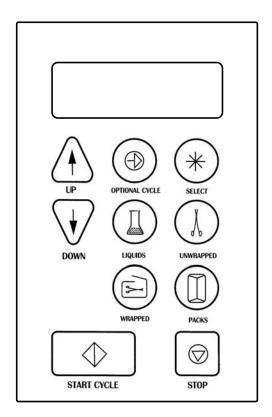
Note

When sterilizing handpieces, refer to the manufacturer's specifications on handpieces for contra indication of sterilization parameters.



Program Summary Chart

Program	Temperature	Time	Drying Time	Items To Be Sterilized
Liquids	121° C (250° F)	15 minutes	None	Distilled water, media solutions, other liquid prepared in closed bottles or flasks (not greater than 2 liters). Not for clinical applications.
Unwrapped	135° C (275° F)	3 minutes	Default: 15 minutes, can be set from 1 to 99 minutes	Unwrapped instruments; metal glass and plastic objects. Heat-resistant rubber tubing which will not be used in surgical applications. Any other items for which 135° C for 3 minutes is appropriate.
Wrapped	135° C (275° F)	10 minutes	Default: 15 minutes, can be set from 1 to 99 minutes	Wrapped cloths, bandages, pads, fabrics, loosely wrapped individual instruments, layers of instruments separated by fabric, wrapped trays of loose instruments, instruments in bags, heat-resistant rubber tubing. Any other items for which 135° C for 10 minutes is appropriate.
Packs	121° C (250° F)	30 minutes	Default: 15 minutes, can be set from 1 to 99 minutes	Packs of towels. Groups of instruments in commercially prepared packs. Instruments subject to prolonged storage. Surgical gloves wrapped for sterilization. Any other items for which 121° C for 30 minutes is appropriate, except liquids.
Optional	User defined from 100° C to 136° C (212° F to 277° F)	User defined from 1 to 99 minutes	User defined from 1 to 99 minutes	Items appropriate to the user defined parameters. Dental handpieces should be run in this cycle at 132° C for 10 minutes.





Note

The "Select" button is used by service personnel to adjust the operating parameters of the sterilizer.

Controls

All cycles and programming are selected and set in using the front touchpad selector buttons.

Power Switch

The Power Switch turns power to the unit on and off. When you turn the power on, the display will be set to select a sterilization cycle. It is located under the right front corner of the sterilizer.

Cycle Buttons (Green)

These buttons allow you to run the preprogrammed cycles at the touch of a button. See <u>Operational Programs</u>.

Optional Cycle (Yellow)

This parameter allows you to select different time and temperature levels for your cycles than those provided with our preset programs. An optional cycle can be run as either a liquid or hard goods cycle. All material run in this cycle must be validated by the user.

Up/Down Arrows (Yellow)

These allow you to set the time and temperature in an optional cycle. They are also used for scrolling through other functions.

Start Cycle (Dark Green)

Pressing the "Start Cycle" Switch activates the currently selected processing cycle. It is also used for scrolling through other functions.

Stop (Red)

This control is used to terminate any cycle. It is also used for scrolling through other functions.

DESCRIPTION

Sterilizer Features

Optional Printer

The optional printer available is an impact printer that records each cycle's performance. See page 39 for more information.

Pressure Monitor

The pressure monitor indicates the pressure inside the chamber. This monitor's readings can be found on the display as each cycle is running.

Door Security

While the chamber is under pressure, the door is held securely closed with three separate locking systems. First, there is a locking handle that you must tighten to hold the door fully closed. The locking handle turns clockwise to close and counterclockwise to open. Second, there is a pressure actuated locking pin which automatically secures the door, preventing it from being inadvertently opened while there is pressure in the chamber. Finally, there is a backup catch which will prevent the door from opening fully even if there is a small amount of pressure in the chamber. You release this catch with a lever which is located in the lower left side of the door. To fully open the door, pull the door release lever toward you.

Optional Non-Recirculating Tank

The optional non-recirculating tank is used to collect the remaining cycle water after a cycle has completed. This prevents any debris from the cycle to go back into the fresh water reservoir.

Door Switch

Actuated by the door, the door switch prevents operation of the sterilizer if the door is not fully closed.

Pressure Relief Valve

This valve protects the coded vessel from pressures exceeding the pressure rating of the vessel. The valve opens and releases steam in the event that pressure in the vessel exceeds 45 PSIG (310 kPa). The pressure line is located in the back of the unit. An



Warning

Pressurized steam will be discharged when the relief valve is opened. To prevent burns, wear gloves or use an extension device if it becomes necessary to operate the pull ring.

access hole is located in the back panel to allow you to periodically check relief valve operation.

Reservoir Drain

A drain assembly is provided to empty the reservoir. The reservoir drain assembly and plug are located at the lower right of the chamber opening on the front of the sterilizer (as you face the unit). The drain assembly attaches to the drain connector so a hose can be attached for draining the sterilizer reservoir into a container.

Trays and Tray Rack

A rack for the inside of the sterilizer is provided to hold the instrument trays. The rack slides out of the chamber to allow periodic cleaning of the chamber and rack.

Three large trays and one small tray can be placed into the rack or the rack can be used with only one or two trays or no trays. Tall items can be sterilized by removing both trays and placing the objects on the bottom surface of the rack. One large and one small tray are provided with the unit. See "Loading the Sterilizer Chamber" on page 31 of this manual.

Installation



Caution

The surface beneath the sterilizer could reach 100°F (38°C).

Location

For optimum performance of your sterilizer, the sterilizer should be installed in conformance to the following parameters:

Surface

For proper operation, the sterilizer must be placed on a level, heat and water resistant surface. If the surface is not level, the water in the sterilizer will be unevenly distributed, possibly resulting in a sterilizer malfunction. Do not adjust position of the feet on the sterilizer.

Clearances

Allow at least 3" (75mm) between the sterilizer and walls on the sides and back for air circulation. Also allow at least 8" (204mm) between the top of the sterilizer and any overhanging cabinet above it. Overhangs should not project more than 8" (204mm) over the rear of the sterilizer.

Surroundings

If the sterilizer will be operated continuously, locate it in an area where its steam emissions will not damage equipment or materials.

Unpacking

Remove the sterilizer carefully and inspect it for any shipping damage. Do not throw away packing materials until you inspect the unit.

- Turn the door handle counterclockwise until it is completely loose and move the locking mechanism to the left. Pull on the latch release lever built into the left side of the sterilizer door and carefully open the sterilizer door.
- Remove all packing materials and accessories from the chamber.
- Remove the trays and rack assembly from the chamber.

Check for any foreign material in the chamber.
 Wipe clean with a damp, lint-free cloth if necessary.



Warning

Connect only to an electrical circuit of the appropriate voltage and load rating.

Electrical Connections

We recommend that you use a separate (dedicated) circuit for this sterilizer. Ensure that the circuit is rated for the load. (See Electrical Specifications.)

- Connect power cord to power entry module on back of unit.
- 2. Plug power cord into a grounded outlet of the appropriate voltage and load rating.

Optional Printer

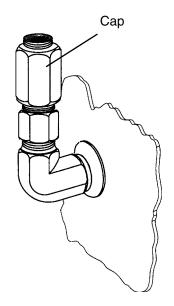
See section "Optional Printer" for installation, startup and operation.

Optional Non-Recirculating Tank

NOTE: If you did not purchase an optional non-recirculation tank, please proceed to **Altitude Adjustment**

Installation Instructions

- To connect the non-recirculating water accessory to the back of the sterilizer.
 - Unplug the sterilizer power cord. Allow the unit to cool to room temperature.
 - Move the sterilizer to gain access to the rear of the unit.
 - c. Unscrew the cap from the nonrecirculating discharge port of the sterilizer (located on the rear of the sterilizer).
 - d. Attach the discharge hose from the non-recirculating discharge port.
 - e. Tighten the nut finger tight plus a quarter turn with a wrench.
 - f. Attach the other end of the discharge hose to the fitting on the lower left (rear) of the non-recirculating cooling tank. Follow the same procedure as steps d and e above.

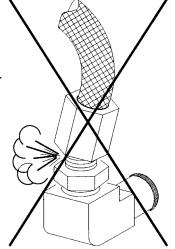


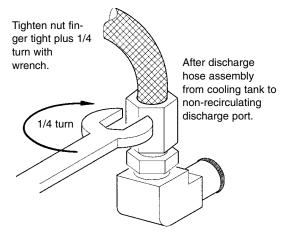
Removing Cap



Caution

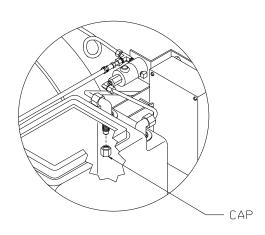
Be sure connection nut is started straight. Cross threading will cause leaks and damage the nut and fitting.





Discharge Hose Connection

OPTIONAL NON-RECIRCULATING TANK



Cap Replacement

- 2. Install the cap removed in step c. To the fitting located in the reservoir. See Cap Replacement
- 3. Fill the cooling tank with distilled or deionized water until the water begins to overflow from the cooling tank into the collection bottle (or into the drain if the overflow tube is installed).
- 4. Plug in the power cord.



Warning

Non-recirculating option must be installed before proceeding.



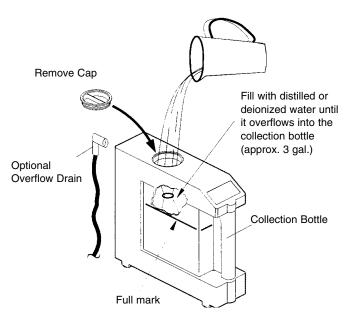
Caution

The non-recirculating tank (cooling tank) must be connected to the sterilizer before filling with distilled or deionized water.



Caution

Do not operate sterilizer unless the non-recirculating tank is filled with distilled or deionized water and attached to the sterilizer.



Filling Cooling Tank

Altitude Adjustment

For proper operation, the sterilizer program accounts for the altitude in controlling certain functions. The sterilizer is shipped with a factory-set altitude value suitable for all altitudes up to an altitude of 1000 feet above sea level. If your altitude is above 1000 feet above sea level, you will need to enter a new value for the altitude adjustment. To change the altitude adjustment value:

- At the "Select Cycle" screen, press the "Select" key and then the up arrow key. The sterilizer will display a "Configuration Info" screen, then it will automatically change to displaying the "Change Time" screen.
- 2. At the "Change Time" screen, press the "Select" key and then the "Liquids" key.
- 3. At the "Altitude Adjustment" screen, press the up arrow to select "Yes".
- 4. At the "Current Altitude" screen, press the up and down arrows to set the value for your location's altitude to the nearest one hundred feet.
- After you have set your altitude value, press the "Start" key to return to the "Select Cycle" screen.

Display Parameter Setup



Note

Sterilemax sterilizers are shipped with the display units set as follows:

120 volt units - °C, PSI

220 volt units - °C, BAR

If your unit is not set to these factory settings or if you require other settings, refer to "Changing Temperature Units" and "Changing Pressure Units" to set the units to your requirements.



VIOTA

If you desire to change the temperature units, press the up arrow to select "Yes", then refer to "Changing Temperature Units."

Setting Month/Date/Year/Hour/ Minute

To set the current date and time:

- From the "Select Cycle" screen, press the "Select" key and then the up arrow key.
- Wait for the sterilizer to display the "Change Time" Screen. Press the up arrow key to select "Yes."
- At the "Set Current Month" screen, press the up or down arrow key to set the current month. Press the "Start" key when the current month is set.
- At the "Set Current Date" screen, press the up or down arrow key to set the current date. Press the "Start" key when the current date is set.
- At the "Set Current Year" screen, press the up or down arrow key to set the current year's final two digits. Press the "Start" key when the current year is set.
- At the "Change Hour" screen, press the up or down arrow key to set the current twenty-four hour clock hour. Press the "Start" key when the current hour is set.
- At the "Change Minute" screen, press the up or down arrow key to set the current minute. Press the "Start" key when the current minute is set.
- At the "Change Temperature Units" screen, press the down arrow key to select "No."
- At the "Change Pressure Units" screen, press the down arrow key to select "No".
- At the "Change Printer Mode" screen, press DOWN ARROW key to select "NO" and return to the "Select Cycle" screen.

DISPLAY PARAMETER SETUP



Note

If you desire to change the pressure units, press the up arrow to select "Yes", then refer to "Changing Pressure Units."



Note

If you desire to change the pressure units press the UP ARROW to select "YES", then refer to "Change Printer Mode."



Note

If you desire to change the pressure units, press the up arrow to select "Yes", then refer to "Changing Pressure Units."

Changing Temperature Units

To change the units in which the chamber temperature is displayed on the digital display and printer tape (°C or °F):

- 1. From the "Select Cycle" screen, press the "Select" key and then the up arrow key.
- Wait for the sterilizer to display the "Change Time" Screen. Press the down arrow key to select "No."
- 3. The sterilizer will then display the "Change Temperature" screen. Press the up arrow key to select "Yes."
- 4. At the "Temperature Units" screen, press the up arrow key to toggle between °C and °F.
- 5. After you have selected your desired temperature units, press the "Start" key.
- At the "Change Pressure Units" screen, press the DOWN ARROW KEY to select "NO".
- 7. At the "Change Printer Mode" screen, press the DOWN ARROW KEY to select "NO" and return to the "Select Cycle" screen.

Changing Pressure Units

To change the units in which the chamber pressure is displayed on the digital display and the printer tape (PSI, BAR or KPA):

- 1. From the "Select Cycle" screen, press the "Select" key and then the up arrow key.
- Wait for the sterilizer to display the "Change Time" Screen. Press the down arrow key to select "No."
- 3. The sterilizer will then display the "Change Temperature" screen. Press the down arrow key to select "No."

DISPLAY PARAMETER SETUP

- 4. At the "Change Pressure Units" screen, press the up arrow key to select "Yes."
- 5. At the "Pressure Units" screen, press the up arrow to cycle between the three available units.
- 6. When you have selected your desired pressure units, press the "Start" key to enter units.
- 7. At the "Change Printer Mode" screen, press the DOWN ARROW key to select "NO" and return to the "Select Cycle" screen.

Changing Printer Modes This display is used to change the mode serial port of use for

This display is used to change the mode serial port of use for optional printers from USED/UNUSED:

- From the "Select Cycle" screen, press the "Select" key and then the UP ARROW key.
- 2. Wait for the "Change Time" screen. Press the DOWN ARROW key to select "NO."
- The sterilizer will then display the "Change Temperature" screen. Press the DOWN ARROW key to select "NO."
- 4. At the "Change Pressure Units" screen, press the DOWN ARROW key to select "NO."
- 5. At the "Change Printer Mode" screen, press the UP ARROW to select "YES."
- At the "Printer Mode" screen, press the UP ARROW to toggle between the available modes.
- 7. When you have selected your desired mode of operation, press the "Start" key to return to the "Select Cycle" screen.

Sterilization Procedures



Warning

Do not attempt to sterilize volatile or toxic substances. Serious injury or death could result.



Caution

Do not attempt to sterilize any object composed of materials which cannot withstand high temperatures (135°C or greater).

Materials Appropriate For Steam Sterilization

- Straight stainless steel instruments
- Surgical stainless steel hinged instruments
- Pouches of instruments
- Carbon steel instruments (see special preparation instructions)
- Air powered instruments made to be autoclaved
- Needles
- Syringes
- Treatment trays
- Heat resistant plastic items
- Rubber gloves
- · Heat resistant rubber tubing
- · Heat resistant rubber sheeting
- · Glass slabs and beakers
- Gauze
- Sutures
- Linen packs
- Liquids, non-clinical
- Other heat-resistant, immersible items

Always check with the manufacturer of your supplies for specific instructions for sterilization.



Warning

Thoroughly clean instruments before placing them in the sterilizer. Sterilizing items contaminated with blood or debris will impede sterilization and may result in unsterile instruments, which may cause personal injury or death.



Warning

Always wear protective gloves when handling soiled instruments to protect yourself from the possibility of serious infection. Clean gloved hands with a germicidal cleaner when finished handling soiled instruments.



Caution

Sterilizing items contaminated with blood or debris may cause staining or damage to the instruments or the sterilizer.



Caution

Use of soaking solutions containing phenols or quaternary ammonium compounds may cause corrosion of the instruments, trays and the stainless steel chamber.

Instrument Cleaning Prior To Sterilization

Transport soiled instruments to your cleanup area on a tray. Sort out any instruments unsuitable for sterilization (see list on page 24).

Follow manufacturer's recommendations for cleaning and preparing any particular item.

In the absence of manufacturer's specific instructions, clean instruments as follows:

- 1. Rinse instruments thoroughly with a hard stream of water to remove debris.
- Sort instruments by their metallic composition. Do not mix instruments of different metals, as instrument damage will result.
- Using either a fresh solution of detergent and distilled water or a germicide solution, wash instruments in an ultrasonic cleaner for five to ten minutes. Clean all instruments in an open position.

Use a detergent or germicide with a neutral pH (7) specifically designed for use in an ultrasonic cleaner.

Use new ultrasonic cleaning solution each day.

- After cleaning, rinse instruments thoroughly in distilled or deionized water. Inspect to ensure that all debris has been removed. Repeat cleaning as necessary.
 - If distilled or deionized water is unavailable and instruments are rinsed in tap water instead, all instruments should be dried before sterilizing to prevent staining.
- Refer to manufacturer's recommendations for lubricating instruments after ultrasonic cleaning. Use a silicon lubricant which will not interfere with sterilization.



Note

Do not place carbon steel instruments directly onto stainless steel trays. Place an unbleached towel or paper wrap on the tray and place the instruments on the towel or paper.

When wrapping instruments for sterilization, use a material which promotes drying.



Warning

Do not overload the trays. Overloading trays may result in inadequate sterilization and unsterile instruments.



Warning

Monitor the sterilization process with process monitors and biological indicators as described in Recommended Monitoring (p. 33).

Preparation of Carbon Steel Instruments

Carbon steel instruments must be carefully prepared prior to sterilization to prevent rusting. After cleaning according to the manufacturer's recommendations or the methods presented in **Instrument Cleaning Prior To Sterilization**, prepare carbon steel instruments as follows:

- Prepare a 2% solution of sodium nitrate in water (approximately one table spoon in a quart of water). Completely immerse the instruments in the solution and allow them to soak for three minutes.
- 2. Remove the instruments and package them for sterilization or place on trays if sterilizing unwrapped. **Do not rinse or wipe instruments prior to sterilization.**

Preparing Items for Sterilization

General Preparation Guidelines

- Clean items thoroughly before placing them in the sterilizer. Follow good laboratory or medical procedures for cleaning and decontamination of items.
- 2. Place absorbent paper or linen towel in the bottom of trays before use.
- Unwrapped goods should only be processed on trays. Do not place items on the rack or the bottom of the sterilizer.
- 4. Liquids must not exceed 75% of capacity of flask. Use self-venting caps.
- 5. Open all hinged instruments.



Caution

Do not mix different metals in the same pack or wrapping or loose on the same tray. Instrument damage will result.



Warning

Unwrapped items cannot be considered sterile once removed from the sterilizer chamber.

Do not overload the trays.

Overloading trays may result in inadequate sterilization and unsterile instruments.



Note

Unwrapped trays are used for sterilizing nonsurgical instruments, canisters and other items to prevent transmitting infectious disease.

- Remove the covers from empty containers. Stand the containers and covers on their sides.
- Turn curved vessels upside down so no water will collect in the vessel.
- Place all sharps (knives, scissors, etc.) so that they do not touch during sterilization. Cotton or gauze may be used to isolate and protect the sharp edges and the smaller instruments.
- 9. Disassemble syringes if possible.
- 10. Do not plug syringes or needles.

Items to be Sterilized Loose and Unwrapped

Items to be sterilized loose and unwrapped should be distributed in a single layer on the bottom of a lined, perforated tray. Do not overload tray; allow space around instruments for steam circulation.

Metal and glass canisters and containers should be placed upside down on a perforated tray. Make sure containers are placed so that they will drain, or they will not dry sufficiently to ensure sterilization.

Appropriate Wrapping Materials for Steam Sterilization (Partial List)

Muslin (2 layers), Nylon bagging material, Commercial autoclave paper (must be as permeable as muslin), Permeable paper and plastic bags, Cloth or paper-covered trays

Materials Inappropriate for Wrapping for Steam Sterilization (Partial List)

Canvas, Impermeable plastics, Aluminum foil, Sealed jars, canisters or tubes.



Warning

Do not wrap packs tightly and do not over fill autoclave bags. Steam must penetrate through entire pack. Inadequate sterilization may result from improper packaging.

Do not seal with staples, pins or other methods which will puncture the wrapping material. If wrapping material is punctured, sterility cannot be assured once items are removed from the sterilizer chamber.

Do not overload the trays. Overloading trays may result in inadequate sterilization and unsterile instruments.

Items to be Sterilized Wrapped

Cleaned items may be wrapped individually in autoclave paper or placed in commercially prepared autoclave bags. Do not wrap tightly. Seal with autoclave tape or heat sealer.

Cleaned items may also be sterilized as a group of instruments wrapped together. You may desire to wrap a group of similar instruments together, or you may desire to wrap together the instruments needed for a particular procedure. Wrap the instruments loosely in 2 to 4 layers of autoclave paper or muslin or place them in autoclave bags. Seal with autoclave tape or heat sealer.

Place wrapped items on a perforated tray. Do not overload tray; allow space around wrapped items for steam circulation.

When using commercial sterilization bags, follow the manufacturer's instructions for proper use.



Note

If you desire to include a large number of instruments in a single package, see **Items to be Sterilized in Packs.**

Appropriate Wrapping Materials for Steam Sterilization (Partial List)

Muslin (2 layers), Nylon bagging material, Commercial autoclave paper (must be as permeable as muslin), Permeable paper and plastic bags, Cloth or paper-covered trays

Materials Inappropriate for Wrapping for Steam Sterilization (Partial List)

Canvas, Impermeable plastics, Aluminum foil, Sealed jars, canisters or tubes.



Warning

Do not seal with staples, pins or other methods which will puncture the wrapping material. If wrapping material is punctured, sterility cannot be assured once items are removed from the sterilizer chamber

Do not wrap items tightly and do not over fill autoclave bags. Steam must penetrate through entire wrapped group. Inadequate sterilization may result from improper wrapping.

Do not overload the trays. Overloading trays may result in inadequate sterilization and unsterile instruments.

Items to be Sterilized on Wrapped Trays

Place cleaned items loose in the bottom of a lined, perforated tray. Additional layers of instruments may be added, separated by fabric. Do not overload the tray; steam must be able to penetrate through the entire tray. Wrap the tray in 2 to 4 layers of muslin or other appropriate wrapping material. Seal with autoclave tape.

Items to be Sterilized in Packs

Use packs to sterilize a number of instruments together, to sterilize textile products and to sterilize surgical gloves. When using commercial sterilization packs, follow manufacturer's instructions for proper use.

Instruments

Loosely package cleaned instruments into packs of not more than 10 instruments each. Instruments which might nest together should be separated by a layer of absorbent material and placed in the pack in a manner that will allow water to flow out of them. Seal with autoclave tape or heat sealer.

Textile Products

Launder textile products before sterilization.

Loosely roll or fold textile products. Place in commercially prepared packages or wrap in 2 to 4 layers of muslin or other appropriate wrapping material. Seal with autoclave tape or heat sealer.

Surgical Gloves

Disposable gloves should not be sterilized.

Clean and dry gloves. Place a piece of muslin or other

Appropriate Wrapping Materials for Steam Sterilization (Partial List)

Muslin (2 layers), Nylon bagging material, Commercial autoclave paper (must be as permeable as muslin), Permeable paper and plastic bags, Cloth or paper-covered trays

Materials Inappropriate for Wrapping for Steam Sterilization (Partial List)

Canvas, Impermeable plastics, Aluminum foil, Sealed jars, canisters or tubes.



Caution

Do not use detergents with a high chlorine or phosphate content or chlorine bleach when laundering items prior to sterilization. Damage to instruments and to the sterilizer chamber could result.

absorbent material into the central area of the glove. Place a strip of muslin or other absorbent material around the cuff and fold the cuff back over it. Wrap the gloves in muslin or other appropriate wrapping material. Seal with autoclave tape.

Place packs on a perforated tray. Place packs of gloves so that the glove stand on end in the sterilizer. Load packs side-by-side; do not stack packs.



Warning

Do not overload tray; allow space around packs for steam circulation. Pack density should not exceed 50% of the capacity of the tray. Metal or glass should not be used to separate packs, as these will inhibit drying. Overloading the tray or failure to allow the packs to dry properly can result in non-sterile goods.

Preparing Liquids for Sterilization

Place liquids in heat-proof containers. Place containers on perforated tray. Do not fill flask more than 75% full.

Items to be Sterilized in Optional Cycle

Place material to be sterilized in appropriate containers or on trays prior to placement in sterilizer. Follow instructions on display for setting cycle time, temperature and drying parameters. If running a liquid-optional cycle, ensure that containers are not more than 75% full. User must follow proper safety procedures and sterilization monitoring procedures for the optional cycle. Every optional cycle should be validated by the user.

Dental handpieces should be run at 132°C for 10 minutes.



Warning

Do not exceed the sterilizer's rated capacity for liquid sterilization. Non-sterile liquids could result. Fill flasks no more than 75% full. User should validate material in optional cycle.



Note

User should not attempt to sterilize more than 10 handpieces per sterilization cycle.



Warning

Use only self-venting, automatic sealing stoppers when processing liquids or media. Use of other stoppers or seals, or lack of stoppers, will create the possibility of burns or injury from boiling liquids and exploding flasks.

If media is processed, bottles and tubes should contain no more than 3/4 the total volume of the container. When processing water bottles and test tubes, the bottles and tubes should contain no more than 3/4 the total volume of the container. Chamber should be cleaned daily when processing media.

Sterilized liquids are for non-clinical applications.



Caution

Packs must be centered in the chamber. Do not allow packs to touch the sterilizer chamber's walls. Allowing packs to touch the sterilizer chamber's walls may create an overheat condition.

Loading the Sterilizer Chamber

Loading Guidelines

- When processing wrapped goods, fabrics and dressings, always place items in one of the three upper positions in the chamber. Processing items in the bottom position could possibly result in wet packs and unsterile goods.
- Do not exceed the specified loads for a cycle: Unwrapped Goods - no more than 14 lbs Wrapped Goods - no more than 14 lbs in no more than 12 small cassettes or 4 large cassettes Packs - no more than 2.8 lbs and no more than 14 towels Liquids - flasks filled no more than 75% full.
- 3. Do not overload the sterilizer. Steam penetrates best with loosely packed loads.
- Do not allow packs or wrappings to touch chamber walls or one another.
- Leave adequate space between trays to allow steam circulation.
- Do not stack trays on top of one another.
- Use a process monitor in each load. We also recommend that you use a biological indicator at weekly intervals. An indicator containing Bacillus stearothermophilus is the proper indicator for steam sterilizers.



Warning

Sterilizer and trays will be hot after cycle is run. Always wear protective gloves and apron when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.

Open door slowly at the end of a liquid sterilization cycle. Do not allow hot bottles to be jolted. This can cause bottle explosions. Do not move bottles if any boiling or bubbling is present.

Allow bottles to cool before attempting to move them from sterilizer shelf or tray(s) to the storage area.

Handling Sterilized Materials

Loads may be removed from the sterilizer at the end of the drying cycle. (Liquids may be removed at the end of the sterilization cycle.) Unwrapped items should be used immediately. Any unwrapped items not used immediately cannot be considered sterile after removal from the sterilizer chamber.

Date all wrapped packages and packs prior to storage. Check the integrity of all wrapping materials prior to opening and using wrapped or packed items; if the wrapping materials are opened or torn, the instruments must be considered potentially unsterile and should be re-sterilized prior to use. Re-sterilize all wrapped packages and packs after one month in storage.

Recommended Monitoring



Note

Refer to the manufacturer's recommendations for proper use of biological indicators. All functions of a sterilizer should be monitored to provide maximum assurance of proper performance.

Process Monitoring

For assurance that minimum sterilizing conditions have been achieved, we recommend the use of a process monitor with each cycle and within each package. This small process monitoring device will provide immediate indication of exposure to temperature and of time in the presence of humidity (steam).

Trays

Place a process monitor in the **center** of each wrapped or unwrapped tray of loose items.

Wrapped Instruments

Place a process monitor inside each package with an instrument.

Wrapped Packages of Instruments

Place a process monitor in each package.

Packs

Place a process monitor inside each pack. When sterilizing textile products, place the process monitor in the center of the stack of textile products. When sterilizing gloves, place a process monitor inside a glove inside each pack.

RECOMMENDED MONITORING



Note

Refer to the manufacturer's recommendations for proper use of biological indicators.



Note

When using a biological indicator for a 135°C cycle, the user must be sure that it has been validated for use at 135°C. We recommend using the Thermo Scientific Biological Indicator (part # AY759X1) for this type of cycle. If any other Biological Indicator is used, the user must ensure that it has been validated for a 135°C cycle.

Biological Indicators

Process monitors do not by themselves prove sterilization has occurred. Biological indicators composed of spores of standard organisms are considered the most reliable means of verifying sterilization. A biological indicator functions by testing the sterilizer's ability to kill test organisms of a known high resistance. Indicators containing *Bacillus stearothermophilus* should be used for steam sterilizers. The Joint Commission on Accreditation of Hospitals recommends that biological indicators be used at least weekly to check the effectiveness of your steam sterilizer's sterilization cycle.

When testing the effectiveness of a sterilization cycle, use the appropriate "worst case" test load described for the cycle in this section:

Unwrapped Instruments

Place 100 instruments on a perforated tray lined with a 100% cotton surgical towel. Place a biological indicator in the **center** of the test tray. Place the test tray in the center rack of the sterilizer chamber. Prepare additional trays in the same manner without biological indicators to bring the total sterilization load to 14 lbs (6.4 kg).

Wrapped Instruments

Load ā small cassette with 6 instruments. Place two biological indicators inside the cassette. Wrap the cassette with two layers of appropriate wrapping. Seal with autoclave tape. Prepare eight other small cassettes in the same manner without the biological indicators. Place the cassette with the biological monitor upright in the center of a tray. Fill the tray with the rest of the cassettes. Place the tray in the center rack of the sterilizer chamber.

RECOMMENDED MONITORING

Packs

Textiles

Prepare a pack of 14 towels (per AAMI ST-8). Place three biological indicators in the center of the pack, between the sixth and seventh towels. Wrap the pack with two strips of autoclave tape, placing the tape around the width of the pack so that the two strips divide the length of the pack into thirds.

Pouches

Place a biological indicator together with a surgical instrument into a self-sealing pouch. Place the pouch with the indicator in the middle of the tray. Place four other surgical instruments into pouches and place them on the tray. Place the tray in the center rack of the sterilizer chamber.

Optional Cycle: For Dental Handpieces Only

Place a biological indicator together with one dental handpiece in a self-sealing pouch. Place the closed pouch in the front of the sterilizer tray. Place the tray in the lowest level of the chamber rack.

Operation



Warning

Keep patients at least six (6) feet away from the sterilizer when it is in use.

Do not operate this sterilizer in the presence of flammable or explosive substances (such as anesthetics). A fire or explosion could occur.



Caution

To prevent collection of mineral deposits and corrosion of chamber components, use distilled or deionized water only. See Specifications. Clean chamber after each use if sterilizing saline solutions.

Do not overfill reservoir. To avoid slippery conditions and possible load recontamination, immediately wipe up all spillage resulting from overfilling chamber or reservoir.



Warning

Do not add water to reservoir while a sterilization cycle is in process. When the cycle ends and steam vents back into the reservoir, a sudden overflow of hot water could occur, possibly resulting in burns to personnel.

Connect the power cord to the unit and to a grounded outlet of appropriate voltage and rating.

Initial Startup

Power On

Push the Power Switch under the right front corner of the sterilizer to the On position. The sterilizer will not operate unless this switch is in the On position.

Filling Reservoir

Remove the cover to the water reservoir and fill the reservoir with distilled or low quality deionized water (minimum 0.5 Megohm/cm, maximum 1.5 Megohm/cm) until the water level reaches the bottom of the fill line in the reservoir. The reservoir will hold approximately 7.0 liters (6.3 quarts) of water. The water level should never be higher than the fill line. Do not overfill.

Refilling Reservoir

When the reservoir runs low on water, the low level sensor will alert you of the low water condition. When the display indicates "Reservoir is empty. Fill and restart sterilization cycle," you will need to add water to the reservoir before you run another cycle. You should never need to add more than 5 liters (5.3 quarts) at a time to the reservoir. The water level should never be higher than the fill line. Do not overfill.

You may determine a refill schedule dependent upon the pattern of operation at you facility. The number of cycles you can run before the reservoir needs to be filled will vary according to your frequency of operation, duration between cycles, type of cycles, etc.

Outline of Operation

Two basic steps are required to initiate a sterilizing cycle after the load has been placed in the chamber and the door closed and latched:

- 1. Select the cycle you desire.
- 2. Follow the displayed directions for the cycle.

Cycle selections cannot be changed once "Start Cycle" has been pressed. To change a setting, the cycle must be terminated by pressing "Stop." When you select a new cycle, the cycle information will be changed automatically.

Details of Operation

Prepare Load

Follow preparation instructions on pages 27-31.

Load the Sterilizer Chamber

You may load wrapped or unwrapped instruments, linen packs, glassware and liquids. Follow loading instructions on page 33.

Close the Sterilizer Door

The door must be fully closed to run a sterilizing cycle. If the door is not fully closed, the sterilizer will stop and indicate, "The door is open. Close door to continue cycle."

Select Processing Cycle

- 1. Select your required cycle.
- 2. Set the drying cycle time for pack, wrapped and unwrapped cycles. (See "Drying Sterilized Loads.")

OPERATION



Warning

Processing goods at less than recommended time/temperature could result in unsterile goods.



Warning

Use caution when opening the sterilizer door. Stand to the side behind the door and open door slowly and partially to protect yourself from escaping steam or boiling liquids and exploding flasks.

Do not attempt to open sterilizer door until the display reads "Cycle Complete." Pressure within the chamber could cause the door to open with extreme force, possibly causing personal injury.

Setting Drying Time

(For Pack, Wrapped and Unwrapped cycles only.)

If drying is desired, set the drying time when you select the sterilization cycle. After you select a Pack, Wrapped or Unwrapped cycle, the cycle parameters will be displayed. After the parameters have been displayed, you will be prompted to enter a figure for drying time. You will find that the default time — displayed at the prompt — is the optimal setting for most loads.

If your application or load composition requires a different drying time to achieve appropriate drying, you can change the drying time setting when the display prompts you. Use the up or down arrow to adjust the displayed drying time until your desired drying time is displayed.

Press "Start Cycle"

Processing will run automatically after you press "Start Cycle."

Drying Sterilized Loads

At the completion of the sterilization cycle, turn the locking handle counter clockwise until the door is held in place by the backup catch. The door must be opened approximately 1 inch to operate the drying cycle. To prevent contamination of wet packs and wrapped items, do not open the door more than 1 inch during the drying cycle. Press "Start Cycle" to start the drying cycle.

When you press "Start Cycle," the Drying Indicator will be displayed, the chamber will heat to a low temperature and the selected drying time will begin to count down. At the end of the drying cycle, a five second alarm will sound.

Optional Drying Cycles

If you desire to run a drying cycle without running a sterilizing cycle with it, you may. Press the "Optional Cycle" button and scroll the setpoint temperature below 100°C. You will enter a menu for an optional drying cycle. Set the drying time as instructed above, then press "Start Cycle" to begin the drying cycle.

Optional Printer

The optional printer provides a paper tape record for future reference and verifies sterilizer performance, load control identification and quality assurance checks for each cycle.

During a sterilization cycle, the printer prints a record of the chamber temperature, pressure and status of the cycle at 1-minute intervals.

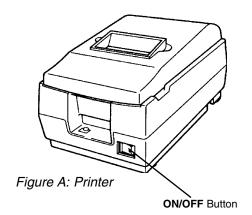
Connecting and Starting the Printer

- Make sure the printer and sterilizer are turned OFF.
- Connect the enclosed data cable to the RS232 connector on the back of the sterilizer and the power cord to the power supply.
- 3. Turn the printer ON.
- Turn the sterilizer ON. The printer should print "Barnstead/Thermolyne Sterilemax," "Software Version X.XX.XX"
- If the printer does not print heading, verify the "Printer Mode" is set to used. See "Changing Printer Mode."
- 6. Turn the sterilizer off and then back on to verify the printer prints out
 "Barnstead/Thermolyne Sterilemax,"
 "Software Version X.XX.XX"
- 7. The printer is now ready to print.

Control Panel (See Figure B)

Power Switch

Located on the front of the printer, this switch turns power to the printer ON and OFF. (See Figure A.) The green POWER light will illuminate when the printer is ON.



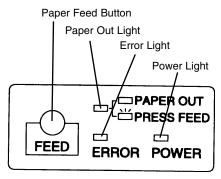


Figure B: Control Panel

PRINTER

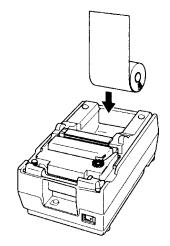


Figure C: Inserting the Paper Roll

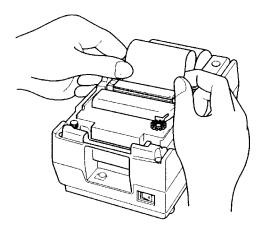


Figure D: Inserting the Paper Into the Paper Slot



A colored stripe along the edge of the paper indicates that you are approaching the end of the tape. When the stripe appears, approx. 23 inches of paper remain, enough for 2-3 cycles. Replace the tape before it is completely exhausted to ensure a complete record of your sterilization procedures

Paper Feed Button

Press this button once to advance the tape one line, or hold the button down to advance paper continuously. When the paper roll nears the end, the red PAPER OUT light will illuminate.

If the red ERROR light illuminates, the printer is off line. This could be a result of the print head being too hot, in which case the printer will resume printing once it cools down; or the paper may be jammed in the printer. Turn the printer OFF before checking for jammed paper. Remove the paper jam and turn the printer back ON. If the printer still will not print, unplug it and refer servicing to qualified personnel.

Installing the Paper Roll
When the red PAPER OUT light illuminates, it is time to replace the paper roll. Replace the paper (AY669X4) roll as follows:

- 1. Turn the printer ON and open the cover.
- 2. Make sure the edge of the paper roll is straight.
- Insert the paper roll into the printer. (See Figure 3. C.)
- 4. Insert the paper straight into the paper slot (see Figure D). The paper will feed automatically.
- 5. Tear off a strip of paper and close the cover. (The red PAPER OUT light will be OFF if paper roll installation is successful.)

Printer Operation

The printer automatically records sterilization cycles. During sterilization cycles, the printer prints the chamber temperature, pressure and status of cycle at one minute intervals.

Printer Tape Description

The printer tape is designed to be easily read as a cycle is running, allowing you to exam at a glance the progress of the current cycle. As a result, a complete tape must be read from the bottom up. (Sample on page 41)

When you turn on the sterilizer, the printer will print "Barnstead|Thermolyne Sterilemax" and the software version number. This will print only immediately after the sterilizer has been turned on.

When you press one of the preset cycle buttons, the printer will print the name of the cycle selected, the parameters set for that cycle and the selected pressure units. If you choose a default optional cycle, the printer will print the current default parameters. If you bypass the default optional cycle for a standard, the printer will print only the name of the cycle and the selected pressure units, since the parameters have not been set.

When you press "Start Cycle", the printer will print the number of cycles that have been run since the unit was turned on, the current date and time, the notation "Cycle Started" and column headers.

During the cycle, the printer will print the elapsed time, the current chamber temperature and the current chamber pressure at one minute intervals, along with a status notation. When you press "Start Cycle", the printer will print the number of cycles that have been run since the unit was turned on, the current date and time, the notation "Cycle Started" and column headers.

During the cycle, the printer will print the elapsed time, the current chamber temperature and the current chamber pressure at one minute intervals, along with a status notation.

When the sterilizer chamber achieves the temperature set by the cycle parameters, the printer will immediately print a record line, regardless of the time since the last record was printed. The status notation will change from "Heatup" to "Exp", indicating that the load is being exposed to the temperature set forth in the cycle parameters. The printer will continue to print record lines at one minute increments, starting one minute after the record line printed at the start of the exposure phase but still showing the total elapsed time for the cycle.

DRY TIME (Min) = 10 LIQUID CYCLE = NO EXPOSURE TEMP= 132 C EXP. TIME (Min) = 10 PARAMETERS ARE: OPTIONAL DEFAULT

Default Optional Cycle Printout

PRINTER

When the sterilizer has achieved the time condition set in the cycle parameters, the printer will print "Vent" in the cycle status column, indicating that the sterilizer is venting.

At the end of the vent phase, the printer will print "Venting Cycle Completed" and instructions for starting the drying cycle. There is no printout during the drying cycle.

Printer Record Storage
To ensure the long-term legibility of your records, it is important that you keep your printed tapes in a dry, cool, dark place.

PRINTER

Instructions for drying	CONTINUE PLEASE OPEN DOOR TO		
End of cycle			
	28:27 125 19 VENT Vent		
	27:27 135 31 VENT Phase		
	26:27 135 32 EXP		
	25:27 135 32 EXP		
	24:27 135 32 EXP 23:27 135 32 EXP		
	22:27 135 32 EXP		
	21:27 135 32 EXP Exposure		
Elapsed time increments by minutes	20:27 135 32 EXP Phase		
from start of sterilization phase	19:27 135 32 EXP		
р	─18:27 135 31 EXP 17:27 135 31 EXP		
Exact point at which sterilization ———	17:00 134 31 HEATUP		
phase begins.	16:00 132 27 HEATUP		
	15:00 129 24 HEATUP		
	14:00 126 21 HEATUP 13:00 124 18 HEATUP		
	13:00 124 18 HEATUP 12:00 121 16 HEATUP		
	11:00 118 13 HEATUP		
Current status of the sucle	10:00 115 10 HEATUP Heatur		
Current status of the cycle	87.88 IIZ 80 DEHIUF Dhoos		
Chamber Pressure —	08:00 108 05 HEATUP PHASE 07:00 103 02 HEATUP		
Shambor rioscare	06:00 101 02 HEATUP		
Chamber Temperature —	05 00 97 01 HEATUP		
	04:00 90 01 HEATUP		
Elapsed time since cycle started	03:00 90 00 HEATUP 02:08 92 00 HEATUP		
	01.00 93 80 HEATUP		
Column Headers	TIME TEMP PRESS STATUS		
	ELAPSED CYCLE		
	CYCLE STARTED		
	TIME AGAIN		
Date and time of cycle initiation	──		
Cycle record number for day ————			
, , , , , , , , , , , , , , , , , , ,	·		
Currently chosen pressure units	PRESSURE IN PSI		
Parameters for this programmed cycle	TEMPERATURE 135 C		
(default for this preset program)	TIME 10 min —DEFAULT PARAMETERS		
Name of preset program chosen for —	── WRAPPED GOODS		
this cycle	Printer Mode is (USED)		
Software version number prints	Version X.XX.XX		
when you turn on the sterilizer.	Sterilemax		
,	Barnstead Thermolyne		

Special Operating Conditions



Warning

Do not attempt to open sterilizer door until the display reads "Cycle Complete". Pressure within the chamber could cause the door to open with extreme force, possibly causing personal injury.

Reprocess your load in the event the sterilizing cycle has been terminated prematurely. The load may not be sterile when the sterilizing cycle has been terminated prematurely.

Failure to drain excess water from the sterilizer chamber after a cycle abort may result in subsequent unsterile loads as a result of contact with water in the chamber. Always drain excess water from the chamber after aborting a cycle.

Allow chamber to cool before draining excess water.



Note

If display shows: "The Mechanical OTP has Tripped. Shutoff Unit Power and Reset - Caution - Unit Hot!!" Reset as described under "Resetting the Mechanical OTP Sensor" in Service Manual.

Emergency Off (Cycle Abort)

Pressing the "Stop" button will immediately terminate sterilization. Allow the sterilizer to cool and press the "Stop" button again to reset the sterilizer. Drain excess water from the sterilizer chamber. Proceed with a new sterilization cycle normally.

When terminating a load, pressing the "Stop" button will vent steam from the chamber back into the reservoir.

Resetting the Automatic OTP

Display shows: "Cycle Aborted Due to AUTO OTP Device. Press Stop Shutoff Unit Power to Reset."

- 1. Press the "Stop" button.
- 2. Wait for the display to read "Select Cycle".
- Turn Power Switch off and then on to reset the Low Water Cutoff.
- 4. Open the chamber door and allow the chamber to cool.
- 5. Select your desired cycle and run the cycle with a loaded chamber to verify operation.
- In the event of a repetition of fault call Customer Service.



Warning

Reprocess your load in the event the sterilizing cycle has been terminated prematurely. The load may not be sterile when the sterilizing cycle has been terminated prematurely.



Warning

Reprocess your load in the event the sterilizing cycle has been terminated prematurely. The load may not be sterile when the sterilizing cycle has been terminated prematurely.

Erratic Controls Display or Operation

Åbnormal sterilizer operation or controls display could be caused by an internal or external electrical voltage surge. Such a voltage surge could be cause be any of a number of events: a momentary surge in the power supply, a nearby lightening storm, or even a static electrical charge carried by operating personnel.

Abnormal operation or displays are not common occurrences and may never happen. No damage to the equipment will occur if such an event should happen.

If an abnormal condition should occur, terminate any processing cycle in process. (Press "Stop.") Reset the sterilizer by turning the power switch (on the front right corner of the unit) to OFF. Wait 30 seconds and turn the power switch back on. Select your desired cycle and proceed with normal operation.

Power Failure During Sterilizing Cycle

All Selector/Indicator Panel lights will be off.

Allow the unit to cool. Reset the sterilizer by turning the power switch (under the front right corner of the unit) to OFF. Wait 30 seconds and turn the power switch back on. Drain excess water from the sterilizer chamber. Then reprocess your load normally.

Problem Solving Chart

Fault Indication	Fault Cause	Solution	
Cycle halted, display reads "Cycle Halted Due To Heatup Exceeding Maximum Time, Push Stop To Reset."	The temperature in the vessel has not reached the specified setpoint within 115 minutes.	 Check for adequate water fill at the beginning of cycle. Check solenoid valves/ door gasket for leaks. See "sterilizer will not heat." 	
Cycle halted, display reads "Cycle Failed Due To Over Temperature Condition, Press Stop To Continue."	The temperature inside the chamber has exceeded more than 5°C above the setpoint.	Press the STOP button, allow chamber to depressurize and cool, drain the chamber, restart cycle.	
Exposure phase lengthened beyond programmed time.	Temperature in the chamber dropped more than 1°C but not more than 5° below the setpoint, causing the exposure phase timer to reset. (Not applicable to liquid cycle.)	None necessary. Load is sterile at end of cycle.	
Cycle halted, display reads "Cycle Failed Due To Low Temperature Condition, Press STOP To Continue."	Temperature in the chamber dropped more than 1°C below the setpoint in a liquid cycle, or more than 5°C in any other cycle.	Press the STOP button, allow chamber to depressurize and cool, drain the chamber, restart cycle.	
Cycle halted, display reads "The Door Has Opened, Sterilization Cycle Aborted, Press Stop."	The door switch opened after the initiation of a cycle.	Press the STOP button, allow chamber to depressurize and cool, drain the chamber, restart cycle, ensuring that the door is securely closed.	
Cycle does not start, display reads "The Door Is Open, Close Door To Continue."	The door switch was open when START was pressed.	Close door securely. Cycle will start when door switch is closed.	
Display reads, "Unit Has Enough Water For One More Cycle, Please Refill Reservoir."	The water level switch in reservoir opened during the fill, indicating low water.	Allow cycle to run. After cycle has ended, refill reservoir before running another cycle.	

Fault Indication	Fault Cause	Solution	
Cycle does not start, display reads "Reservoir is Empty. Fill and Restart Sterilization Cycle."	The water level switch is open at the beginning of a cycle, indicating low water.	Refill reservoir. Restart cycle.	
When STOP is pressed the display reads "Pressure Greater Than 1 psi, Please Wait To Stop."	The cycle has stopped, but the chamber pressure is too great to safely open the door.	Wait for pressure to drop.	
When START is pressed at the end of venting to begin the drying phase, the display reads "Door Must Be Open To Begin Drying Cycle."	Door is closed. (Door must be open for adequate drying.)	Open door. Press START.	
Mechanical over pressure relief valve opens, venting pressure from chamber.	Pressure in the chamber has exceeded 45 psi.	Press the STOP button, allow chamber to depressurize. Restart cycle. In the event of a repetition of fault, call Barnstead International Customer Service.	
Display reads "Cycle Aborted Due To Auto OTP Device. Press STOP, shutoff unit power to reset.	Temperature sensor on the heater has reached its preset cutoff point or sensor failure.	See Resetting the Automatic OTP. In the event of a repetition of fault, call Barnstead International Customer Service.	
Sterilizer will not heat. Display reads: "The Mechanical OTP Has Tripped. Shutoff Unit And Restart. Caution - Unit Hot!!"	The fail-safe mechanical over temperature switch has opened due to significant thermal runaway.	Reset as described under Resetting the Mechanical OTP Sensor. In the event of a repetition of fault, call Barnstead International Customer Service.	
No display or printout, but fan on back is running.	Fuse protecting the power supply are blown.	Replace fuse as described under Replacing The Power Supply Fuses.	

Maintenance Schedule Chart

Maintenance Required	Person Responsible	
Daily		
Clean Door Gasket	User	
Clean Chamber*	User	
Weekly		
Clean Chamber, Trays and Rack	User	
Monthly		
Check Pressure Relief Valve	Qualified Service Personnel	
Clean Reservoir	User	
Yearly		
Temperature Readout Verification	Qualified Service Personnel	
As Required		
Install Paper Roll	User	
Changing Door Gasket	Qualified Service Personnel	

^{*}When processing liquid loads

Maintenance



Warning

Refer servicing to qualified personnel

Never use a wire brush, steel wool, abrasive material, or chloride-containing products to clean door and chamber assembly.

"Caution: Hot Surface. Avoid Contact." Ensure that the sterilizer is cool before cleaning to avoid burns.



Caution

Failure to keep the interior of the stainless steel chamber free of mineral deposits and debris can cause premature failure of the sterilizer.



Warning

To prevent collection of mineral deposits and corrosion of chamber components, use distilled or deionized water only as specified. Clean chamber after each use if sterilizing saline solutions.

Daily Maintenance

Cleaning Door Gasket

The door gasket and the mating surface should be wiped clean each day with a clean, damp cloth. Do not use abrasive cleaners on the gasket or mating surface.

The gasket should be examined for cracks and damage that could result in a poor pressure seal. If replacement is necessary, refer to Gasket Replacement under the When Required heading of this Maintenance section.

Cleaning After Liquid Loads

Biological media tends to boil at a higher rate than other liquids during venting. This causes media to be spattered inside the chamber. Therefore, the chamber must be cleaned daily when you are sterilizing media. Clean as follows:

- Allow unit to cool.
- Wipe out chamber and door with a clean, damp cloth.

Weekly Maintenance

(More often if necessary.)

Cleaning Chamber, Trays and Rack

At least once a week, the trays and tray rack should be removed from the sterilizer chamber. The trays, tray rack and chamber should be thoroughly cleaned to remove any deposits from the surfaces.

Clean the trays, rack and chamber (especially the bottom of the chamber) with appropriate anti-biological cleaners. Wipe all residue from the surfaces with a dampened, lint-free cloth.

MAINTENANCE



Warning

Pressurized steam will be discharged when the relief valve is opened. To prevent burns, place a steam barrier (such as a rolled towel) around the opening in the back of the unit. To prevent burns, wear gloves or use an extension device if it becomes necessary to operate the pull ring.



Note

In the event that you have lost the supplied drain tubing, you can drain the reservoir as follows:

- Tilt the front of the sterilizer up until you can access the small panel on the bottom front of the sterilizer, beneath the drain assembly.
- 2. Remove the screws securing the panel. Remove the panel.
- 3. Have a suitable container prepared for the water in the reservoir. Disconnect the reservoir drain tube from the quick disconnect fixture on the front of the sterilizer. The reservoir will drain.



Note

Do not add more than 7 liters of water to the reservoir after cleaning.

Monthly Maintenance

Pressure Relief Valve Check

To ensure that the pressure relief valve is functioning properly, you must have a qualified person check the valve each month.

The pressure relief valve is located on the pressure line in the back of the unit and is accessed through a round access hole in the back panel. A suitable tool (screwdriver, rod, etc.) will be needed to test the pressure valve.

- Run a sterilize cycle at 135°C (275°F) without a load in the chamber.
- 2. Allow the pressure in the chamber to reach 30 psi (206 kPa).
- Insert a suitable tool through the access hole and push the lever on the pressure relief valve. Push the valve lever away from the valve to open the valve. Hold the valve open for 3 seconds. Steam should discharge freely.
- 4. Release the valve lever. The steam discharge should cease entirely.
- 5. After checking the valve, turn the sterilizer off by pressing "Stop" to prevent overheating.

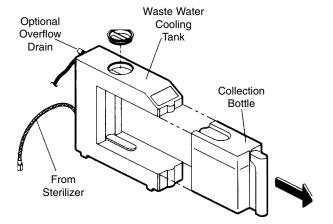
If the valve malfunctions, the valve must be replaced.

Cleaning Reservoir

- The reservoir drain assembly is located on the lower right front side of the sterilizer cabinet. Place a suitable container below the drain assembly. Connect the drain adapter and tube to the drain assembly and drain the reservoir into the container.
- When the reservoir is empty, wipe out the inside of the reservoir with a clean, lint-free cloth. Take care not to push debris back into the water line.
- Refill the reservoir with distilled or low quality deionized water (minimum 0.5 megohms/cm, maximum 1.5 megohms/cm) and replace the reservoir cover.

Emptying Collection Bottle

- Empty the collection bottle when the water in the bottle reaches the FULL mark.
- 3. Slide the bottle away from the cooling tank to remove.
- 4. Pour the contents down the drain.





Warning

BURN HAZARD: Do not empty the collection bottle when the sterilizer is in operation.



Note

It is important to periodically check the water level in the collection bottle. Failure to empty the bottle will result in water overflowing onto surrounding surfaces.

MAINTENANCE



Warning

BURN HAZARD: Do not clean the tank when the sterilizer is in operation. Allow the non-recirculating cooling tank to cool to room temperature **before** cleaning the tank.

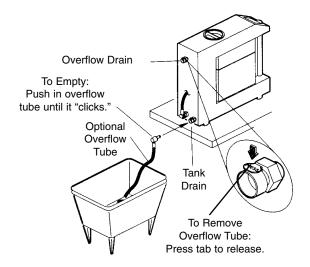
Cleaning Non-Recirculating Water Cooling Tank

The non-recirculating water cooling tank should be drained and rinsed out every six months. Do not clean the tank when the sterilizer is in operation.

Using the optional overflow tube (supplied), push the connector fitting into the drain connection at the bottom of the tank to empty it.

Remove the drain tube when the tank is empty, and rinse the tank with a solution of household bleach (3/4 cup) and distilled or deionized water (1 gal.). Drain solution and rinse with distilled or deionized water before refilling.

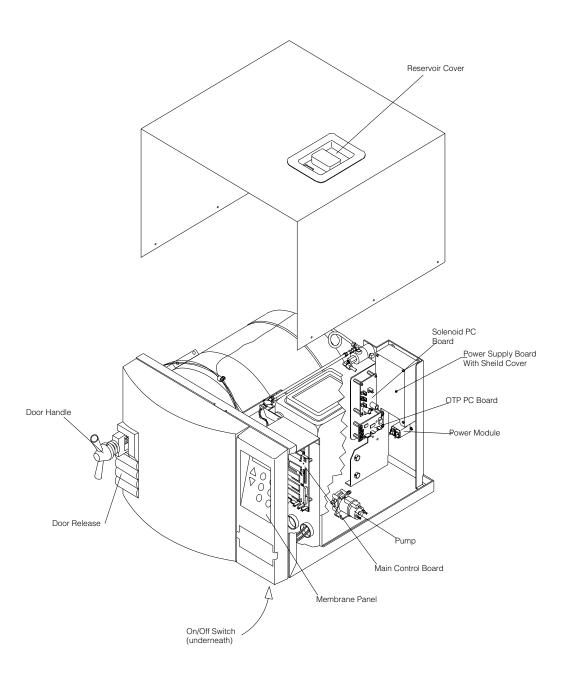
Refill the tank with clean distilled or deionized water to put the system back in service.



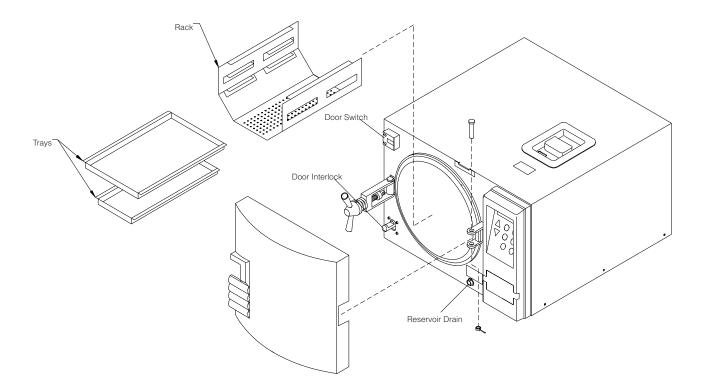
Changing Door Gasket 1. Disconnect the sterilizer from the power supply.

- 1. Disconnect the sterilizer from the power supply. Ensure that the sterilizer is cool and depressurized
- 2. Remove the old gasket by pulling it out of the
- 3. Use a warm, soapy water combination to lubricate the gasket for easier installation.
- 4. Working around the door from one point, insert the outer edge of the gasket under the machined lip of the gasket groove in the door.
- 5. Working around the door from one point, press the inner edge of the gasket into the gasket groove, ensuring that the gasket is fully seated in the groove.
- 6. Reconnect the sterilizer to the power supply.

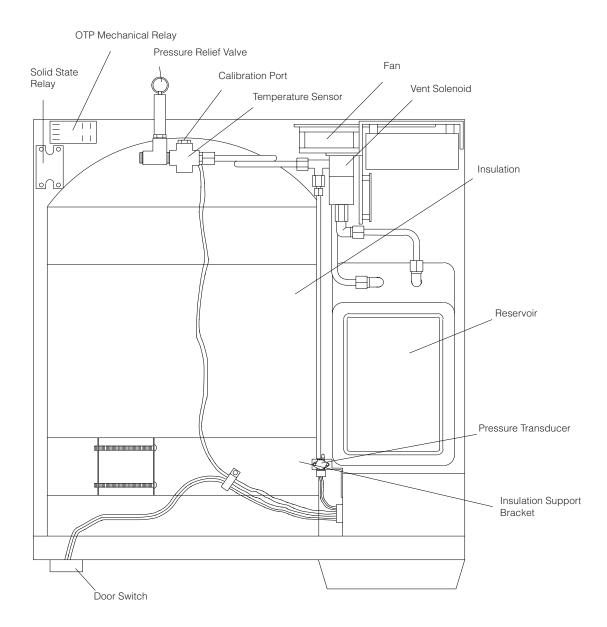
Figures



FIGURES



FIGURES



Parts List



Warning
Replace fuses with same type and rating

		<u>120 V</u>	220V~
Qty.	Description	Part No.	Part No.
1	Printer Ribbon	MZZA101055	MZZA101055
1	Printer Paper Tape Roll	MZZA101056	MZZA101056
2	Solenoid Valve	MZZA101057	MZZA101057
1	Power Supply	MZZA101058	MZZA101058
	PC Board (Solenoid)	MZZA101059	MZZA101059
	Pressure Relief Valve	MZZA101060	MZZA101060
	Tank, Lower Float	MZZA101061	MZZA101061
	PC Board (Logic)	MZZA101062	MZZA101062
	ON/OFF Switch	MZZA101063	N/A
	Terminal Strip	MZZA101065	MZZA101065
	Relay Contact	N/A	N/A
	Pump	MZZA101067	MZZA101067
	Door Gasket	MZZA101068	MZZA101068
	Fan	MZZA101069	MZZA101070
	Heater	MZZA101071	MZZA101072
	Gasket (Chamber)	MZZA101073	MZZA101073
	Relay, Solid State	MZZA101074	MZZA101074
	PC Board (OTP)	MZZA101075	MZZA101075
	Tray (Large)	MZZA101076	MZZA101076
	Tray (Small)	MZZA101077	MZZA101077
	Door Switch	MZZA101078	MZZA101078
	Membrane Panel	MZZA101079	MZZA101079
	Water Reservoir	N/A	N/A
	Safety Latch	MZZA101081	MZZA101081
	Shaft Ass'y (Main Door Latch)	MZZA101082	MZZA101082
	Pressure Pin (Door)	MZZA101083	MZZA101083
2	Handle (Yoke Assembly)	MZZA101084	MZZA101084
1	Drain Tube Assembly	MZZA101085	MZZA101085
	Reservoir Cover	MZZA101086	MZZA101086
	Chamber Temp. Sensor	MZZA101087	MZZA101087
	Automatic OTP Sensor	MZZA101088	MZZA101088
	Mechanical OTP Sensor	MZZA101089	MZZA101089
1	Pressure Transducer	MZZA101090	MZZA101090
	Fuse for TBX116	MZZA101091	MZZA101091

Ordering Procedures

Please refer to the Specification Plate for the complete model number, serial number, and series number when requesting service, replacement parts or in any correspondence concerning this unit.

All parts listed herein may be ordered from the **Thermo Scientific** dealer from whom you purchased this unit or can be obtained promptly from the factory. When service or replacement parts are needed we ask that you check first with your dealer. If the dealer cannot handle your request, then contact our Customer Service Department at 563-556-2241 or 800-553-0039.

Prior to returning any materials, please contact our Customer Service Department for a "Return Materials Authorization" number (RMA). Material returned without an RMA number will be refused.

Decontamination Statement

We cannot accept any product or component sent for repair or credit that is contaminated with or has been exposed to potentially infectious agents or radioactive materials.

No product or component will be accepted without a "Return Materials Authorization" (RMA) number.

One Year Limited Warranty

This Thermo Scientific product shall be free of defects in materials and workmanship for one (1) year from the first to occur of (i) the date the product is sold by the manufacturer or (ii) the date the product is purchased by the original retail customer (the "Commencement Date"). Except as expressly stated above, WE MAKE NO OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO THE PRODUCTS AND EXPRESSLY DISCLAIM ANY AND ALL WARRANTIES, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF DESIGN, MERCHANT ABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

An authorized representative of the manufacturer must perform all warranty inspections. In the event of a defect covered by this warranty, the manufacturer shall, as its sole obligation and exclusive remedy, provide free replacement parts to remedy the defective product. In addition, for products sold by the manufacturer within the continental United States or Canada, the manufacturer shall provide free labor to repair the products with the replacement parts, but only for a period of ninety (90) days from the Commencement Date.

The warranty provided hereunder shall be null and void and without further force or effect if there is any (i) repair made to the product by a party other than the manufacturer or its duly authorized service representative, (ii) misuse (including use inconsistent with written operating instructions for the product), mishandling, contamination, overheating, modification or alteration of the product by any customer or third party or (iii) use of replacement parts that are obtained from a party who is not an authorized dealer of Thermo Scientific products.

Heating elements, because of their susceptibility to overheating and contamination, must be returned to the factory and if, upon inspection, it is concluded that failure is due to factors other than excessive high temperature or contamination, the manufacturer will provide warranty replacement. As a condition to the return of any product, or any constituent part thereof, to the factory, it shall be sent prepaid and a prior written authorization from the manufacturer assigning a Return Materials Number (RMA) to the product or part shall be obtained.

IN NO EVENT SHALL THE MANUFACTURER BE LIABLE TO ANY PARTY FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR ANY DAMAGES RESULTING FROM LOSS OF USE OR PROFITS, ANTICIPATED OR OTHERWISE, ARISING OUT OF OR IN CONNECTION WITH THE SALE, USE OR PERFORMANCE OF ANY PRODUCTS, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT (INCLUDING NEGLIGENCE), ANY THEORY OF STRICT LIABILITY OR REGULATORY ACTION.

For the name of the authorized Thermo Scientific dealer nearest you or any additional information, contact us: