3M™ Steri-Vac™
Sterilizer/Aerator
GSX Series

Operator's Manual

3M

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Explanation of Symbols: product and package labels and pictograms

Refer to the package and product labels to see which symbols apply to specific products.

Attention - Refer to the Operator Manual for additional information.

Warning - Indicates a hazardous situation, which, if not avoided, could result in death or serious injury.

Waste Electrical and Electronic Equipment (WEEE) and EU Battery Directive. This symbol indicates that both the device and lithium ion battery contained therein need to be disposed of properly.

EO GAS STERILIZER
AS TO ELECTRICAL FIRE, SHOCK, AND
MECHANICAL HAZARDS ONLY
E160704

UL Classified to U.S. and Canadian Safety Standards.

Mark of Conformity to European Directives.

Compliant to all applicable ACMA regulatory arrangements (RCM).

Serial number - This symbol is accompanied by the serial number relevant to the device bearing the symbol.

Catalog - This symbol is accompanied by the catalog number relevant to the device bearing the symbol.

Authorized representative for the European Community – This symbol is accompanied by the name and the address of the authorized representative in the European Community.

Manufacturer – This symbol is accompanied by the name and address of the manufacturer.

Date of Manufacture - This symbol is accompanied by the date of manufacture.

Do not top load.

Lift with forklift.

Fragile.

Keep dry.

This way up.

Pictograms are documented according to the European Union (EU) Classification Labeling and Packaging (CLP) Regulation and the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals.

Flame - Flammable Gas: Category 1

Skull and Cross Bones - Acute Toxicity (inhalation): Category 3

Health Hazards

Classification Labeling and Packaging (CLP) Regulation

Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319

Skin Corrosion/Irritation, Category 2 - Skin Irrit. 2; H315

Carcinogenicity, Category 1B - Carc. 1B; H350

Germ Cell Mutagenicity, Category 1B - Muta. 1B; H340

Specific Target Organ Toxicity-Single Exposure, Category 3 - STOT SE 3; H335

Globally Harmonized System (GHS) of Classification and Labeling of Chemicals

Specific Target Organ Toxicity (single exposure): Category 1

Specific Target Organ Toxicity (repeated exposure): Category 1

Specific Target Organ Toxicity (central nervous system): Category 3

Carcinogenicity: Category 1A

Reproductive Toxicity: Category 2

Germ Cell Mutagenicity: Category 1B

Eye Irritation: Category 2A

Skin Irritation: Category 2

Additional pictograms for Globally Harmonized System (GHS) of Classification and Labeling of Chemicals

Gas Cylinder - Gas Under Pressure: Liquefied Gas

The gas cylinder pictogram applies to Globally Harmonized System (GHS) of Classification and Labeling of Chemicals. The gas cylinder is not applicable where the European Union (EU) Classification Labeling and Packaging (CLP) Regulation applies.

Exclamation Mark - Irritant, Acute toxicity (harmful) Respiratory Tract, Irritation

The exclamation mark in red border pictogram applies to Globally Harmonized System (GHS) of Classification and Labeling of Chemicals. The exclamation mark in red border is not applicable where the European Union (EU) Classification Labeling and Packaging (CLP) Regulation applies.

Explanation of Symbols: Operator Manual

⚠ **Danger:** Indicates a hazardous situation which, if not avoided, will result in death or serious injury.

⚠ **Warning:** Indicates a hazardous situation, which, if not avoided, could result in death or serious injury.

⚠ **Caution:** Indicates a hazardous situation, which, if not avoided, could result in minor or moderate injury.

NOTICE: Indicates a hazardous situation which, if not avoided, may result in property damage.

Content Disclaimers

Pictorial Disclaimer

Sample printouts, graphics, displays and screens are for information and illustration purposes only and shall not be used for clinical or maintenance evaluations. Data shown in sample printouts and screens do not reflect actual names or test results.

Hardware Disclaimer

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series hardware and software are subject to change. The system images, screen images, hardware components, and hardware specifications included in the manual may not match the system as installed. In the event that hardware or software changes are made, 3M will verify their compatibility with the functionality described in this document.

Serial Number

For easy identification, each 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series has a unique serial number printed on the serial label (e.g. EA343434) found on the right side of the unit and displayed on the printout for each cycle completed. Record your serial number in this manual for future reference: _____.

1. Description

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series is for use in industrial sterilization, research, lab, veterinary surgical and other appropriate settings. When installed, operated and maintained as described in this Operator Manual, the equipment is safe and effective. All Operators must be fully trained in the recommended operation of this device.

The GSX Series sterilizer utilizes an embedded software controlled system to ensure that specified sterilization conditions are met and to minimize the possibility of operator exposure to ethylene oxide (EO) gas. Use of this equipment in a manner not specified by 3M has not been evaluated and may lead to an unsafe condition.

The GSX Series sterilizer, with the 3M™ Cycle Programmer, provides the user with options to develop optimized and unique EO processes specialized and tailored to the user's specific product requirements (e.g. drug-device combination products). The 3M Cycle Programmer allows programming of 28 different parameters in eight of the nine active stages of the EO sterilization process and operates on a personal computer (PC) supplied by the user. Custom cycles are created with the 3M Cycle Programmer and imported to the GSX Series sterilizer using a USB drive. Alternatively, the user can choose to operate the GSX Series sterilizer by using the two 3M validated preprogrammed sterilizer cycles, GSX 38C and GSX 55C. The user can also choose to develop a combination cycle containing preprogrammed and customized cycle parameters to meet the configuration of their product design. The GSX Series sterilizer can automatically aerate the processed load in the sterilization chamber after sterilization. If preferred, the load can be transferred to the 3M™ Steri-Vac™ XL Aerator, aeration cabinet, or aeration room for aeration thereby releasing the sterilizer for the next load.

The 3M Cycle Programmer operates on an independent PC computer supplied by the user. Custom cycles are created within the 3M Cycle Programmer and are imported to the GSX Series sterilizer from a USB drive. The 3M Cycle Programmer will not function directly on the GSX Series sterilizer.

The GSX Series sterilizer contains two preprogrammed cycles, GSX 38C and GSX 55C, that can be selected and used without modification by the end user. The critical sterilization process set points (e.g. temperature, humidity level, sterilant concentration, exposure time) for these preprogrammed cycles are identical to the critical process set points in the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series, Models GS5 and GS8, and have been validated per US FDA Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities reference 510(k) number K142034. These critical sterilization process parameters and set points for the preprogrammed cycles are documented in Table 1. The end user is responsible for determining if these preprogrammed cycles are suitable for their specific application, with regards to safety and efficacy, and for any verification or validation documentation required for their application.

Preprogrammed Cycle	Process Temperature (°C)	Process Relative Humidity %RH	EO Gas Concentration* (mg/L)	EO Exposure Time (hour + min)	Aeration Temp (°C)	Aeration Time (hours)
GSX 38C	38 ± 3	40 - 80	GS5X w/ 4-100 = 735	4.5 hr ± 5.4 min	38 ± 3	Programmable by the Operator
			GS5X w/ 4-134 = 934			
			GS8X w/ 4-100 = 446			
			GS8X w/ 4-134 = 567			
			GS8X w/ 8-170 = 759			
GSX 55C	55 ± 3	40 - 80	GS5X w/ 4-100 = 735	1.0 hr ± 1.2 min	55 ± 3	
			GS5X w/ 4-134 = 934			
			GS8X w/ 4-100 = 446			
			GS8X w/ 4-134 = 567			
			GS8X w/ 8-170 = 759			

* EO Gas Concentration is calculated by dividing the 3M™ Steri-Gas™ EO Gas Cartridge nominal fill weight by the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series chamber volume. Data supplied above is based on an empty chamber.

Table 1. Preprogrammed Critical Cycle Parameters for GSX Series Sterilizers

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series' ethylene oxide (EO) sterilization cycles consist of ten stages. After the sterilization cycle is complete, an aeration cycle is required to remove any residual EO from the medical devices per manufacturers' instructions for use (IFUs).

An EO sterilization cycle is defined as a treatment in a sealed, temperature-controlled chamber comprised of air removal, conditioning, and injecting of EO, exposure to EO, removal of EO and flushing, aerating, and air admission allowing the opening of the chamber door. Figure 1 is a graph of a Pressure Profile of the cycle stages of a GSX Series sterilizer EO sterilization cycle.

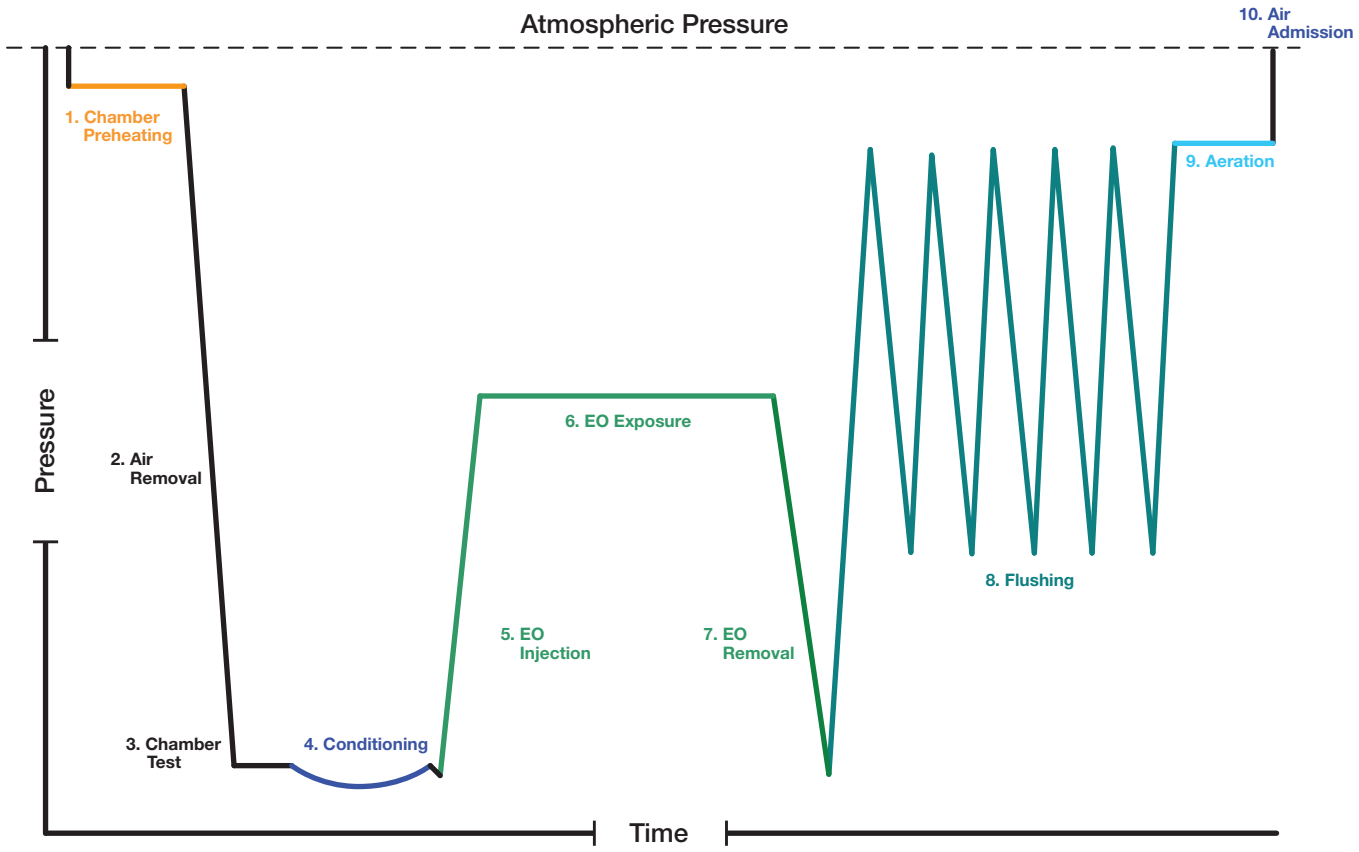


Figure 1.
Pressure Profile GSX Series Sterilizer EO Sterilization Cycle

2. Intended Use

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series is intended for the development and validation of ethylene oxide (EO) sterilization process parameters used in product development and manufacturing and for routine sterilization of products that require 100% ethylene oxide sterilization in the manufacturing process. The GSX Series sterilizer is not intended for use in health care facilities.

Always obtain, understand, and follow national and local regulations before installing a GSX Series sterilizer.

⚠ CAUTION: To reduce the risk of injury,

always follow the procedures described in this manual.

3. Safety

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series was developed with the safety of operators and patients in mind. The GSX Series sterilizers are designed with state-of-the-art safety features that include:

- Hardware and mechanical components of the GSX Series sterilizers meet or exceed the compliance requirements of current, recognized national and international safety standards including applicable sections of IEC/EN61010-1, ANSI/AAMI ST24, and EN1422.
- The sterilization process is performed completely under a vacuum. If the system integrity is compromised during ethylene oxide (EO) gas exposure, room air will enter the chamber. In this situation, the system will detect a rise in pressure and will safely cancel the cycle when the system cannot maintain a vacuum. Sterilization and aeration can be conducted within the same chamber. Aeration in the sterilization chamber eliminates the need to transfer product loads outside the sterilization chamber when longer aeration times are required.
- EO sterilant is delivered in single-dose cartridges placed inside the sterilization chamber. The use of single-dose cartridges reduces the risk of leaking ethylene oxide delivery lines and EO tank changes and provides increased control of sterilant quality.
- GSX Series sterilizers are designed with an internal processor that automatically controls and independently monitors the physical process parameters to ensure sterilization conditions are maintained throughout the sterilization cycle. The GSX Series sterilizers' embedded software regulates, independently monitors, and records critical sterilization process parameters including pressure, temperature, and percent relative humidity (%RH) during conditioning.
- Automatic fault notification and safe state recovery processes provide additional protection for the Operator. If the GSX Series sterilizer detects a cycle fault, an error message will alert the Operator. Additionally, an optional audible notification will accompany the error code message. Immediately after detecting a fault, the GSX Series sterilizer will automatically complete an error recovery process to bring the sterilizer to a safe-state prior to further action.
- GSX Series sterilizers are designed with a state-of-the-art proprietary humidification process. In the Conditioning stage of the sterilization cycle, GSX Series sterilizers contain a custom 3M designed humidification process that adds, measures, adapts, and controls %RH to accommodate different loads and packaging materials to achieve proper humidification prior to EO gas injection.
- Control and monitor sensors detect critical sterilization process parameters. GSX Series sterilizers have control sensors for temperature, %RH, and pressure that provide information to the control embedded software. The sterilizer has a duplicate set of monitoring sensors that provide independent data and performance monitoring to an independent monitoring processor during critical sterilization stages for temperature, %RH, and pressure.
- Over-the-door vent hood (i.e. exhaust hood) supplements the room's directional air flow, and draws air away from Operators removing a load from the chamber.
- The GSX Series sterilizers are designed with a specialized disposal cycle for full damaged, expired, or excess 3M™ Steri-Gas™ EO Gas Cartridges. The Cartridge Dispose Cycle is a custom, abbreviated cycle that safely empties and aerates the Steri-Gas EO Gas Cartridges at a rate of one per cycle. Disposal cycles have restricted access to a Supervisor PIN only.

The GSX Series sterilizers and their related devices and accessories are designed to provide safe and reliable service when used according to the provided instructions for use. Please read, understand, and follow all safety information contained in the instructions for use prior to using a sterilizer. Use this equipment only for the purpose described in this Operator Manual. Retain these instructions for future reference. If this equipment is used in a manner not specified, the protection provided by the equipment may be impaired.

It is the user's facility management's responsibility to ensure that all personnel who operate or maintain the equipment are trained in its operation and safe use. There are no formal safety inspections required by the Operator. It is the user's facility management's responsibility to assure safety inspections are complete. Contact your local 3M Health Care service personnel or authorized 3M service personnel for required safety inspections.

The user's facility management has the responsibility to provide Operators and staff with the appropriate mitigations for safety regarding the configuration of the process parameters and the operation of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. These mitigations include end user validation of custom cycles and the identification, training, and use of appropriate protective measures (e.g. engineering controls, work practices, or personal protective equipment (PPE)); instruction for use of the equipment, with custom process parameters as defined by the end user, and comprehensive instruction regarding ethylene oxide (EO), including information on relevant health hazards, national regulations, methods for safe use, and methods to detect escape of the agent.

⚠ **DANGER: To reduce the risks associated with exposure to ethylene oxide:**
Short term exposure limits (STEL) or long term exposure limits (LTEL) or immediately dangerous to life or health (IDLH) levels could be exceeded during NORMAL use. The user's facility management is responsible for providing Operators, staff, and personnel working with 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series equipment comprehensive instructions in the process. This instruction includes information on relevant health hazards.
It is the user's facility management's responsibility to ensure that all personnel working with toxic chemicals, gases, and vapors are given comprehensive instruction in their use. This instruction includes information on relevant health hazards, national regulations, methods for safe use, and methods to detect the escape of the agent.
It is the user's facility management's responsibility to ensure regular training of all personnel involved with the operation and maintenance of the equipment, including emergency procedures for any toxic, flammable, or explosive material released into the environment and to maintain records of attendance and evidence of demonstrated understanding from training sessions.

National regulation regarding limitations on airborne EO concentration in the workplace exist in the United States. Many countries outside of the US have regulations regarding limitations of EO concentration the workplace as well.

User's facility management shall identify and validate appropriate engineering controls, work practices, personal protective equipment (PPE) and training requirements for Operators and staff prior to running a custom cycle. Prior to the user's facility management exposure assessment, EO levels may be at or above IDLH (Immediately Dangerous to Life or Health) limits. User's facility management shall provide protective measures in accordance with United States 29 CFR 1910.134 and 29 CFR 1910.1047 until validation of facility procedures that meet national, state, and local requirements for short term exposure limits (STELs) and long term exposure limits (LTELs).

Good practice should include a risk analysis of the EO gas sterilization processes, a written Emergency Response Plan, and an Employee Notification plan for EO leaks.

The following warnings and precautions should be observed to avoid unsafe actions that could result in personal injury or damage to the instrument.

4. Dangers and First Aid

⚠ DANGER: Potential health effects of ethylene oxide

Users in the United States must follow the requirements of the United States Occupational Exposure Standard for Ethylene Oxide OSHA (29 CFR 1910.1047). 100% ethylene oxide (EO) CAS number 75-21-8 is a colorless gas at ambient conditions. Do not rely on sense of smell for the detection of ethylene oxide. EO has a high odor threshold and can only be detected by sense of smell when it exceeds 500 - 750 parts per million (PPM). EO has a characteristic ether-like odor (i.e. a sweet and irritating solvent smell).

4.1. Dangers

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide:
Short term exposure limits (STEL) or long term exposure limits (LTEL) or immediately dangerous to life or health (IDLH) levels could be exceeded during NORMAL use. The user's facility management is responsible for providing Operators, staff, and personnel working with 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series equipment comprehensive instructions in the process. This instruction includes information on relevant health hazards.
Short term exposure limits (STEL) or long term exposure limits (LTEL,) or immediately dangerous to life or health (IDLH) limit could be exceeded during NORMAL use. Operators and staff must use protective measures (e.g. engineering controls, work practices, or personal protective equipment (PPE)) in accordance with United States 29 CFR 1910.134 and 29 CFR 1910.1047 under NORMAL use conditions until the user's facility management completes an exposure assessment on each custom cycle validating facility protective measures meet national, state, and local requirements for short term exposure limits (STELs) and long term exposure limits (LTELs).
Ensure Operator selects the correct cycle for the intended application.
Ensure a minimum of ten (10) air exchanges per hour (ACH's) for the room in which the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series is installed.
Inspect display screen and cycle reports for error codes and listen for audible notifications (if enabled). Always take action for error codes as indicated in this manual.
For reusable device sterilization, always follow device manufacturer's instructions for use (IFU), including device cleaning, drying, packaging, sterilizing, and aerating.
Do not overload the sterilization chamber. Use good practices for loading the sterilizer chamber.
Never use force to access the inside of the sterilization chamber.
Always review the elapsed aeration time on the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series display prior to opening the sterilizer door.
Always inspect cycle reports (printout or electronic) to ensure the total aeration time matches the device manufacturer's instructions for use (IFU) or as programmed by the Operator.
Do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series outside specified environmental conditions as stated in this manual.
Only use 3M™ Steri-Gas™ EO Gas Cartridges as listed in this manual. Do not use other brands or types of sterilant cartridges.
Do not force the 3M™ Steri-Gas™ EO Gas Cartridges into the cartridge holder as excessive force could damage the cartridge and result in a cartridge leak.
Do not use damaged 3M™ Steri-Gas™ EO Gas Cartridges.
If an individual 3M™ Steri-Gas™ EO Gas Cartridge is ever dropped, the cartridge should be used immediately or disposed of as described in the cartridge disposal section of this manual.
Sterilize only medical devices manufactured with materials compatible with ethylene oxide (EO) sterilization processes. Do not sterilize leather, liquids, or materials reactive to EO.
Ensure that the compressed air supply is clean, with a maximum allowable dirt particle size of 0.5 microns, and that the air supply is free of oil. Ensure that the air filters on the compressed air supply contain a water trap and are cleaned daily (if applicable) and are properly maintained.
Call 3M Health Care service personnel or authorized 3M service personnel immediately if there is a failure of the display or backlight and the sterilizer continues to operate.
It is the user's facility management's responsibility to ensure that all personnel working with toxic chemicals, gases, and vapors are given comprehensive instruction in their use. This manual includes information on relevant health hazards, national regulations, methods for safe use, and methods to detect escape of the agent.
It is the user's facility management's responsibility to ensure regular training of all personnel involved with the operation and maintenance of the equipment, including emergency procedures for any toxic, flammable, or explosive material released into the environment and to maintain records of attendance and document evidence of demonstrated understanding from training sessions.

4.2. First Aid

Inhalation:

Move person to fresh air and seek medical attention.

Skin or Clothing Contact:

Immediately wash with soap and water. Remove contaminated clothing and wash clothing before reuse. If signs/symptoms develop, seek medical attention.

Eye Contact:

Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do so. Continue rinsing. Immediately seek medical attention.

If Swallowed:

Rinse mouth. DO NOT INDUCE VOMITING. Immediately seek medical attention.

Hazard statements of ethylene oxide (EO):

- Extremely flammable gas
- Contains gas under pressure, may explode if heated
- Toxic if inhaled
- Causes serious eye irritation
- May cause drowsiness or dizziness
- Suspected of damaging fertility or an unborn child
- May cause cancer
- May cause genetic defects

Consult the 3M™ Steri-Gas™ EO Gas Cartridge Safety Data Sheet (SDS) for additional information (www.3M.com).

5. Warnings

⚠ WARNING: To reduce the risks associated with fire and explosion:

3M™ Steri-Gas™ EO Gas Cartridges contain 100% ethylene oxide (EO) which is an extremely flammable gas and a liquid under pressure. Do not use near flame, electrical sparks, hot surfaces, or allow sources of ignition near the cartridges. Do not puncture cartridge outside the sterilization chamber. Do not incinerate cartridges. Exposure to temperatures above 150ºF (65.5ºC) may cause cartridge to burst.

3M™ Steri-Gas™ EO Gas Cartridge Catalog Number	3M™ Steri-Vac™ Sterilizer GSX Series Model	Nominal Net Weight of Ethylene Oxide (EO)
4-100	GS5X or GS8X	EO net wt. 100 g. (3.52 oz.)
8-170	GS8X	EO net wt. 170 g. (5.99 oz.)
4-134	GS5X or GS8X	EO net wt. 127 g. (4.47 oz.)
4-60	GS5X or GS8X	Custom EO net wt.

Do not sterilize devices with energy sources which could create a spark in the sterilization chamber during the sterilization cycle.

For reusable device sterilization, always follow device manufacturer's instructions for use (IFU), including device cleaning, drying, packaging, sterilization, and aeration.

Inspect display screen and cycle reports for error codes and listen for audible notifications (if enabled). Always take action with error codes as indicated in this manual.

Do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. Operators should not service the GSX Series sterilizer as there are no user serviceable parts.

⚠ WARNING: To reduce the risk of shock due to hazardous voltage:

Do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. Operators should not service the GSX Series sterilizer as there are no user serviceable parts.

Customer must provide a properly grounded outlet (an earth ground) for installation as described in the installation requirements section of this manual.

Do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series outside the environmental conditions as stated in this manual.

Use only 3M Health Care service personnel or authorized 3M service personnel for installation and maintenance.

Do not modify any part of 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series.

6. Cautions

⚠ CAUTION: To reduce the risk of injury:
Always follow the procedures described in this manual.
Follow good ergonomic practices. Loading baskets should not be overfilled requiring excessive force in pulling and pushing loaded baskets in and out of the sterilizer chamber. Reference facility policies and procedures for appropriate ergonomic practices.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures:
The user must validate the sterile efficacy of each custom cycle intended to sterilize products that are labeled as 'Sterile'.
Ensure Operator selects the correct cycle for the intended application.
Inspect display screen and cycle reports for error codes and listen for audible notifications (if enabled). Always take action for error codes as indicated in this manual.
Always use chemical indicators and biological indicators for monitoring the performance of sterilization cycles as described in this manual. Always use chemical indicators and biological indicators per the device manufacturer's instructions for use (IFU).
Always inspect cycle reports (printout or electronic file) to ensure the Operator's programmed parameters or the device manufacturer's instructions for use (IFU) matches: • %RH at the End of Conditioning, • Temperature at the End of Conditioning, • Actual Gas Exposure Time.
Complete maintenance at routine scheduled intervals of a maximum of every six (6) months. There are no user-serviceable parts. Only use 3M Health Care service personnel or authorized 3M service personnel for maintenance.
For reusable device sterilization, always follow device manufacturer's instructions for use (IFU), including device cleaning, drying, packaging, sterilization, and aeration.
Do not overload the sterilization chamber. Use good practices for loading the sterilizer chamber.
Sterilize only medical devices manufactured with materials compatible with ethylene oxide (EO) sterilization processes. Do not sterilize leather, liquids, or materials reactive to EO.
Only use 3M™ Steri-Gas™ EO Gas Cartridges as listed in this manual. Do not use other brands or types of sterilant cartridges.
Do not force the 3M™ Steri-Gas™ EO Gas Cartridges into the cartridge holder. Excessive force could damage the cartridge and result in a cartridge leak.
Do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series outside the environmental conditions as stated in this manual.
Immediately call 3M Health Care service personnel or authorized 3M service personnel if there is a failure of the display or backlight and the GSX Series sterilizer continues to operate.
Do not modify any data or records from the sterilizer system which may lead to misinterpretation of physical monitor results.
Do not place any device emitting strong electronic magnetic fields (EMFs) near the sterilizer.

7. Specifications

7.1. 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series Structural Specifications

	GS5X	GS8X
Operational Weight	127 kg (281 lbs.) single door 132 kg (290 lbs.) double door	261 kg (576 lbs.) single door 269 kg (593 lbs.) double door
Exterior Dimensions	H 70.9 cm x W 76.2 cm x D 95.0 cm H 27.9 in. x W 30.0 in. x D 37.4 in.	H 179.8 cm x W 94.0 cm x D 109.0 cm H 70.8 in. x W 37.0 in. x D 42.9 in.
Chamber Internal Volume	136 L (4.8 cubic feet)	224 L (7.9 cubic feet)
Chamber Internal Dimensions	H 38.0 cm x W 43.0 cm x D 83.0 cm H 15.0 in. x W 17.0 in. x D 32.5 in.	H 46.0 cm x W 51.0 cm x D 97.0 cm H 18.0 in. x W 20.0 in. x D 38.0 in.

7.2. Sound Power Levels Specifications

	GS5X	GS8X
A-weighted	< 85 dBa	< 85 dBa

7.3. Power Specifications

⚠ WARNING: To reduce the risk of shock due to hazardous voltage,

the customer must provide a properly grounded outlet (an earth ground) for installation as described in the installation requirements section of this manual.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,

do not place any device emitting strong electronic magnetic fields (EMFs) near the sterilizer.

Electrical Power	Operating Condition	Units
Voltage Range	200 - 240	VAC
Frequency	50/60	Hertz
Phase	Single	Not Applicable
GS5X Current	7	Amps
GS8X Current	12	Amps

7.4. Air Supply Specifications

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide,

ensure that the compressed air supply is clean, with a maximum allowable dirt particle size of 0.5 microns, and that the air supply is free of oil. Ensure that the air filters on the compressed air supply contain a water trap and are cleaned daily (if applicable) and are properly maintained.

Air Supply Feature	Specification
Pressure	7.0 kg/cm^2 (100 psig) minimum to 10.5 kg/cm^2 (150 psig) maximum
Flow Rate	2.2 liters per second at 5.3 kg/cm^2 (4.7 standard cubic feet per minute at 75 psig) per sterilizer based on 100% duty cycle compressor
Quality	Clean air supply with a maximum allowable dirt particle size of 0.5 microns and free of oil
Moisture Content	Less than 10°C (50°F) dew point

8. Compliance and Reference Standards

8.1. Device Safety Compliance

Ethylene oxide (EO) sterilizers, for use in industrial applications, (i.e. outside a health care facility) are not regulated as medical devices by the United States FDA; therefore, they are not eligible for 510(k) review and clearance.

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series complies with the following standards as demonstrated by the CB Scheme Certificate and test report issued by the Underwriters Laboratories (UL):

- IEC / EN 61010-1 (2001) Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
- IEC / EN 61010-2-010 (2003) Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.
- IEC / EN 61010-2-040 (2005) Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical devices. The following clauses were not evaluated as part of the IEC 61010-2-040: Clause 13.1, 13.1.101.2, 13.1.101.4, 13.1.102, 13.1.103.2, 13.1.103.3, 13.101.

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series is listed as Laboratory Electrical Equipment for Use in Health Care Applications (Certified for Canada) and carries the UL mark with adjacent indicators "C" and "US" based on compliance to the standards UL 61010-1 and CAN/CSA 22.2 No. 61010-1.

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series complies with the CE mark related to the Low Voltage Directive (LVD) 2006/95/EC as confirmed in the Declaration of Conformity.

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series complies with the RoHS Directive, Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

In the European Union, the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series are certified as exempt from the scope of the ATEX Directive.

8.2. Electromagnetic Compatibility (EMC) Compliance

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series complies with the following EMC standards as confirmed in the Certificate of Compliance generated by 3M:

IEC 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series complies with the EMC requirements of the CE mark EMC Directive 2004/108/EC.

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series complies with the Australian EMC requirements as confirmed in the Supplier's Declaration of Conformity that is linked to the RCM Mark.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide a reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates and can radiate radio frequency energy; and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his/her own expense. In addition, operation of this device must accept any interference received, including interference that may cause undesired operation.

This Class A digital equipment meets all requirements of the Canadian Interference-Causing Equipment Regulations.

9. Installation and Set Up

To ensure proper operation of this equipment and Operator safety, the 3M™ Steri-Vac™ Site Planning and Installation Guide must be followed and the equipment must be installed by authorized 3M service personnel. To arrange installation, contact your local 3M subsidiary (www.3m.com)

⚠ WARNING: To reduce the risk of shock due to hazardous voltage,

only use 3M Health Care service personnel or authorized 3M service personnel for installation and maintenance.

9.1. Environmental Operating Conditions

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide,

do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series outside the environmental conditions as stated in this manual.

⚠ WARNING: To reduce the risk of shock due to hazardous voltage,

do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series outside the environmental conditions as stated in this manual.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,

do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series outside the environmental conditions as stated in this manual.

Environmental Condition	Operating Condition	Units
Altitude	2500 (max)	Meters
*Operating Temperature	15 - 35	ºC
Operating Relative Humidity	20 - 80 (non-condensing)	%RH
Installation/ Transient Over Voltage	Category II	
Pollution Degree	2	

***Note:** Operating the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series in a temperature environment that is close to the sterilization process temperature set point (e.g. 35ºC operating environment and a 38ºC sterilization process temperature set point) may result in a temperature fault during the sterilization process.

9.2. Room and Installation Requirements

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide,

ensure a minimum of ten (10) air exchanges per hour (ACHs) for the room in which the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series is installed.

Location	Do not place the sterilizer or ethylene oxide (EO) cartridges in an area of possible ignition sources. ONLY USE INDOORS.
Room Size	Greater than 30m^3 (1,000 ft^3)
Spacing	Allow 51cm (20 inches) of clearance space at the top, rear, and sides of the sterilizer for maintenance and service and a minimum of 10 cm (4 inches) from the rear wall for single door units. Ensure sufficient space
Ventilation	Negative pressure with a minimum of ten (10) air exchanges per hour. The ventilation system should be non-recirculating and dedicated.
Air Flow	Air flow washes the entire room. Air movement is away from the sterilizer Operator. See Figure 2.

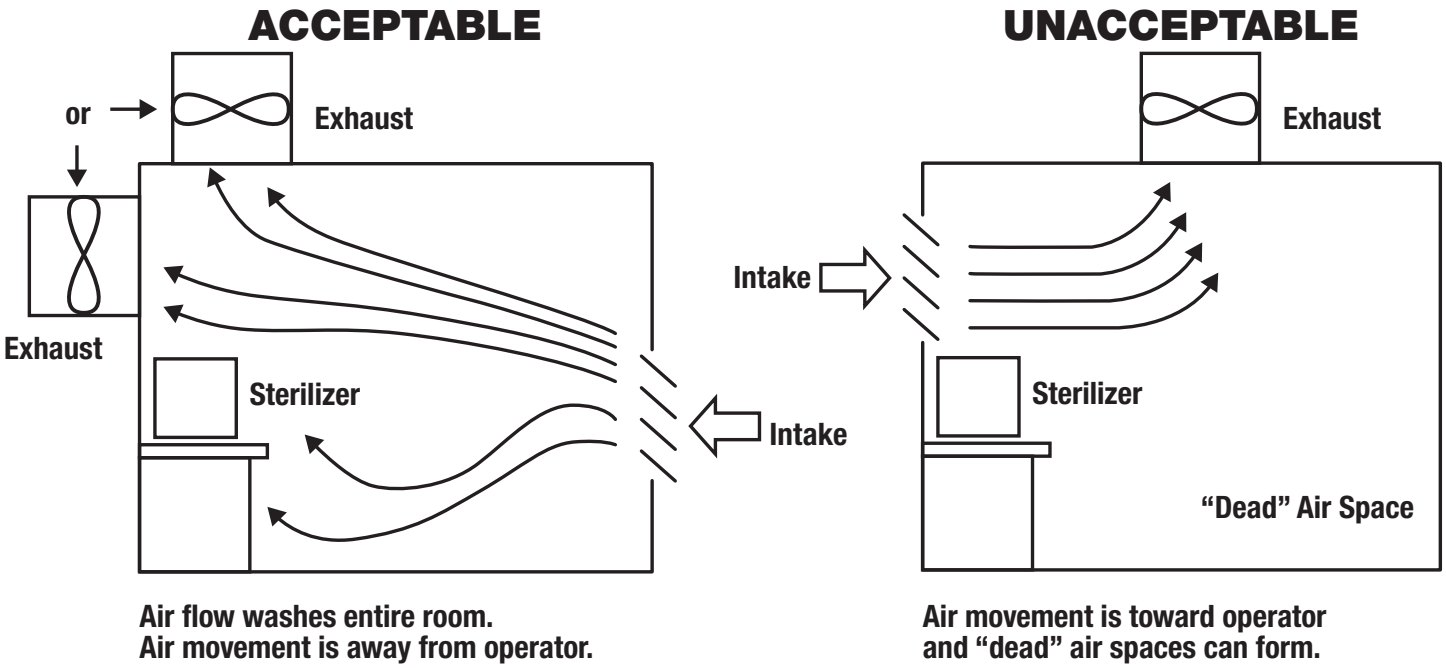


Figure 2.
Acceptable and Unacceptable Installation Air Flow

9.3. Set up and Connections

Figures 3 - 7 illustrate the components and connections for the 3M™ Steri-Vac™ Sterilizer/Aerator Series, Models GS5X and GS8X. Table 3 contains additional details regarding specific components and connections for the GSX Series Models GS5X and GS8X.

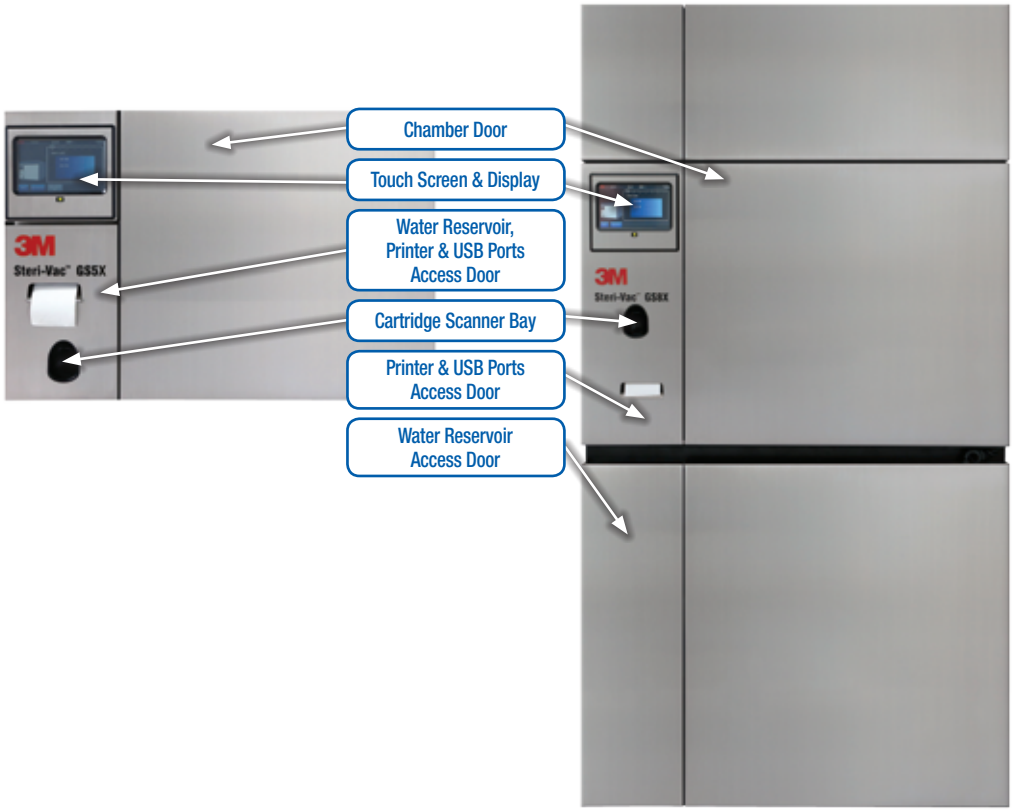


Figure 3.
Front View 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series, Models GS5X & GS8X

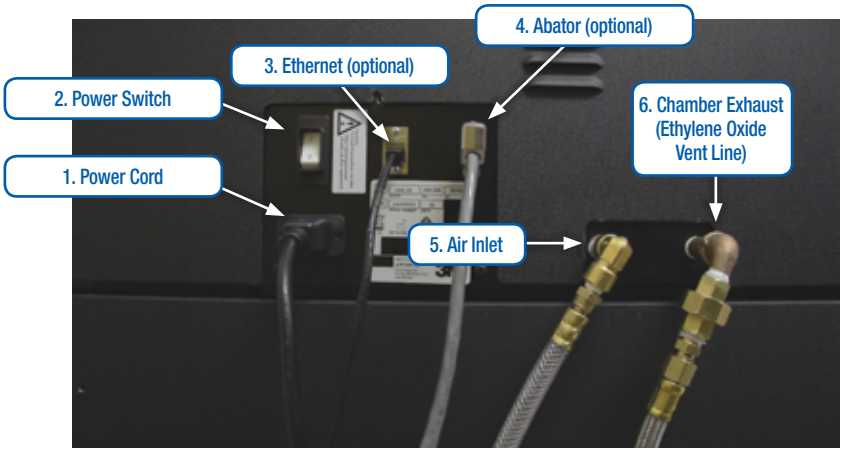


Figure 4.
Left Side Connections - 3M™ Steri-Vac™ Sterilizer/ Aerator GSX Series

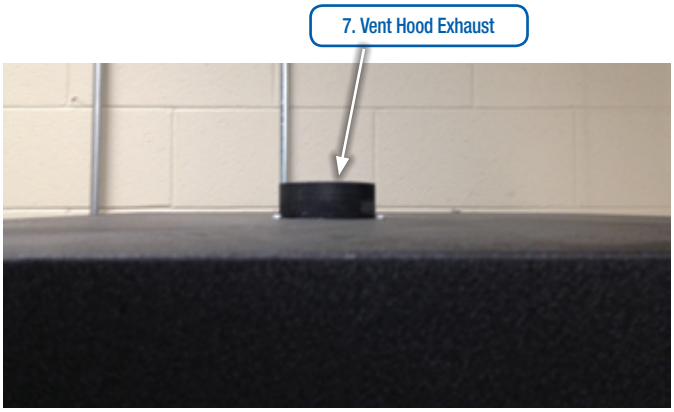


Figure 5.
Top Connection - 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series

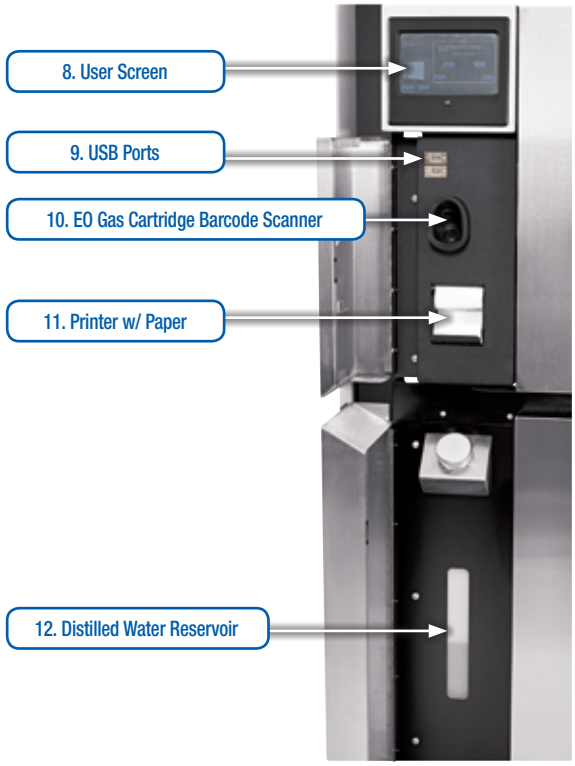


Figure 6.
Front Panel, 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series, Model GS8X

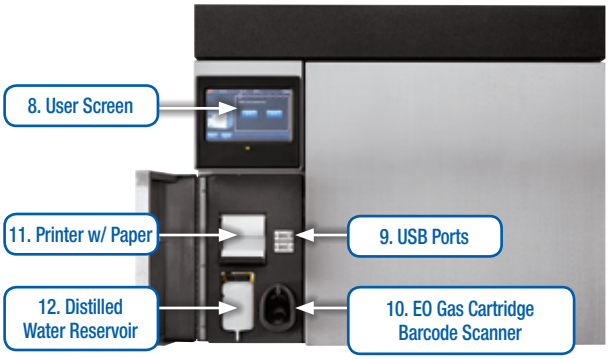


Figure 7.
Front Panel, 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series, Model GS5X

Connection or Component Number	Connection or Component Name	Connection or Component Description
1	Power Cord	Use the supplied power cord for connection of the system to a properly grounded outlet as specified in the 3M™ Steri-Vac™ Site Planning and Installation Guide. Ensure there is adequate space at installation to disconnect the power cord when required.
2	Power Switch	The power switch turns power to the GSX Series sterilizer OFF and ON. The switch is intended to remain ON at all times in order to simplify operation and to allow the sterilizer electronics to continually monitor sterilizer functions. It is recommended to keep the power ON at all times unless otherwise instructed by 3M Health Care service personnel or authorized 3M service personnel.
3	Ethernet	The Ethernet connection is not required for normal operation of the system. Connecting to Ethernet provides 3M Health Care Service with a means to access Service diagnostic information on the GSX Series sterilizer from a desktop computer located on-site within the clinic network. 3M Health Care Service can access cycle information, reports (e.g. calibration, site setup) and service diagnostic information directly on the sterilizer. Devices connected to the Ethernet port must be 60950-1 (General Requirements for Information Technology Safety) compliant. Do not connect devices that are not compliant to 60950-1. Reference Chapter 13 for additional information.
4	Abator	The Abator connection is only provided for connection to an emission control device (i.e. an EO Abator), only if such a device is required by local laws/codes. Do not connect any other device to this connector. Abator connection is for sterilizer communication to an emission control device. Abator installation may be optional and not required for the normal operation of the system but is required in some localities. The Abator connection is intended to only be made by 3M Health Care service personnel or authorized 3M service personnel during installation.
5	Air Inlet	Air inlet is for the connection of the compressed air supply per Chapter 9 and is intended to only be made by 3M Health Care service personnel or authorized 3M service personnel.
6	Chamber Exhaust (Ethylene Oxide Vent Line)	Connect the GSX Series sterilizer to a dedicated vent line in order to exhaust ethylene oxide (EO) to the outside atmosphere or to an emission control device, an EO Abator. The requirements for venting the sterilizer must be met as documented in the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series Site Planning and Installation Guide and is intended to be made only by 3M Health Care service personnel or authorized 3M service personnel.
7	Vent Hood Exhaust	The over-the-door vent hood (i.e. exhaust hood) supplements the room's directional air flow and is designed to draw air away from Operators removing a load from the chamber. The hood is connected by 3M Health Care service personnel or authorized 3M service personnel to a customer supplied dedicated exhaust system during installation of the sterilizer. The vent hood (i.e. exhaust hood) is monitored for an adequate standard cubic feet per minute (SCFM) air flow rate. If the sterilizer detects the air flow is too low (< 125 SCFM) through the vent hood, the sterilizer door will remain locked until a minimum of three (3) hours of aeration is fulfilled. Monitoring of the vent hood air flow is optional and can be disabled by an authorized 3M service provider in the **Site Setup<Setup Tab - Options** Set (Figure 24. Chapter 10). If vent hood monitoring is disabled, there will be no caution message if the air flow SCFM is too low (< 125 SCFM) and the sterilizer door will remain locked until a minimum of three (3) hours of aeration is fulfilled.
8	User Screen	User and display screen for the Operator interface with the sterilizer control features. See Chapter 10 for more details.
9	USB Ports	The USB ports are available for Universal Serial Bus (USB) drives to export multiple types of cycle reports, sterilizer and cycle settings, and to load and remove custom cycles programmed on the 3M™ Cycle Programmer. See Chapter 11 for more details. Recommended USB drives include drives with FAT32 formatting. Drives with pre-loaded software (e.g. SanDisk's Cruzer®) are not recommended. Only USB drives, for the sole purpose of exporting and importing data and cycles, are to be connected to the USB ports. Do not connect external USB devices that supply power. See Chapter 11 for more details.
10	3M™ Steri-Gas™ EO Gas Cartridge Barcode Scanner	Location of cartridge scanner bay. Scanning the 3M™ Steri-Gas™ EO Gas Cartridge bar code ensures that the cartridge is valid for use. See Chapter 13 for more details.
11	Printer w/ Paper	The built-in printer provides easy-to-read information for each sterilization cycle. The printer can also be used to print multiple types of cycle reports, in addition to sterilizer and cycle settings. The cycle report printout is essential in analyzing the GSX Series sterilizer performance and can be retained to meet cycle verification policies. See Chapter 13 for more details.
12	Distilled Water Reservoir	Distilled water is used for humidification of the EO sterilization process. Ensure the distilled water reservoir is adequately filled. The GSX Series sterilizer will display an error message if the distilled water level is too low to run a sterilization cycle. Do not overfill water reservoirs.
Not Numbered	Location of the temperature sensor used for process control	The temperature sensor used for process control is located inside the sterilizer chamber, protruding from the right side chamber wall bottom section, towards the loading chamber door.

Table 2. Sterilization Connection and Component Explanations

10. Using the Touch Screen

10.1. Main Screen

Figure 8 shows the Main Screen of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series that appears after the power cycles ON.

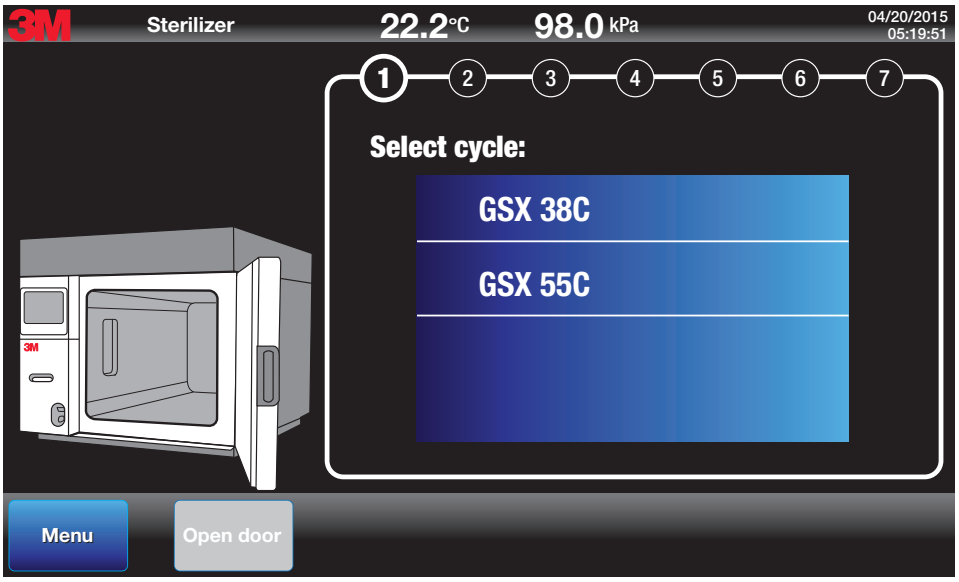


Figure 8.
GSX Series Sterilizer Main Screen

10.2. Menu

The **Menu** button in the bottom left hand corner is used to access the following options: Reports, Cycles, Setup, Status and Service. Figure 9 shows the Menu options screen.

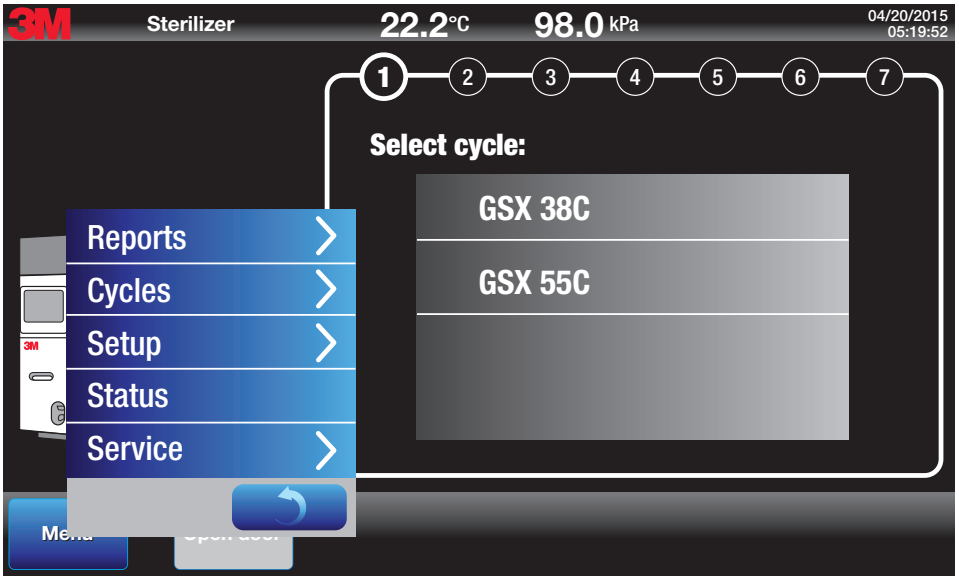


Figure 9.
GSX Series Sterilizer Menu Options

10.3. Reports

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series has a variety of reporting options as shown in Figure 10.

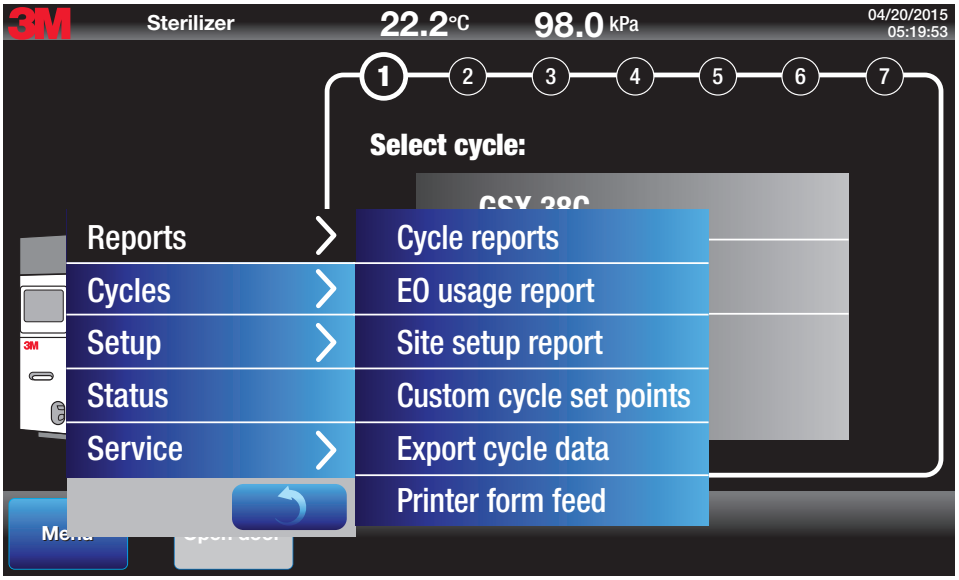


Figure 10.
Reports Menu

10.3.1. Cycle Reports

Figure 11 outlines the options for 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series Cycle Reports.

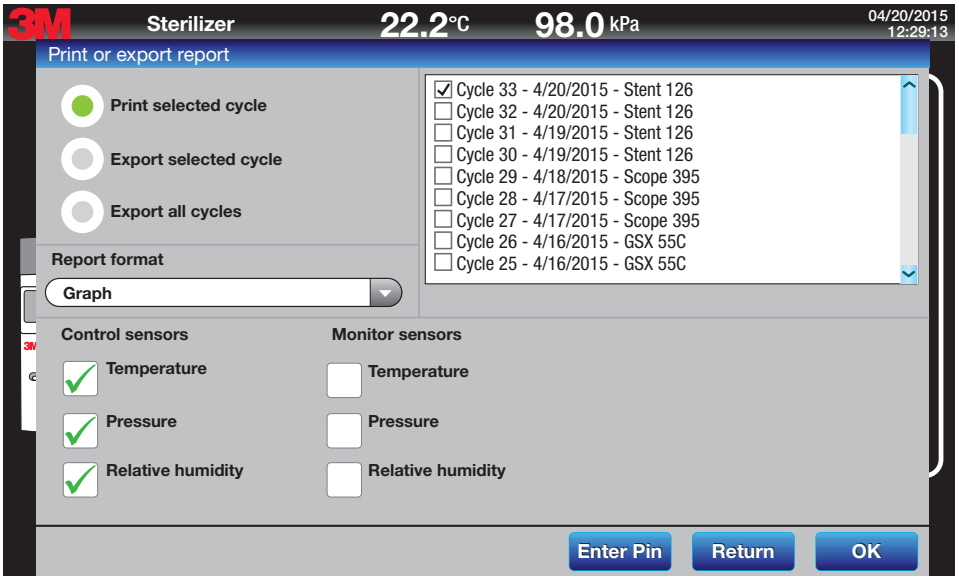


Figure 11.
Cycle Report Setup

Reports from the last 100 cycles can be printed or exported electronically to a USB drive. When the 100 cycle limit is reached, the oldest cycles are replaced with the most recently run cycles. Select the desired cycle(s) from the list of the last 100 cycles (sorted with the most recently run cycles at the top) and select the desired function from the following options: print selected cycle, export selected cycles, or export all cycles. Only one cycle may be selected for printing. Multiple cycles can be selected for export to a USB drive.

To export electronic reports, insert a USB drive (data storage device) into one of two USB ports on the GSX Series sterilizer. Recommended USB drives include those with FAT32 formatting. USB drives with pre-loaded software (e.g. SanDisk's Cruzer®) are not recommended. Connect only USB drives for the export of data to the USB ports. Do not connect external USB devices that supply power to the USB ports.

Select the cycle(s) for which you wish to export reports and press the **OK** button. The selected reports are stored in the USB directory selected by the user. The sterilizer will ask for confirmation of the Folder designation before export. The electronic reports are generated in color and are sized as 20.3 cm (8 in.) x 27.9 cm (11 in.) images and contain the same information as the strip chart reports.

The GSX Series sterilizer has control sensors for temperature, %RH, and pressure that provide information to the control embedded software. In addition, the sterilizer has a duplicate set of monitoring sensors that provide independent data and performance monitoring during critical sterilization stages for temperature, %RH, and pressure. The sterilizer defaults to report only on the control sensors. Monitoring sensors can be selected for reporting in the Cycle Report options screen in Figure 11.

There are three (3) Cycle Report formats. The desired format can be selected in the Cycle Report options screen (Figure 11). Each of the Cycle Report formats is described in Chapter 17 in Table 6.

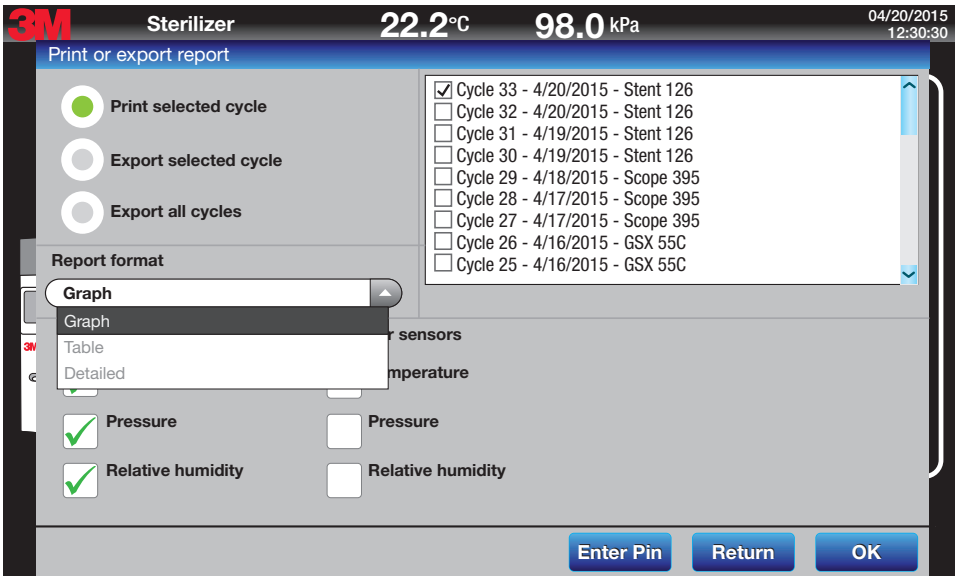


Figure 12.
Selecting Report Formats

10.3.2. Ethylene Oxide Usage Reports

Generate a report for ethylene oxide (EO) usage from the **Menu>Reports>EO Usage Report** screen. Generate an EO Usage Report for specific dates as illustrated in Figure 13.

View the report on the display screen, print the report directly from the sterilizer, or export electronically to a USB drive. Figure 14 is an example of a printed EO Usage Report.

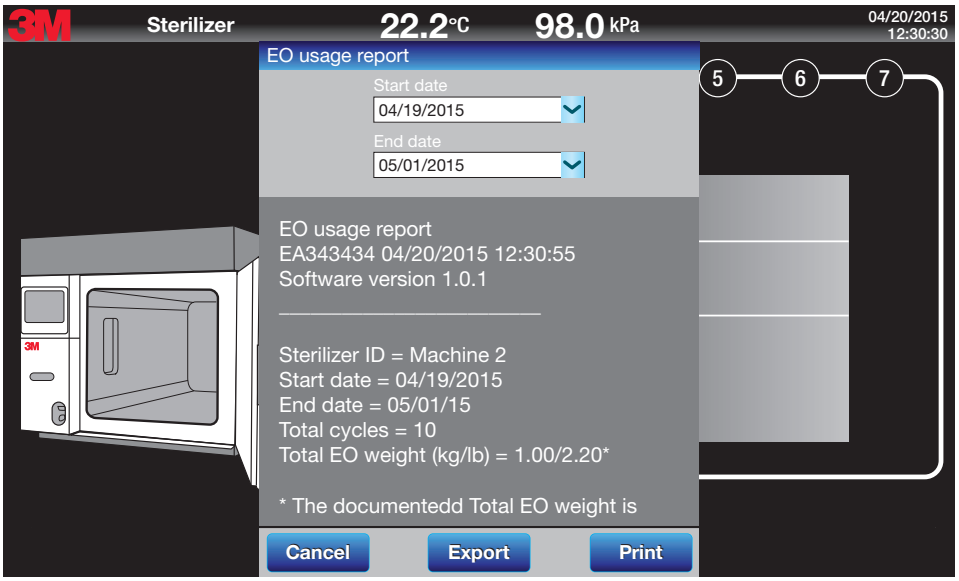


Figure 13.
Selecting Dates for EO Usage Reports

EO usage report
EA343434 04/20/2015 12:30:55
Software version 1.0.1

Sterilizer ID = Machine 2
Start date = 04/19/2015
End date = 05/01/15
Total cycles = 10
Total EO weight (kg/lb) = 1.00/2.20*

*The documented Total EO weight is based on the NOMINAL fill weight of 100% Ethylene Oxide. The ACTUAL fill weight may be different. ACTUAL fill weight met all 3M specifications at the time of product release.

Figure 14.
Printed EO Usage Report

10.3.3. Site Setup Report

View a Site Setup Report for the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series by viewing, printing, or exporting electronically to a USB drive via **Menu>Reports>Site Setup Report**. The Site Setup Report contains the site settings established in the Site Setup menu. Figure 15 is the display screen view of the Site Setup Report.

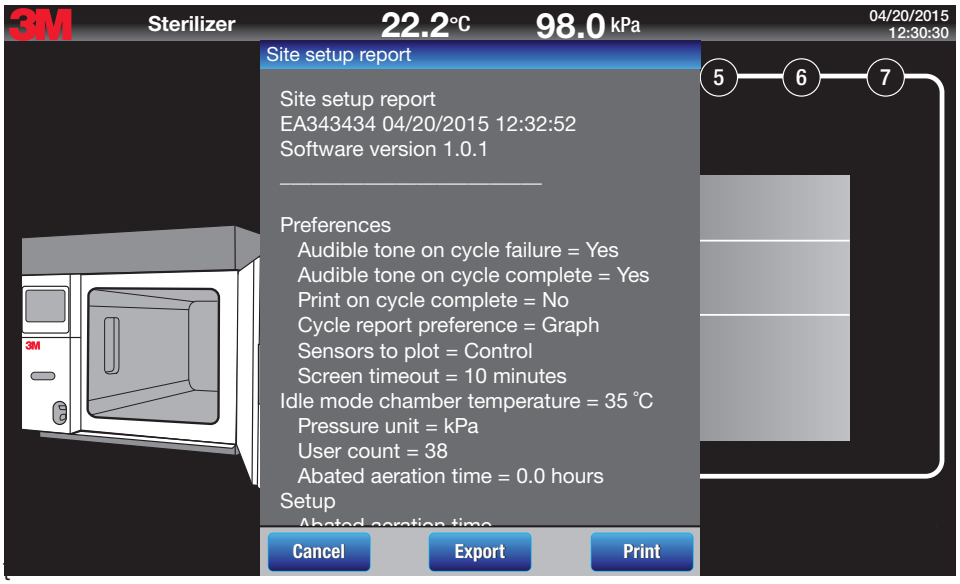


Figure 15.
Display Screen View of the Site Setup Report

10.3.4. Printer Form Feed

The Printer Form Feed button advances the printer paper by approximately 5cm (2 in.). Figure 16 details the location of the Printer Form Feed button.

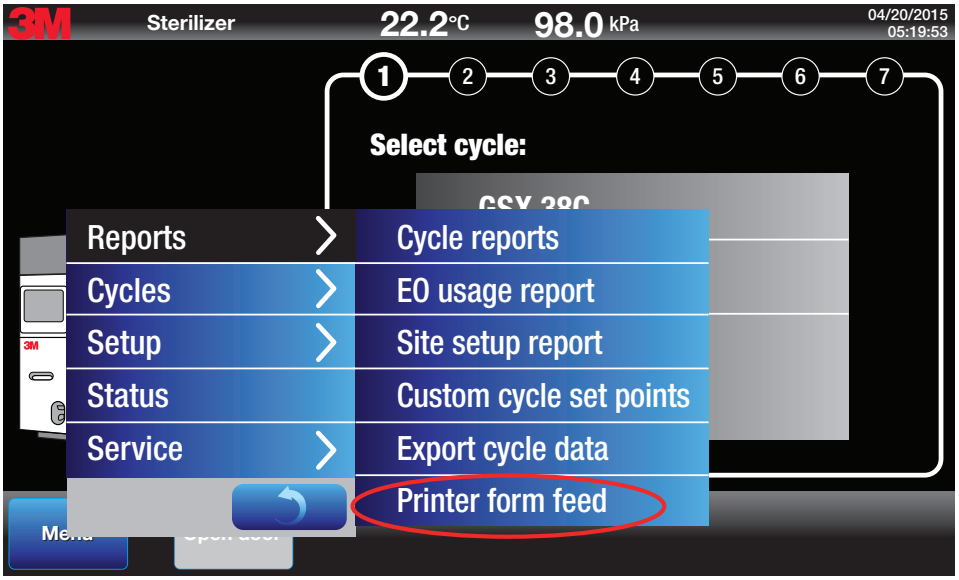


Figure 16.
Location of the Printer Form Feed Button

10.4. Cycle Categories

There are two categories of cycles: standard Operator Cycles and specialized Supervisor Cycles. Figure 17 shows the Cycles Options Menu - Operator Cycles.

10.4.1. Operator Cycles

Selecting Operator Cycles allows the Operator Cycles to appear on the Main screen (Figure 17).

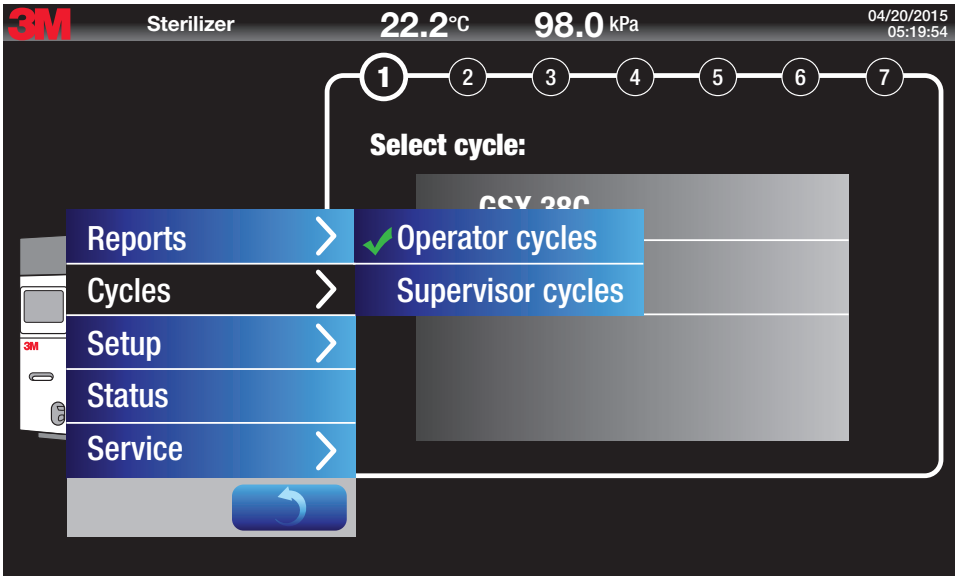


Figure 17.
Cycle Options Menu - Operator Cycles

10.4.2. Supervisor Cycles

Selecting Supervisor Cycles requires a Supervisor Personal Identification Number (PIN) which is established in **Menu>Setup>User setup**. Selecting Supervisor Cycles allows the Supervisor Cycles to appear on the Main Screen (Figure 19) in place of the Operator Cycles. Figure 18 shows the Cycles Option Menu - Supervisor Cycles.

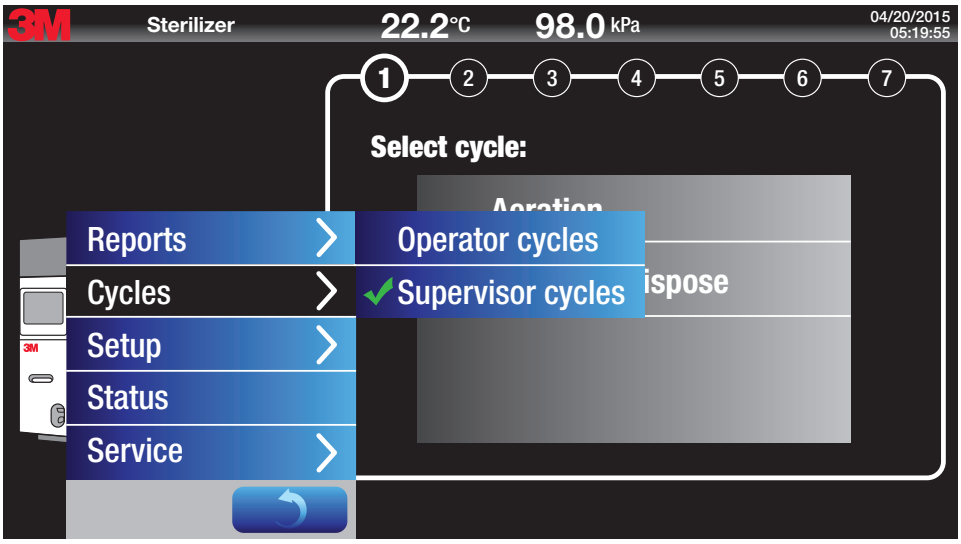


Figure 18.
Cycles Option Menu - Supervisor Cycles

There are two (2) preprogrammed Supervisor Cycles: Aeration and Cartridge Dispose. Program each cycle by following the step-by-step instructions as they appear on the screen.

1. **Aeration** performs aeration only at the selected temperature. Duration is user-programmed in either 30 minute intervals or continuous.
2. **Cartridge Dispose** is a custom abbreviated cycle used to safely empty and aerate 3M™ Steri-Gas™ EO Gas Cartridges at the rate of one per cycle. This cycle cannot sterilize devices. Refer to the Cartridge Dispose Cycle - 3M™ Steri-Gas™ EO Gas Cartridges section for additional information.

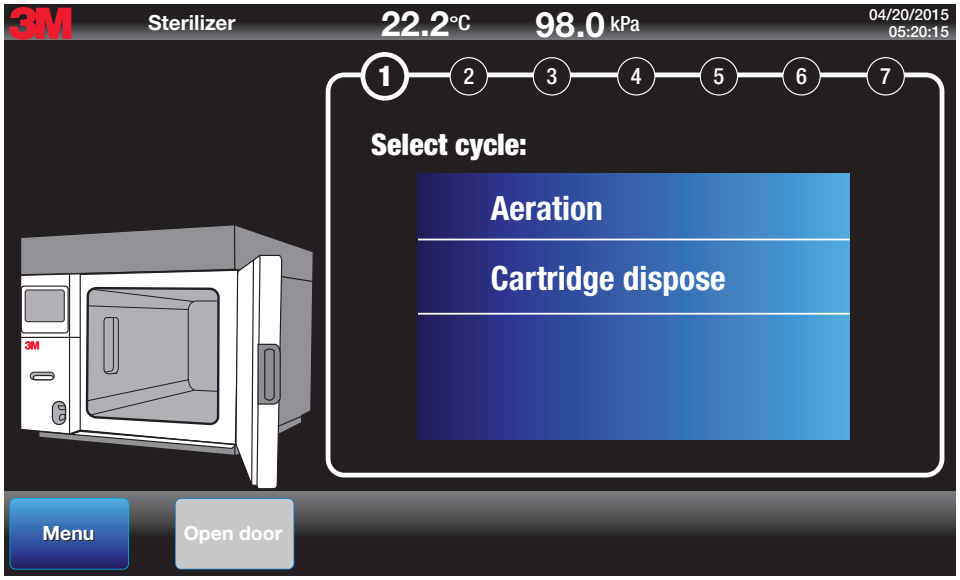


Figure 19.
Main Screen - Supervisor Cycles Displayed

10.5. Setup Menu

The Setup Menu provides several options for customizing the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series function and preferences. Site setup is specific for the GSX Series sterilizer. The User setup is specific for Operators and Supervisors. Figure 20 illustrates the button to access the Site Setup options.

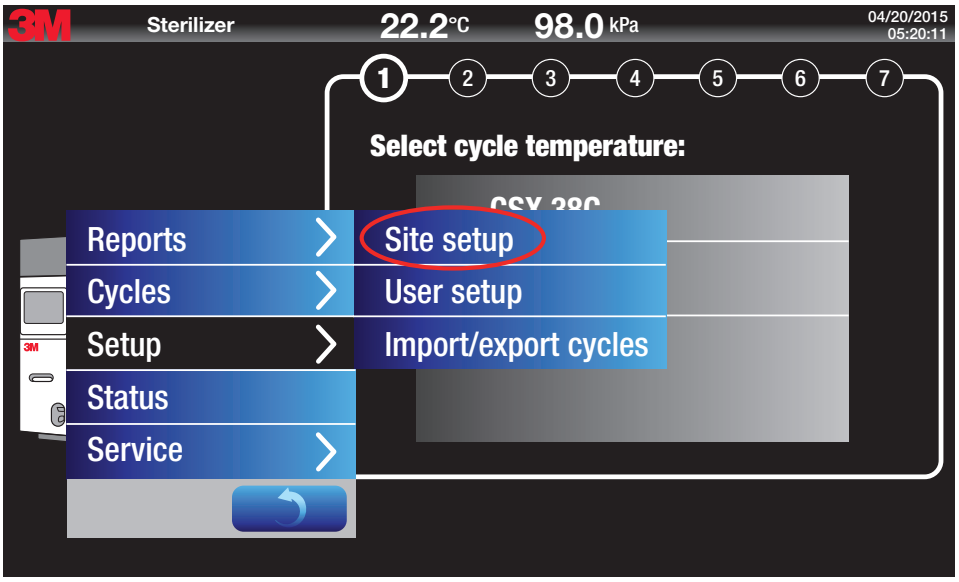


Figure 20.
Button to Access Site Setup Options

10.5.1. Site Setup

The **Site Setup>Preferences** tab includes the options listed below in Figure 21. The selected options in Figure 21 are the default settings.

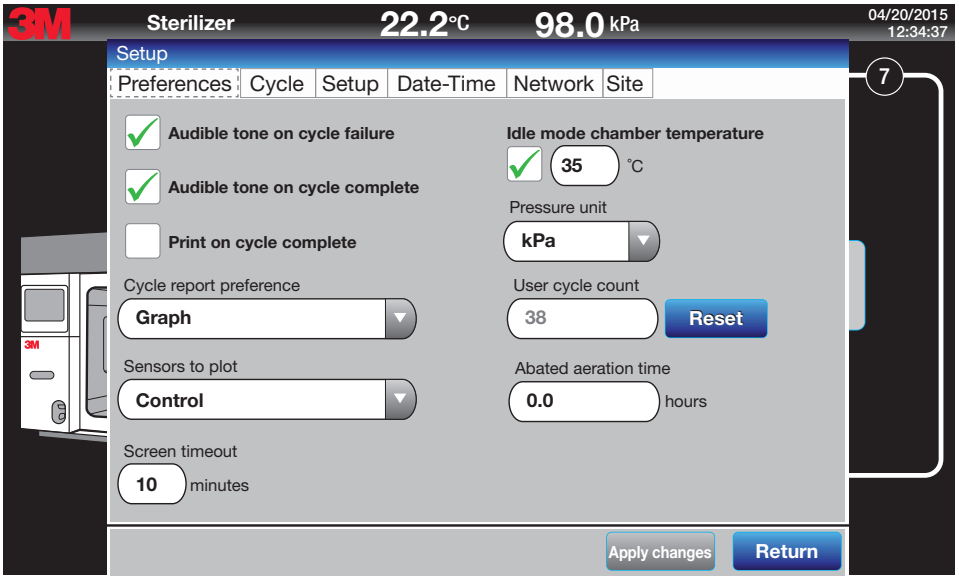


Figure 21.
Site Setup Preferences – Default Settings

Table 3 outlines the parameters in **Site Setup>Preferences** including description, default value, and minimum access level.

Parameter Display Name	Parameter Description	Data Range (or Format)	Default Value	Minimum Access Level to Edit
Audible tone on cycle failure	When enabled, system will produce an audible tone upon cycle failure. The audible notification will sound at a pulsed rate of two (2) seconds on, one (1) second off, for total of 30 seconds.	Disabled, Enabled	Disabled	Supervisor
Audible tone on cycle complete	When enabled, system will produce an audible tone upon cycle completion. The audible notification will sound continuous for total of 20 seconds.	Disabled, Enabled	Disabled	Supervisor
Print on cycle complete	When enabled, system will automatically print cycle reports on sterilizer printer.	Disabled, Enabled	Enabled	Supervisor
Cycle report preference	Allows user to select default cycle report type for printing and saving.	Graph, Table, or Detailed	Graph	Supervisor
Sensor to plot	Allows user to select default sensors that will be plotted on graph of cycle reports.	Control, Monitor, Both	Control	Supervisor
Screen timeout	Allows user to select amount of time in minutes that must pass without a detected touch before the system will dim the display.	[1:60] minutes	10 minutes	Supervisor
Idle mode chamber temperature	When enabled, the system will maintain user-entered target temperature while in Idle mode.	Off, GSX [30 - 60] °C	Off	Supervisor
Pressure unit	Allows user to select preferred units for pressure on display and select reports.	mbar, kPa	mbar	Supervisor
User cycle count	Will count cycles performed between supervisor access level resets. Incremented at start of a cycle.	[0 - 2147483647]	0	Supervisor- Reset to zero only
Reset (User cycle count)	When enabled with supervisor level access, will reset User cycle count indicator.	Disabled, Enabled	0	Supervisor- Reset to zero only
Abated aeration time	If the system is configured to use an Abator, this control will allow the user to enter how many hours into aeration the system shall request the Abator to run. Abator start will remain on for this amount of time after the start of aeration.	0 to 999:30 hours, adjustable by 0.5 hour increments	0	Supervisor

Table 3 Site Setup Preferences Parameters

The **Site Setup>Cycle** tab provides the option to select the cycles that will appear on the Main Screen for the Operator, Supervisor, and Service. Figure 22 illustrates the options when selecting the Operator Cycles for the Main Screen.

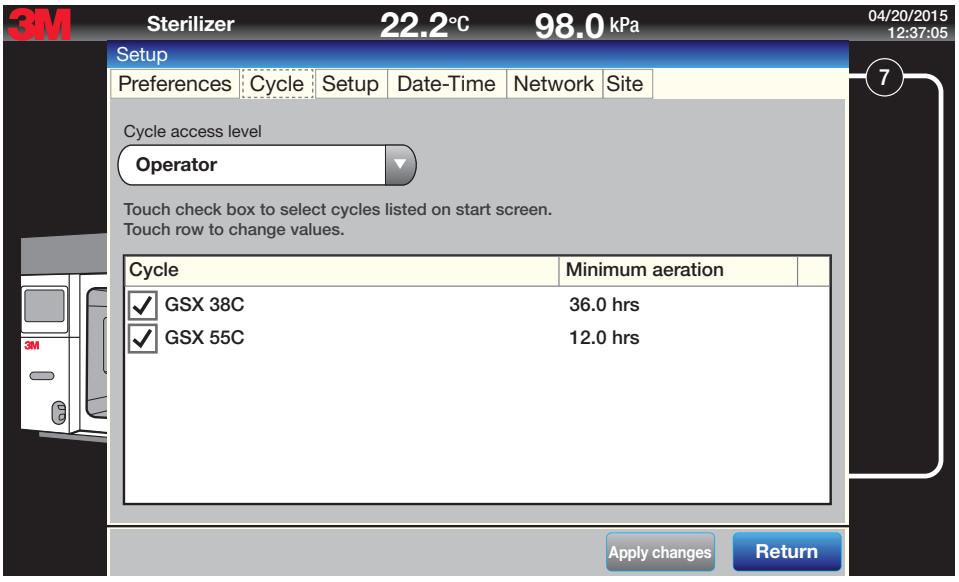


Figure 22.
Setup Cycle Options for Operator Cycles

The minimum default aeration time on the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series can be changed for the preprogrammed GSX 38C and GSX 55C cycles. Press the **minimum aeration** time and an iWheel will appear to adjust the minimum aeration default time. Figure 23 illustrates changing the minimum aeration default time.

Minimum aeration times cannot be changed in this view for custom cycles. Custom cycle minimum aeration times must be changed in the 3M™ Cycle Programmer and imported back to the GSX Series sterilizer.

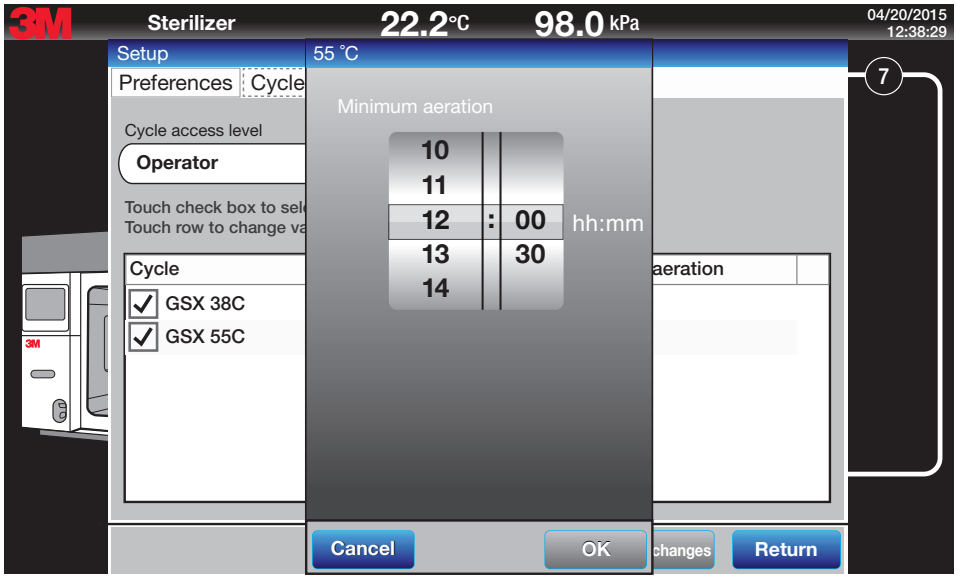


Figure 23.
Changing the Minimum Aeration Default Time

The **Site Setup>Setup tab** (Figure 24) provides the specific configuration and maintenance details for your site; this is established by authorized 3M service personnel during installation.

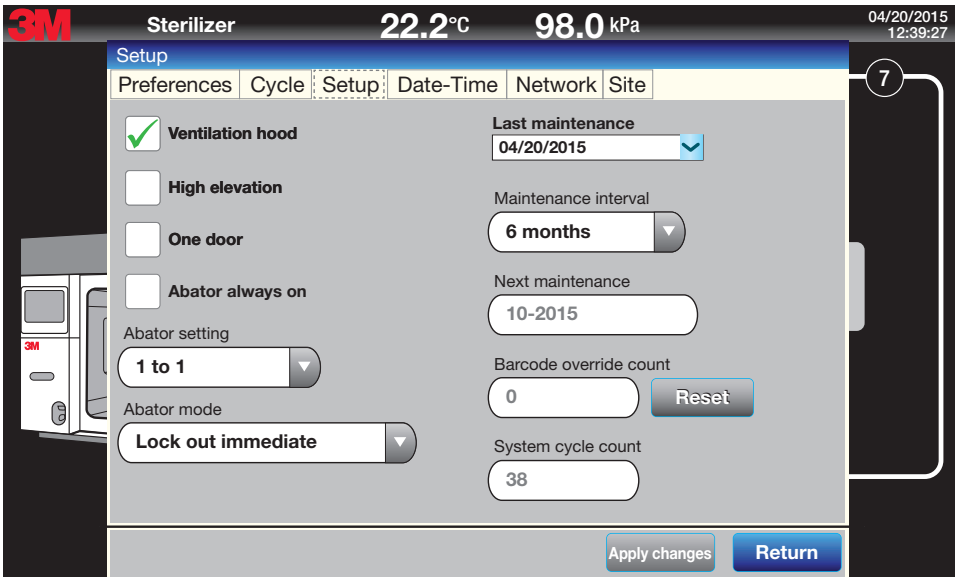


Figure 24.
Site Setup>Setup Tab - Options

The **Site Setup>Date-Time** tab (Figure 25) provides options for setting the date and time for the GSX Series sterilizer.

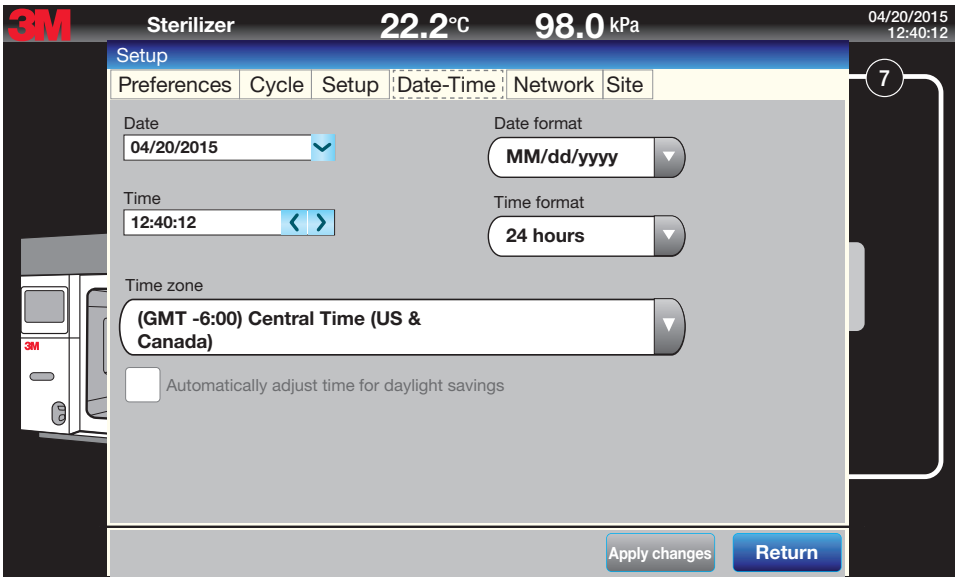


Figure 25.
Site Setup>Date-Time Options

The **Site Setup>Network** (Figure 26) tab provides the entry point for specific networking codes. Refer to the Ethernet connection section of the Operator Manual for more details.

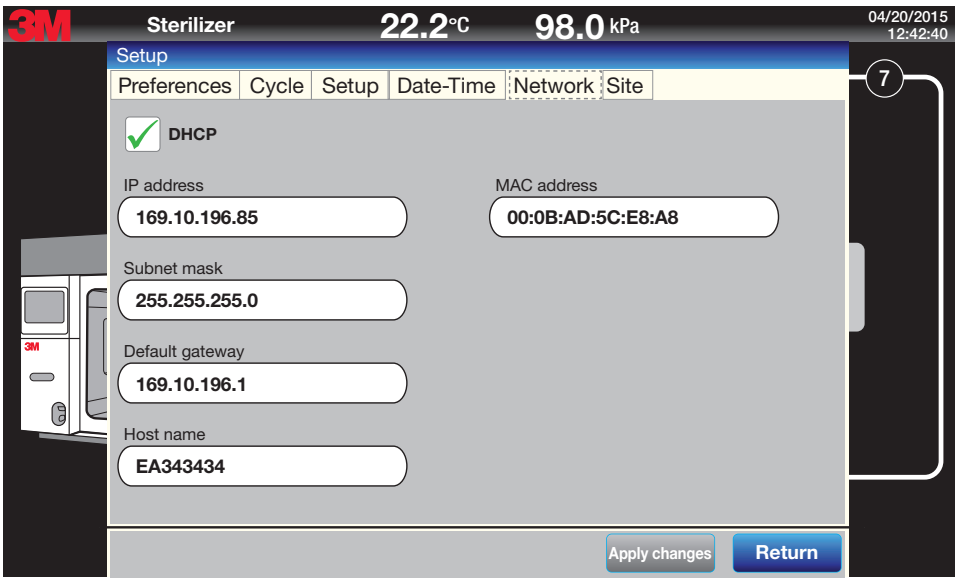


Figure 26.
Site Setup>Network Information

The **Site Setup>Site** tab (Figure 27) provides options for entering the facility name, naming the sterilizer, and setting the language.

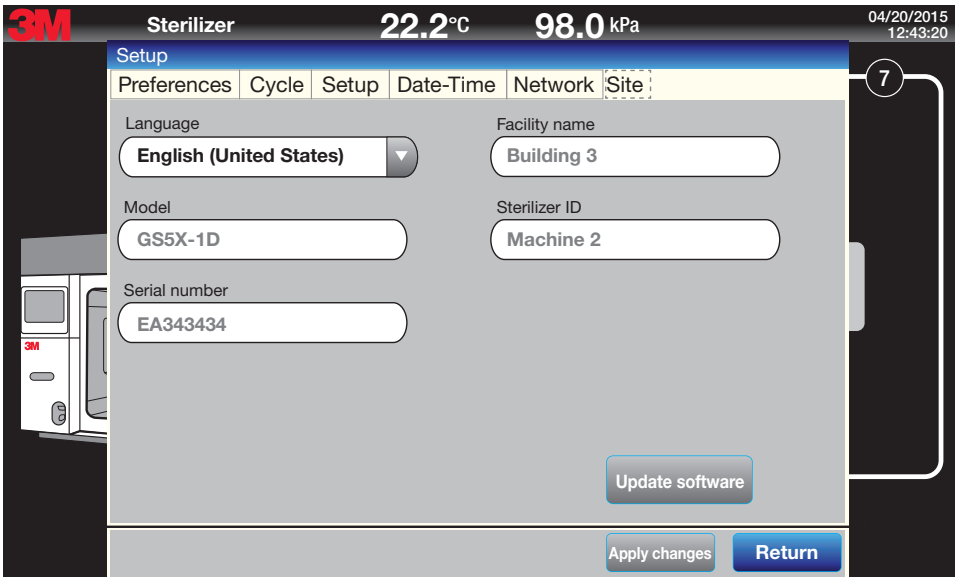


Figure 27.
Site Setup>Site Tab Fields

10.5.2. User Setup

Access the User Setup menu (Figure 28) to establish personal identification numbers (PINs) for Supervisors and Service. A Service access level PIN is required to create the first Supervisor user. Supervisors can then set up additional Supervisors. Only Service can set up additional Service users. Figures 28 - 31 illustrate the use of the User Setup Menu.

The User Name field will accept 1 to 20 characters from the following character set: A-Z, a-z, and 0-9. Spaces are not accepted.

Note: 3M Health Care service personnel or authorized 3M service personnel must create the first Supervisor user and PIN on the GSX Series sterilizer. Additional Supervisor users and PINs can be created by established Supervisors.

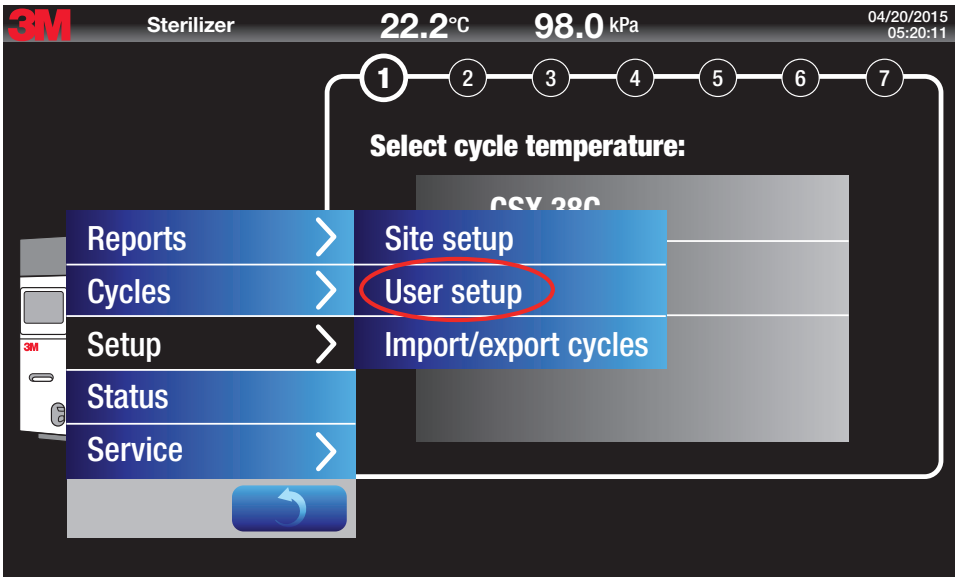


Figure 28.
User Setup Menu

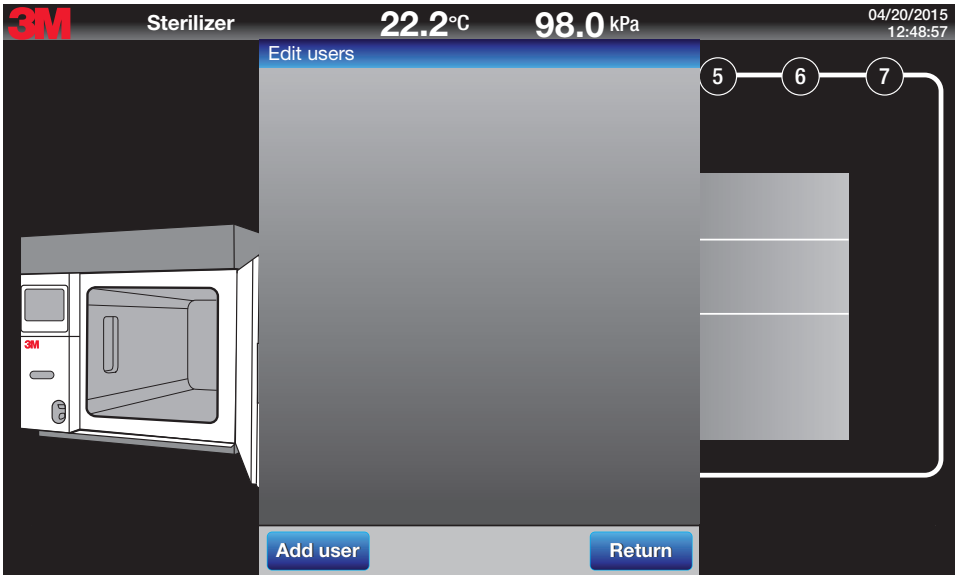


Figure 29.
User Setup Menu – Blank User List

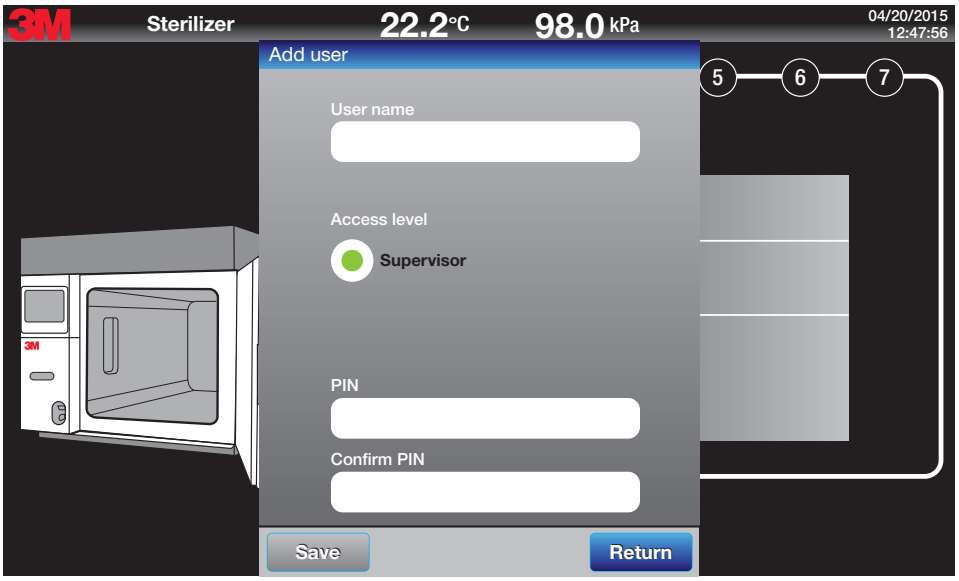


Figure 30.
User Setup Menu – Adding
a Supervisor

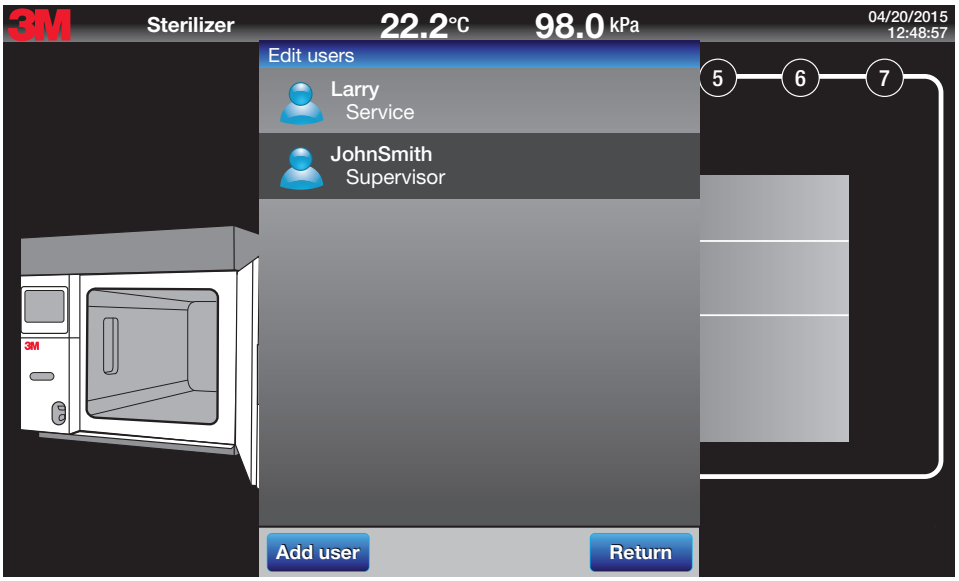


Figure 31.
User Setup Menu – Populated User List

10.6. Status

The **Status** button provides information on the current functional state of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. The Status option provides viewing access to three features; Control, Info and Log. These features are primarily used by 3M Health Care service personnel or authorized 3M service personnel. Figure 32 illustrates the location of the Status button.

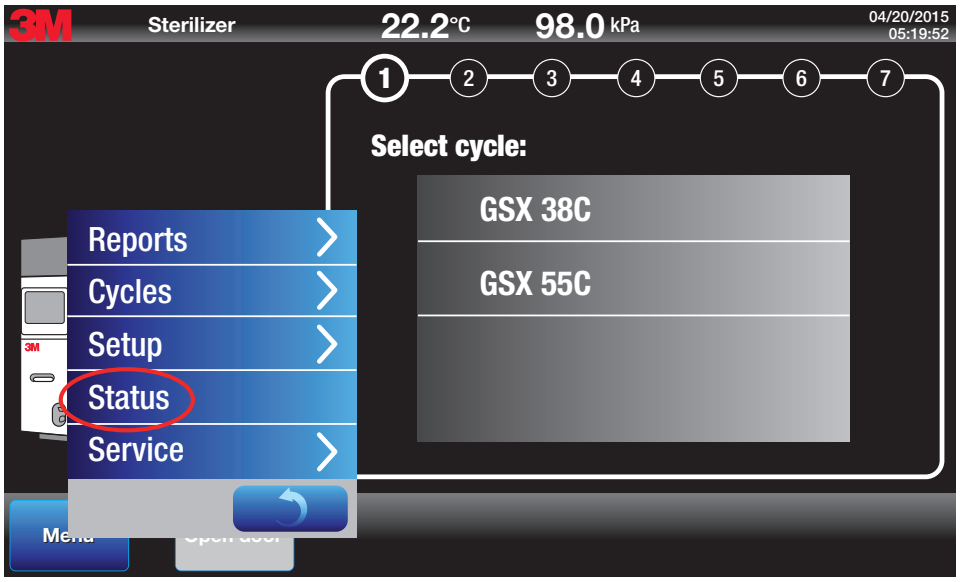


Figure 32.
Status Button

10.6.1. Control

The **Control** tab of the Status option provides information on the current state of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series sensors, valves and software conditions.

10.6.2. Info

The **Info** tab of the Status option provides version numbers for 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series components and software.

10.6.3. Log

The **Log** tab of the Status option provides ongoing output of the software commands while the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series is running a cycle. The Log is not saved and is overwritten as new data information appears.

11. 3M™ Cycle Programmer

11.1. 3M™ Cycle Programmer Overview

3M™ Cycle Programmer is a software program that allows the user to customize sterilization cycles. Before using the software, the user must download the software onto an independent personal computer (PC). The user can then change or modify parameters to create a custom cycle to meet specific device requirements or sterilization needs.

The 3M Cycle Programmer software cannot be used directly on the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. Custom cycles must be configured on an independent PC and saved to a USB drive. The user then transfers the custom cycle file(s) from the USB drive onto the GSX Series sterilizer. Once the file(s) are loaded onto the GSX Series sterilizer, any custom cycle can be selected to run on the sterilizer.

Use of custom cycles on the GSX Series sterilizer requires a Supervisor PIN for multiple steps of the custom cycle process. 3**M Health Care service personnel or authorized 3M service personnel must create the first Supervisor user and PIN on the sterilizer.**

Figure 33 is an illustration of the basic process for creating and importing custom cycles.

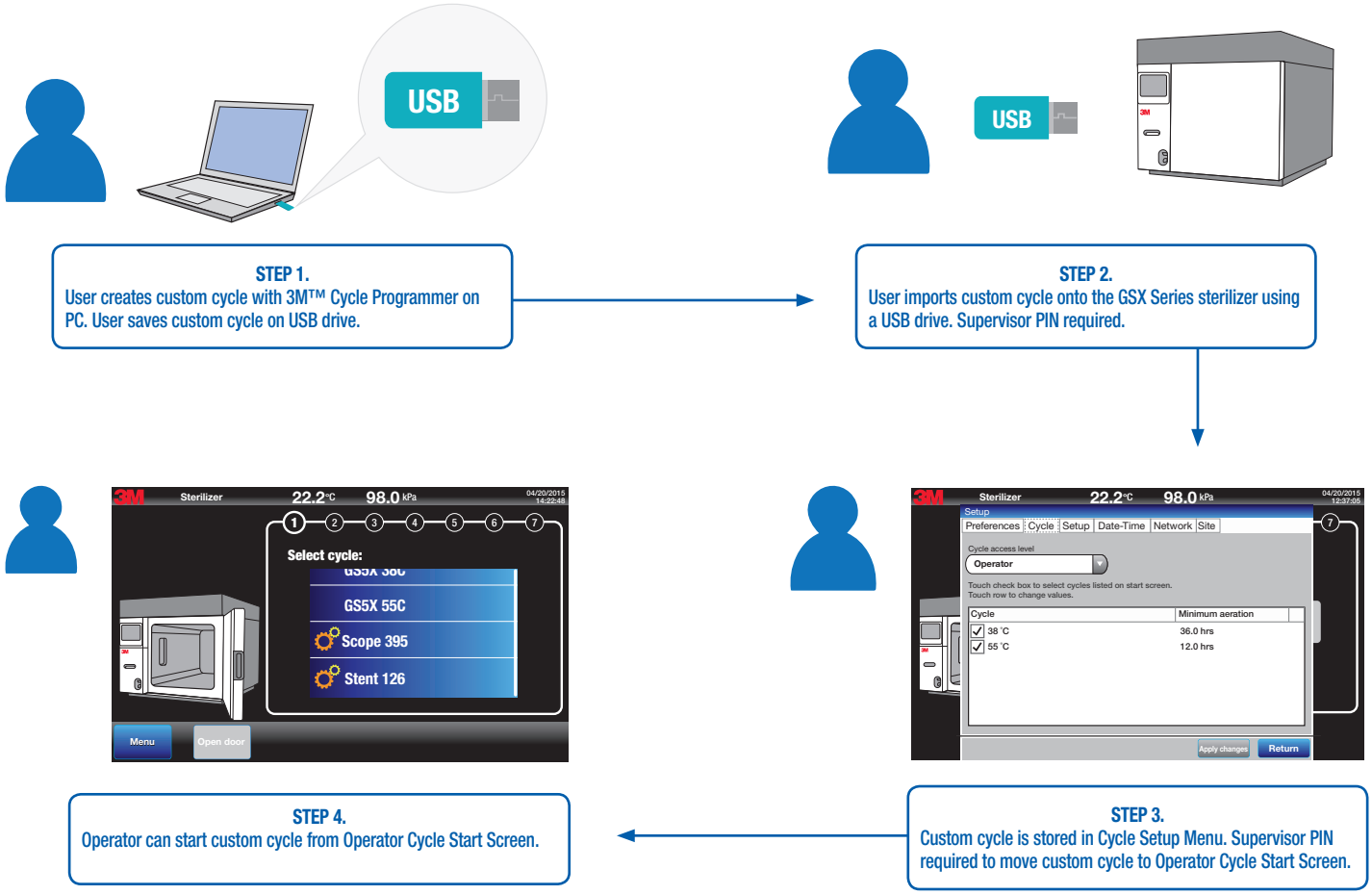


Figure 33.
Process of Creating and Importing Custom Cycles

11.2. 3M™ Cycle Programmer Hardware and Software Requirements

11.2.1. Hardware Requirements

- The 3M™ Cycle Programmer operates on an independent personal computer, laptop computer or desktop computer (a.k.a. PC) that is supplied by the user.
- Recommended USB drives include drives with FAT32 formatting. Drives with pre-loaded software (e.g., SanDisk's Cruzer®) are not recommended.
- Connect only USB drives, for the sole purpose of importing custom cycles or exporting data, to the USB ports. Do not connect external USB devices that supply power.

11.2.2. Software Requirements

The minimum software requirements are:

- Windows 7 (32 bit & 64 bit) or Windows 8/8.1 (32 bit & 64 bit) with a display screen resolution of 1024 x 768 pixels.
- Microsoft .NET Framework version 4.0.
- The 3M™ Cycle Programmer is not available for use on Macintosh or Apple computers.
- 3M Cycle Programmer software should be installed and run on a computer that contains up-to-date anti-virus software and up-to-date operating system patches.

11.3. Installing the 3M™ Cycle Programmer

1. To obtain the 3M Cycle Programmer software and company specific license file, register the GSX Series sterilizer installation location and serial number at: www.3M.com/SteriVacServiceLSS.
2. An email from 3M Health Care will be sent with instructions on how to download the software. A 3M-generated, company-specific license file is required to activate the installed 3M Cycle Programmer software. The license file accompanies the 3M Cycle Programmer software.
3. Once downloaded, double click the "3M_Cycle_Programmer(Version).exe" file to install the application. Microsoft .NET Framework version 4.0 will be installed by the program if the software does not exist on the user's computer.
4. From the drop down box, select the desired language for the 3M Cycle Programmer.
5. Review the end user license agreement for the 3M Cycle Programmer. Check the box "I agree to the license terms and conditions".
6. Select **Install**.
7. Wait for the Setup to progress to Successful.
8. Select **Launch**.
9. Double click on the 3M™ Cycle Programmer icon.
10. Install the company-specific license file obtained from 3M. Click on the **Browse** button (Figure 34) and locate the license file (Figure 35). Highlight the license file; click **Open** (Figure 35), then **Submit** (Figure 36). Once loaded, the 3M Cycle Programmer is ready for use. Install the 3M Cycle Programmer on an unlimited number of computers within the same company location using the same license file; however, the license agreement prohibits distribution of the 3M Cycle Programmer outside the registered company site.

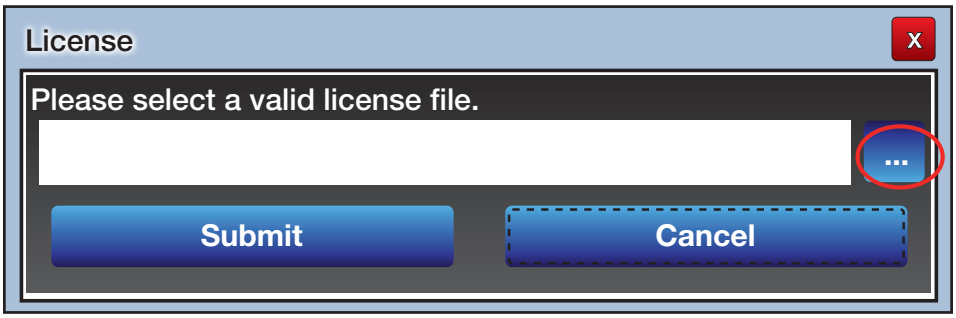


Figure 34.
Browse Button for Searching License File

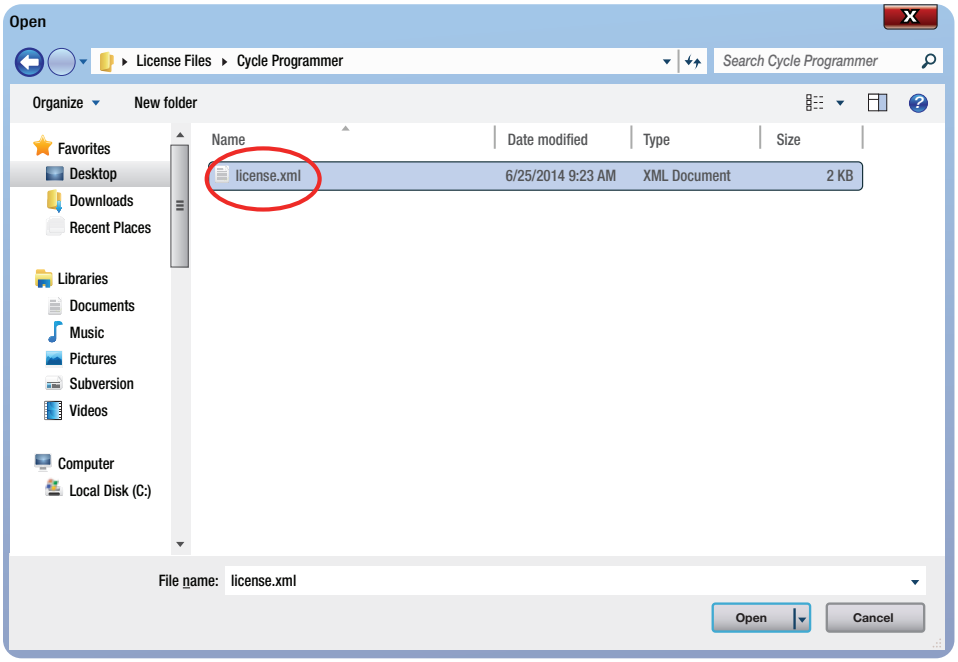


Figure 35.
Locating the Saved License.xml File

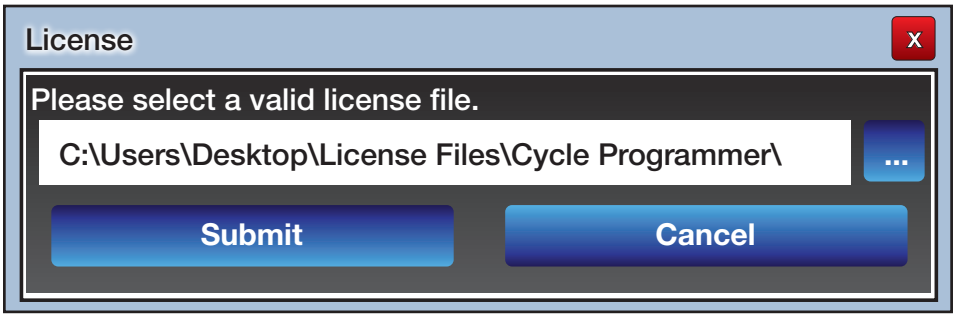


Figure 36.
File Loaded and Ready to Submit

For Technical Support:

In the US, contact 3M Health Care Service Center Customer Service 1-800-292-6298, Option 0.

Outside the US, contact your local 3M office or visit www.3m.com for locations and contact information.

11.4. Creating a Cycle in the 3M™ Cycle Programmer

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide:

Short term exposure limits (STEL) or long term exposure limits (LTEL,) or immediately dangerous to life or health (IDLH) limit could be exceeded during NORMAL use. Operators and staff must use protective measures (e.g. engineering controls, work practices, or personal protective equipment (PPE)) in accordance with United States 29 CFR 1910.134 and 29 CFR 1910.1047 under NORMAL use conditions until the user's facility management completes an exposure assessment on each custom cycle validating facility protective measures meet national, state, and local requirements for short term exposure limits (STELs) and long term exposure limits (LTELs).

⚠ CAUTION: To reduce risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures:

The user must validate the sterile efficacy of each custom cycle intended to sterilize products labeled 'Sterile'.

1. Each time the 3M Cycle Programmer is opened, the user must be aware that Flushing and Aeration stages affect occupational exposure levels of ethylene oxide (EO), therefore the user must acknowledge this safety feature prior to creating or modifying a custom EO cycle. (Figure 37).

   Read all **DANGERs: To reduce the risks associated with exposure to ethylene oxide** and read sections on defining set points for cycle stages specifically for the Flushing and Aeration stages of the cycle (Chapter 11, Sections 11.5.8 and 11.5.9) prior to running custom cycles with ethlyene oxide.

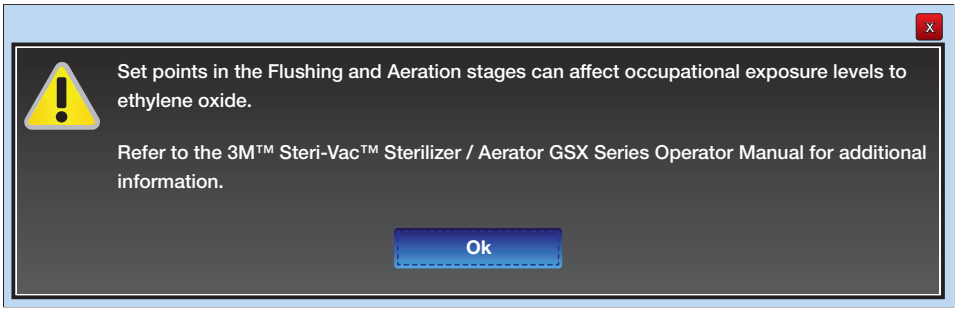


Figure 37.
Acknowledging Importance of Flushing and Aeration Stages Set Points

2. To create or edit a custom cycle, select either **New**, or **Open** an existing custom cycle (Figure 38).

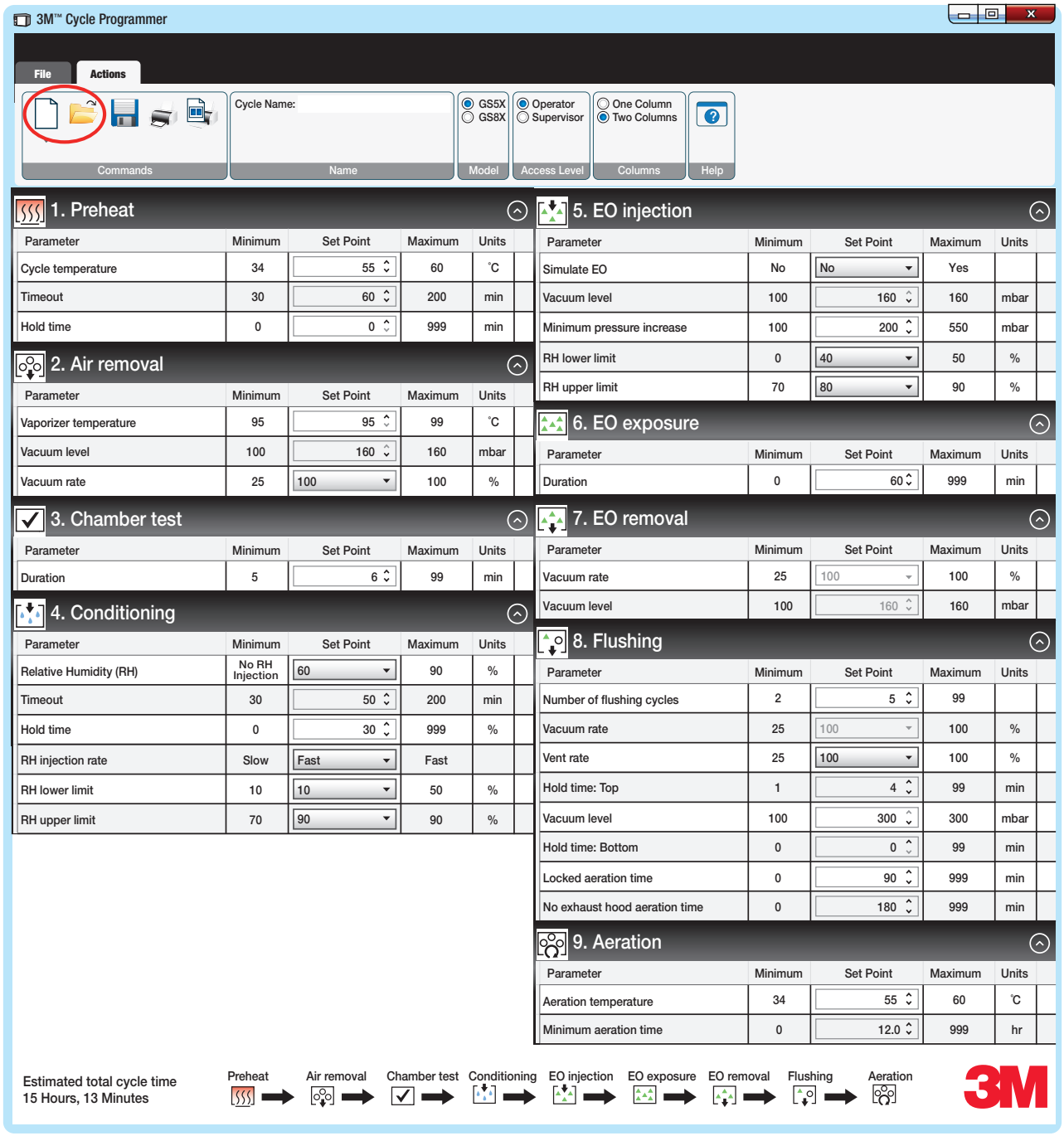


Figure 38.
3M™ Cycle Programmer

3. This message will appear upon opening a custom cycle if potential conflicts exist between software versions of the saved custom cycle, the 3M Cycle Programmer, and the sterilizer software version (Figure 39). For more information, in the US contact 3M Health Care Helpline at 1-800-228-3957. Outside the US contact your local 3M office or to locate your local office go to www.3M.com.

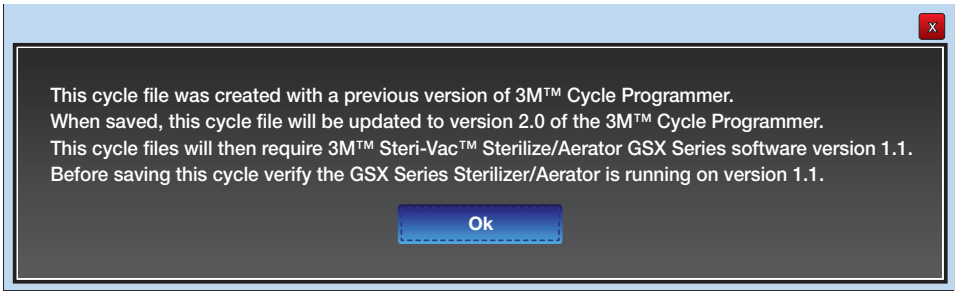


Figure 39.
Example Message of Potential Software Version Conflicts

4. Enter a **Cycle Name**. The Cycle Name can be a combination of up to 20 characters. The system will accept 'A –Z', 'a-z', 0-9, space, period, and dash ("-"). Every custom cycle must have a valid Cycle Name. Ensure custom cycle names are clear and distinct to the Operator. Avoid using a single digit as a custom cycle name to minimize risk of Operator cycle selection errors.

   Note: Only one custom cycle with the same name can be imported into the GSX Series sterilizer. The sterilizer will check the custom cycle names before allowing the custom cycles to be imported.

5. Select sterilizer **Model**.

   Select the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series model for the custom cycle - either GS5X or GS8X. The custom cycle will only work on the GSX Series sterilizer model for which it was created (i.e. GS5X cycle cannot be run on a GS8X nor can a GS8X cycle be run on a GS5X).

6. Select cycle **Access Level**.

   Select either Operator or Supervisor access level for the custom cycle. This feature allows custom cycles to be stored and accessed in different locations on the 3M™ Steri-Vac™ Sterilizer/ Aerator GSX Series to help assure Operator selects the correct cycle for the intended application.

   A custom cycle with Operator access level is only available for use from the Operator Cycle Start screen.

   A custom cycle with Supervisor Access level is only available for use from the Supervisor Cycle Start screen

7. Select display preference – **One Column or Two Columns**.

   Choose one column to display the cycle stages and parameters in a one column list or choose two columns to display the cycle stages and parameters across two columns. Some languages require a one column list display.

8. Define the set points for each stage of the ethylene oxide (EO) sterilization custom cycle.

   - Figure 1 is a Pressure Profile of the ten (10) stages of the preprogrammed EO Sterilization Cycles. Stage 7 (EO Removal) and Stage 10 (Air Admission) do not have any user programmable set points.
   - The variable parameters and ranges for each programmable stage are detailed in the following sections. The user must define a set point for each parameter. The user can choose the preprogrammed cycle set points or the user can do a combination of both defining and choosing preprogrammed cycle set points. Some set points also allow the user to set a minimum and maximum limit.
   - There may be a combination of set points, environmental operating conditions, and product loads that will routinely result in a sterilization process fault. If this occurs, the combination of set points, environmental operating conditions, or product loads will need to be adjusted. For more information: inside the US, contact 3M Health Care Helpline at 1-800-228 3957, or outside the US, contact your local 3M office. To locate your local office, go to www.3M.com.
   - The preprogrammed cycle set points for each variable parameter are the values that populate the 3M™ Cycle Programmer when a new custom cycle is opened (Figure 38).

9. **Save** the programmed custom cycle to the personal computer. The custom cycle will have an .eto extension to designate the file as a custom cycle for the 3M™ Steri-Vac™ Sterilizer/ Aerator GSX Series.

10. Use a USB drive to move custom cycles from the personal computer to the GSX Series sterilizer. Custom cycles must be saved in a Folder on the USB drive. The GSX Series sterilizer only looks for Folders on the USB drive at the beginning of the custom cycle import process (Chapter 11).

Note: 3M recommends that the 3M™ Cycle Programmer software be installed and run on a computer that contains up-to-date anti-virus software and up-to-date operating system patches.

Custom cycle files are in a proprietary and encrypted format and must be correctly formatted for the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series to accept for import. This check and confirmation by the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series ensures that the stored cycle is acceptable.

11.5. Defining Set Points for Cycle Stages and Parameters

11.5.1. Preheat Stage

- **Cycle temperature** is the target chamber temperature for the entire sterilization process.
- **Timeout** is the maximum time allowed for the chamber and the vaporizer to reach target temperatures. Reference the Air Removal Stage for a description of the vaporizer.
- **Hold time** is the duration of time to maintain chamber temperature before exiting the Preheat stage.

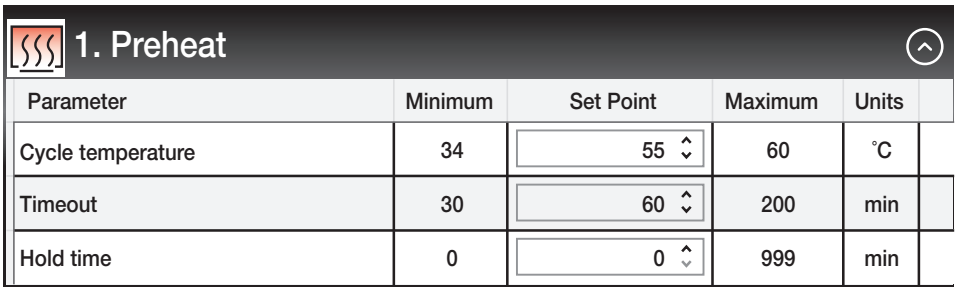


Figure 40.
Preheat Stage

11.5.2. Air Removal Stage

- The vaporizer is a heating element connected directly to the GSX Series sterilizer chamber used to vaporize distilled water for the conditioning stage. The vaporizer is also used in vaporizing liquid ethylene oxide (EO) during the EO Injection stage.
- **Vaporizer temperature** is the target vaporizer temperature for the Conditioning stage and EO Injection stage.
- **Vacuum level** is the target chamber pressure for the Air Removal stage.
- **Vacuum rate** is the rate air is removed from the chamber while proceeding to the programmed vacuum level. Four (4) vacuum rates are available; 100%, 75%, 50% and 25%. The vacuum rate programmed in the Air Removal stage will be applied to **all** vacuums of the sterilization process.

  Note: The **Vacuum rate** is controlled by the percentage of time the vacuum is applied to the chamber.

  - A **Vacuum rate** set point of 100% is the fastest air removal rate. The vacuum is applied to the chamber 100% of the time until the programmed vacuum level is reached. The preprogrammed cycle vacuum rate is 100%.
  - A **Vacuum rate** set point of 25% is the slowest rate during which the vacuum is applied to the chamber 25% of the time while proceeding to the programmed vacuum level.

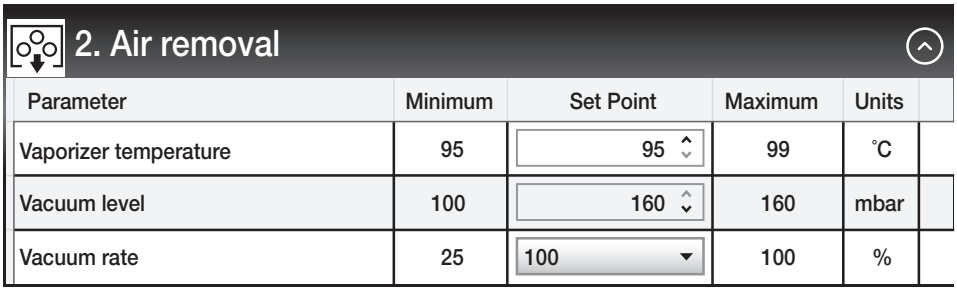


Figure 41.
Air Removal Stage

11.5.3. Chamber Test Stage

- The Chamber Test stage is a check on the chamber integrity to assure the chamber and system are adequately sealed before proceeding with the cycle. If the Chamber Test fails, the cycle will automatically cancel.
- **Duration** of the Chamber Test is the programmed time between the initial chamber pressure measurement at start of the stage and the final pressure measurement at the end of the stage.
- To pass the Chamber Test the final pressure measurement minus the initial chamber pressure measurement must be less than 18 mBar (1.8 kPa).

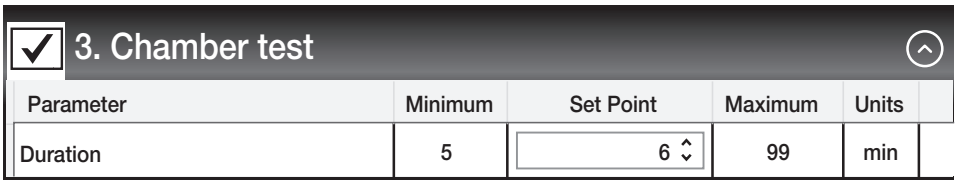


Figure 42.
Chamber Test Stage

11.5.4. Conditioning Stage

The Conditioning stage is partitioned into two sequences: RH ramp-up and RH hold.

- **RH ramp-up** is responsible for increasing the relative humidity (RH) in the sterilization chamber to the target RH.
- **RH hold** is responsible for maintaining the programmed RH level for the specified amount of time to ensure the load has sufficient time to absorb water vapor.

- **Relative Humidity (RH)** is the target %RH for the Conditioning stage.

  Special product loads or special cycles may require a very low %RH. Select **No %RH Injection** to create a custom cycle where no vaporized distilled water is injected during the Conditioning stage.

- **Timeout** is the maximum time allowed for the chamber to reach target %RH during RH ramp-up.
- **Hold time** is the duration of time to maintain chamber target %RH (RH hold sequence) before exiting the Conditioning stage.
- **RH injection rate** is the time period to allow water vapor to absorb before calculating the next RH injection duration. There are three set points: fast, medium, and slow. The Fast set point is the preprogrammed setting. Medium and Slow set points may be used depending on the absorption characteristics of the load. Studies on each load type may be required to optimize the RH injection rate parameter.
- **RH lower limit** is the tolerance on the lowest allowable %RH during RH hold. If the %RH falls below the programmed tolerance during RH hold, the GSX Series sterilizer will automatically cancel the cycle.
- **RH upper limit** is the tolerance on the maximum allowable %RH during RH hold. If the %RH rises above the programmed tolerance during RH hold, the GSX Series sterilizer will automatically cancel the cycle.

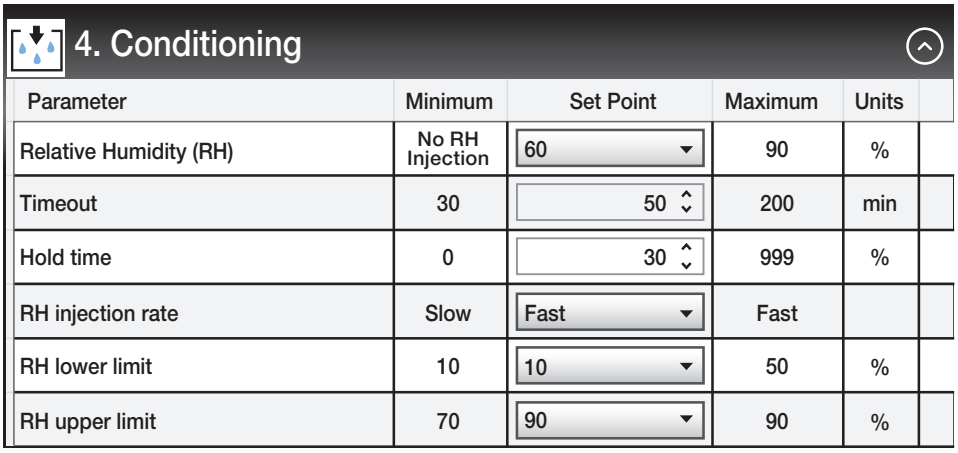


Figure43.
Conditioning Stage

11.5.5. EO Injection Stage

- **Simulate EO** is an option to run an entire cycle without using ethylene oxide (EO). If the Simulate EO set point is 'Yes' the pressure will rise with filtered air during the EO Exposure stage to an estimated level of 20 mBar (2.0 kPa) above the Minimum Pressure Increase set point programmed by the user (see below). A 3M™ Steri-Gas™ EO Gas Cartridge will not be accepted by the sterilizer for cycles that Simulate EO.

  Note – If a cycle error occurs during a simulated EO cycle, after the conditioning stage, the GSX Series will perform a full error recovery which includes 5 flushes and a minimum of 90 minutes of aeration (an estimated 2 – 3 hours of error recovery).

- V**acuum level** is the target chamber pressure just prior to puncturing the 3M™ Steri-Gas™ EO Gas Cartridge. The preprogrammed cycle setting for EO injection vacuum level is 160 mBar (kPa 16.0).

- **Minimum pressure increase** is the required minimum chamber pressure rise in 70 seconds after EO injection. If the chamber pressure does not rise above the minimum pressure increase, the cycle will automatically cancel and will proceed to EO Removal, Flushing and Locked Aeration (if programmed) before the user can access the chamber.

Table 4 is the calculated minimum pressure rise 70 seconds after EO injection for the four available 3M™ Steri-Gas™ EO Gas Cartridges for each chamber size GS5X and GS8X. Calculations are based on nominal fill weights of the Steri-Gas EO Gas Cartridges.

GS5X	Nominal Weight of EO (grams)	Calculated Empty Chamber Gas Concentration (mg / L)	Process Temperature Range (°C)	Calculated Minimum Pressure Increase (mBar & kPa)
4-100	100 g	735 mg/L	34 - 60°C	427 – 463 mBar 42.7 - 46.3 kPa
4-134	127 g	934 mg/L	34 - 60°C	542 – 582 mBar 54.2 - 58.2 kPa
8-170	N/A	N/A	N/A	N/A
4-60*	Custom	Custom	34 - 60°C	Custom
GS8X				
4-100**	100 g	446 mg/L	34 - 60°C	259 – 281 mBar 25.9 – 28.1 kPa
4-134**	127 g	567 mg/L	34 - 60°C	329 – 357 mBar 32.9 – 35.7 kPa
8-170	170 g	759 mg/L	34 - 60°C	440 – 478 mBar 44.0 - 47.8 kPa
4-60*	Custom	Custom	34 - 60°C	Custom

*4-60 catalog number is a custom fill 3M™ Steri-Gas™ EO Gas Cartridge.

** The use of a 4-100 and 4-134 catalog number in the GS8X requires a special adaptor. For more information, in the US contact 3M Health Care Helpline at 1-800-228-3957. Outside the US contact your local 3M office or to locate your local office go to www.3M.com.

Table 4. Calculate Minimum Pressure Increase

- **RH lower limit** is the tolerance on the lowest allowable percent just prior to puncturing the Steri-Gas EO Gas Cartridge. If the %RH falls below the programmed tolerance, the GSX Series sterilizer will automatically cancel the cycle and proceed to EO Removal, Flushing and Locked Aeration (if programmed) before the user can access the chamber.
- **RH upper limit** is the tolerance on the maximum allowable %RH just prior to puncturing the Steri-Gas EO Gas Cartridge. If the %RH rises above the programmed tolerance, the GSX Series sterilizer will automatically cancel the cycle and proceed to EO Removal, Flushing and Locked Aeration (if programmed) before the user can access the chamber.

5. EO injection

Parameter	Minimum	Set Point	Maximum	Units
Simulate EO	No	No	Yes	
Vacuum level	100	160	160	mbar
Minimum pressure increase	100	200	550	mbar
RH lower limit	0	40	50	%
RH upper limit	70	80	90	%

Figure 44.
EO Injection Stage

11.5.6. EO Exposure Stage

Duration for EO (ethylene oxide) Exposure is the time period between the end of EO Injection and the beginning of EO Removal, when EO is sterilizing the load. No other parameters are programmed during the EO Exposure stage.

6. EO exposure

Parameter	Minimum	Set Point	Maximum	Units
Duration	0	60	999	min

Figure 45.
EO Exposure Stage

11.5.7. EO Removal Stage

There are no additional programmable parameters for the EO (ethylene oxide) Removal stage.

- The **Vacuum level** is the target chamber pressure for the EO Removal stage. The vacuum level for EO Removal stage is the same vacuum level as programmed in the Air Removal stage.
- The **Vacuum rate** is the rate air and EO are removed from the chamber while proceeding to the programmed vacuum level. The vacuum rate for EO Removal will be the slower of two rates 1) the vacuum rate as programmed in the Air Removal stage or 2) as required if the sterilizer is connected to an Abator.

7. EO removal

Parameter	Minimum	Set Point	Maximum	Units
Vacuum rate	25	100	100	%
Vacuum level	100	160	160	mbar

Figure 46.
EO Removal Stage

11.5.8. Flushing Stage

An exposure assessment should be conducted to determine appropriate Flushing and Aeration parameter set points. The Flushing stage and Aeration stage are typically necessary for removing ethylene oxide (EO) from the chamber, packaging, and load materials.

Removal of EO from the chamber and the load depends on multiple factors, including but not limited to: material composition of the load, the size of the load, the temperature and time, and the parameters set in the Flushing stage and Aeration stage.

The preprogrammed cycle parameters for the Flushing stage are the set points that populate the 3M™ Cycle Programmer when creating a new cycle.

Note: Use of preprogrammed cycle set points for the Flushing stage also requires assessment on each custom cycle for validating that facility procedures meet national, state, and local requirements for short term exposure limits (STELs) and long term exposure limits (LTELs).

- **Number of flushing cycles** is the number of fresh air purges and complete vacuums performed for the Flushing stage.
- **Vent rate** is the rate that filtered air is allowed into the chamber raising the pressure while proceeding to the flushing **Hold time: Top** set point (see Figure 48). Four (4) vent rates are available; 100%, 75%, 50% and 25%. The **vent rate** programmed will apply for all programmed flushing cycles. Vent rate is controlled by the percentage of time the vent valve is energized and opened to the chamber.
  - A **Vent rate** set point of 100% is the fastest pressure rise rate. The vent valve is open to chamber 100% of the time until the programmed flushing hold time: top is satisfied. The preprogrammed cycle vent rate is 100%.
  - A **Vent rate** set point of 25% is the slowest rate in which the vent valve is open to chamber 25% of the time until the programmed flushing hold time: top is satisfied.
- **Hold time: Top** is the amount of time the vent will remain open while the vacuum draws air through the chamber. The Hold time: Top timer starts after Hold time: Bottom is complete. A set point of one minute will produce a sharp transition to the next programmed flushing cycle (Figure 48). A longer Hold time: Top set point will produce a gradual transition to equilibrium of air flowing thorough the chamber, several mBar (kPa) below atmosphere, until the Hold time: Top duration is satisfied and the cycle proceeds to the next programmed flushing cycle (Figure 48).
- **Vacuum level** is the target chamber pressure for each flushing cycle.
- **Hold time: Bottom** is the duration the chamber will hold parameters constant after the vacuum level is attained (Figure 48).
- **Locked aeration time** is the amount of aeration the cycle will perform prior to allowing Operator or Supervisor access to the chamber.
- **No exhaust hood aeration time** is the minimum amount of aeration the cycle will perform, prior to allowing an Operator or Supervisor access to the chamber, if the exhaust hood option is not enabled or if the required air flow is not adequate through the exhaust hood.

8. Flushing

Parameter	Minimum	Set Point	Maximum	Units
Number of flushing cycles	2	5	99	
Vacuum rate	25	100	100	%
Vent rate	25	100	100	%
Hold time: Top	1	4	99	min
Vacuum level	100	300	300	mbar
Hold time: Bottom	0	0	99	min
Locked aeration time	0	90	999	min
No exhaust hood aeration time	0	180	999	min

Figure 47.
Flushing Stage

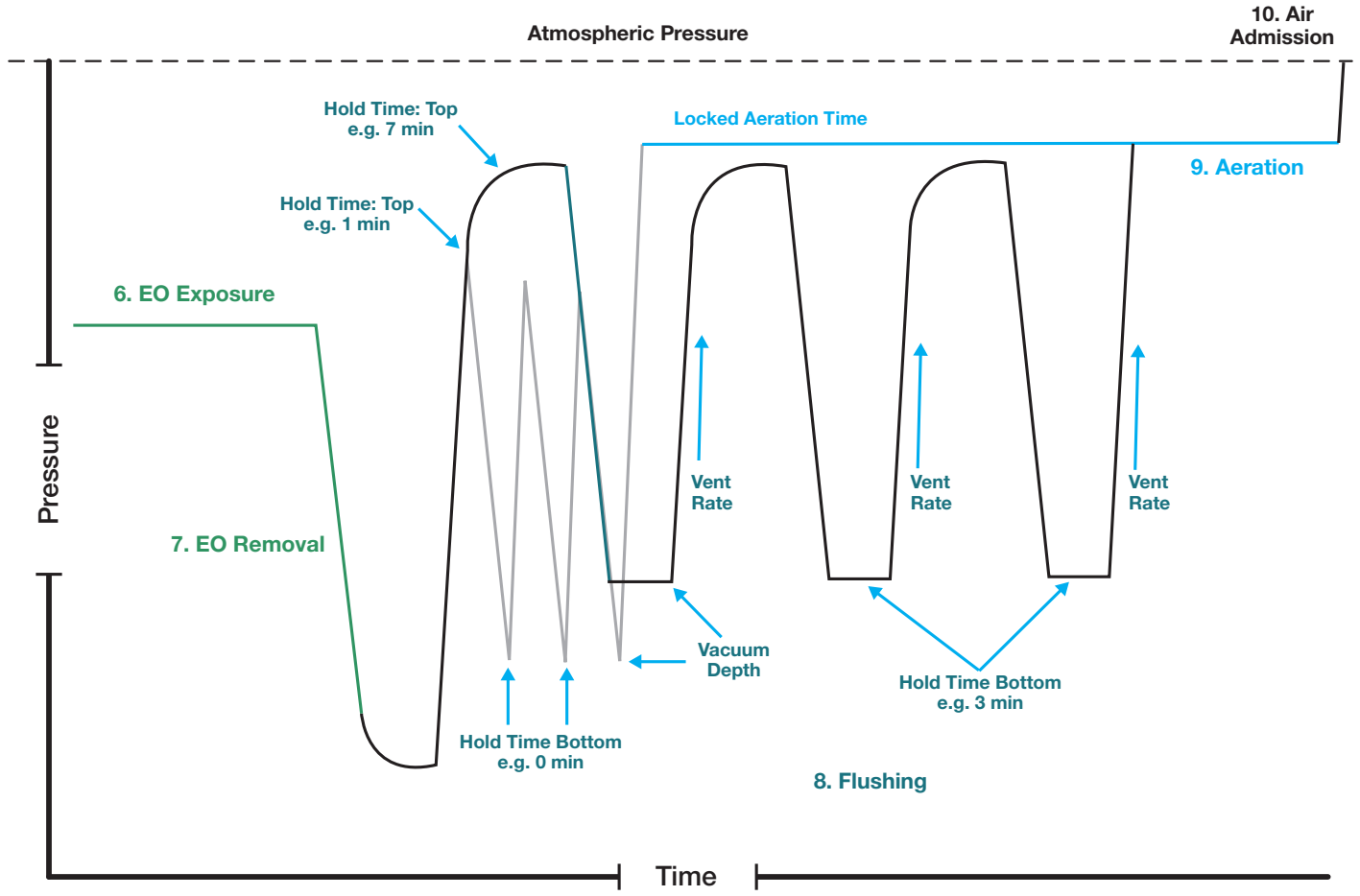


Figure 48.
Example of Two Different Flushing Stages, Each with Three Flushing Cycles

11.5.9. Aeration Stage

- **Aeration temperature** is the temperature target set point for all aeration after the Flushing stage.
- The **minimum aeration time** parameter is the minimum amount of time the aeration stage will run before proceeding to Standby Pulses. Additional aeration can be applied to the custom cycle during cycle start up. A Supervisor PIN is required to stop the Aeration stage before the minimum aeration time is complete.

9. Aeration

Parameter	Minimum	Set Point	Maximum	Units
Aeration temperature	34	55	60	℃
Minimum aeration time	0	12.0	999	hr

Figure 49.
Aeration Stage

11.5.10. Save a Custom Cycle

1. Select **File>Save** or use the Save icon to save the custom cycle.
2. Select a Folder location to store the newly created custom cycle, or create a new Folder on the USB to store the custom cycle.
3. Custom cycles cannot have the same file name.
4. The custom cycle will be saved as an .eto file.

Note:

- A USB drive must be used to import custom cycles onto the GSX Series sterilizer.
- The GSX Series sterilizer only looks for Folders on the USB drive at the beginning of the custom cycle import process.
- Saving the custom cycle onto a USB drive inside a Folder will save time during the custom cycle import process (Chapter 11).

11.5.11. Standby Stage

Once programmed aeration time elapses, the system will proceed from the Aeration stage to Standby. In this stage, the system will perform either pulsed or continuous room temperature aeration. If this stage was reached upon completion of programmed aeration, without any errors, the system will perform pulsed room temperature aeration (Figure 50). If this stage was reached following specified error recovery modes, the system will perform continuous room temperature aeration.

Like the Aeration stage, the Standby stage admits air into the chamber through a filter with a series of timed vacuum draws. Standby stage will reduce the potential buildup of residual EO in the chamber before the chamber door is opened and the load is removed. **The Standby stage is preprogrammed and cannot be changed by the user.** Standby stage stops when the chamber door is opened and the red Stop button is pressed.

The Standby stage should be considered and evaluated during:

- user's facility management exposure assessments
- developing and validating cycles for sterilization
- before implementing facility standard operating procedures (SOPs) for the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series.

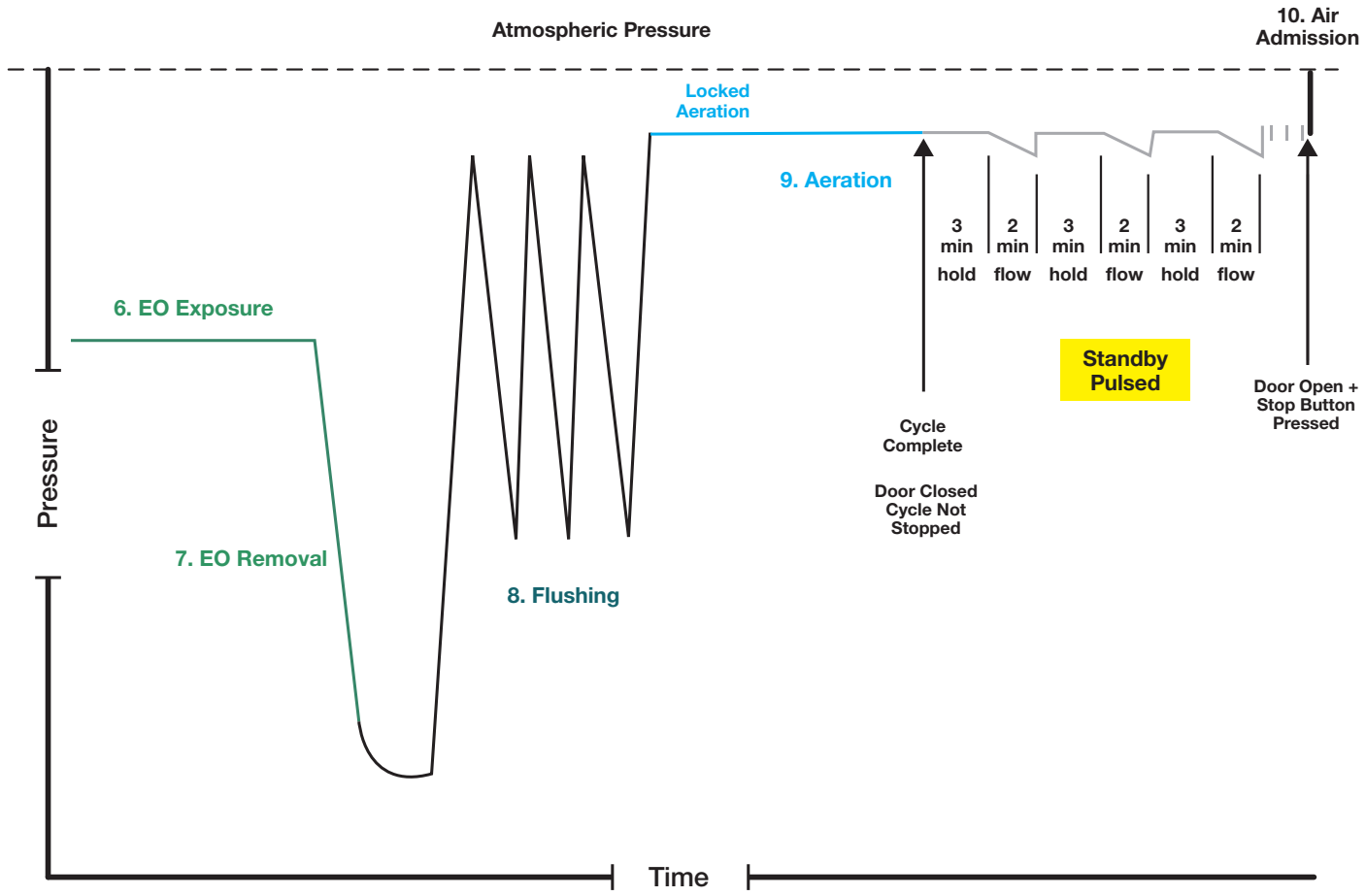


Figure 50.
Example of Standby Stage –Pulsed

11.5.12. Estimated Total Cycle Time

The 3M™ Cycle Programmer will estimate the total cycle time with each set-point change. The estimated total cycle time includes programmed Aeration stage. **The connection of a 3M™ Abator will add an estimated 25-50 minutes to the total cycle time during the EO Removal stage which is not included in the 3M Cycle Programmer estimate.**

11.6. Importing Custom Cycles to the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series

Importing custom cycles onto the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series requires a Supervisor PIN. **3M Health Care service personnel or authorized 3M service personnel must create the first Supervisor user and PIN on the GSX Series sterilizer.** Additional Supervisor users and PINs can be created by established Supervisors.

1. Insert a Universal Serial Bus (USB) drive into one of the two available ports located behind the GSX Series sterilizer access door (Figure 51). Recommended USB drives include drives with FAT32 formatting. Drives with pre-loaded software (e.g., SanDisk's Cruzer®) are not recommended. Only USB drives, for the sole purpose of exporting data, are to be connected to the USB ports. Do not connect external USB devices that supply power.

Figure 51.
Inserting a USB Drive into the sterilizer USB Port

2. Go to **Menu>Setup>Import/export cycles** (Figure 52). Import/export of custom cycles requires a Supervisor PIN. **Custom cycles must be saved in a Folder on a USB drive.** The GSX Series sterilizer only looks for Folders on the USB drive at the beginning of the cycle import process.

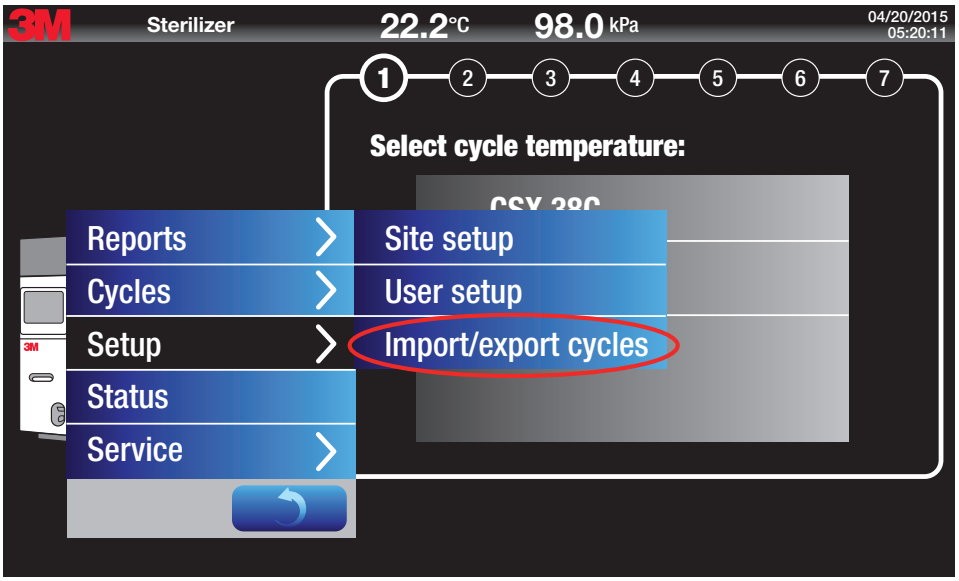


Figure 52.
Selecting the Import/Export Cycles Option

3. Before a USB drive is detected, all functionality buttons on this screen will be disabled (gray) (Figure 53). Once the USB drive is detected, the functionality buttons will turn blue.
4. Press the blue **Browse** button to search for valid Folders on the USB drive. Choose the desired USB folder by pressing the folder name, then **OK** (Figure 53).

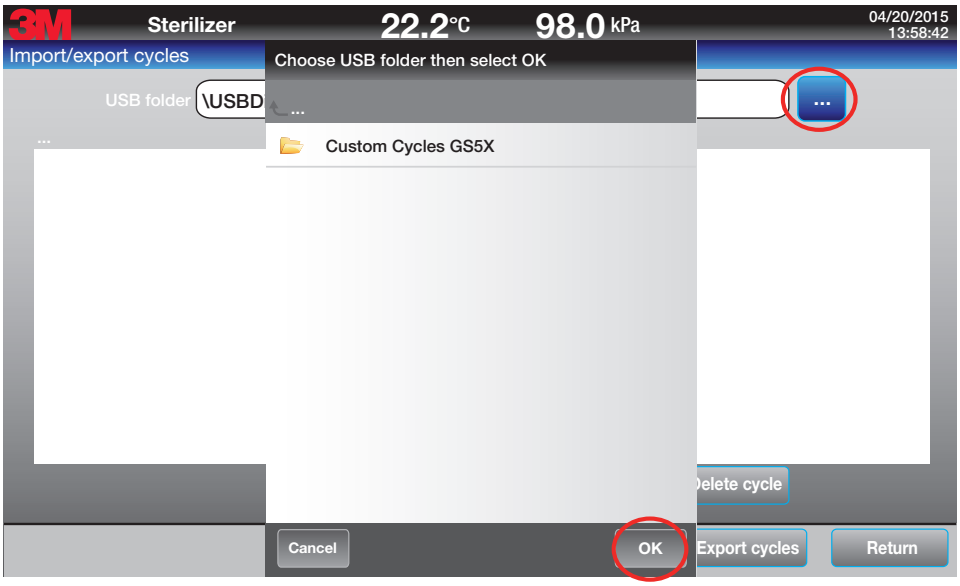


Figure 53.
Finding Folders on the USB Drive

5. Custom cycle files in the selected Folder will appear in the left window for the option of importing. To import a single file, press (">"). To import all files, press (">>") (Figure 54).

Figure 54.
Custom Cycle Files Found

Once a cycle(s) has been selected for import, the file(s) will move to the right hand window. A green check mark indicates that selected cycles are new to the GSX Series sterilizer and are ready to be imported (Figure 55). Press **Import cycles** to import. The check mark will be removed upon successful import; however, the file name will remain in the right window (Figure 56).

Figure 55.
Custom Cycles Ready for Import

Figure 56.
Successful Import of Custom Cycles

Press **Return** to go back to the main screen.

11.7. Running Custom Cycles on the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide:

Short term exposure limits (STEL) or long term exposure limits (LTEL) or immediately dangerous to life or health (IDLH) limit could be exceeded during NORMAL use. Operators and staff must use protective measures (e.g. engineering controls, work practices, or personal protective equipment (PPE)) in accordance with United States 29 CFR 1910.134 and 29 CFR 1910.1047 under NORMAL use conditions until the user's facility management completes an exposure assessment on each custom cycle that validates facility protective measures meet national, state, and local requirements for short term exposure limits (STELs) and long term exposure limits (LTELs).

Assure Operator selects the correct cycle for the intended application.

⚠ CAUTION: To reduce risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures:

The user must validate the sterile efficacy of each custom cycle intended to sterilize products labeled 'Sterile'.

Assure Operator selects the correct cycle for the intended application.

1. A Supervisor must access **Menu>Site Setup>Setup>Cycle** to enable newly imported cycles on the Operator Cycle Start Screen. Newly imported cycles are not automatically added to the Operator Cycle Start Screen view (Figure 57).

   Note:

   - Cycles created for the Operator will be selectable in Operator view.
   - Cycles created for the Supervisor will be selectable in Supervisor view.
   - Once selections are made, press **Apply Changes**.

   Press **Return** to go back to the main screen.

   Note:

   - This feature allows custom cycles to be stored and accessed in different locations on the GSX Series sterilizer to help assure Operator selects and starts the correct cycle for the intended application.
   - Minimum aeration times can not be changed in this view for custom cycles. Minimum aeration times must be changed in the 3M™ Cycle Programmer and then imported back to the GSX Series sterilizer.

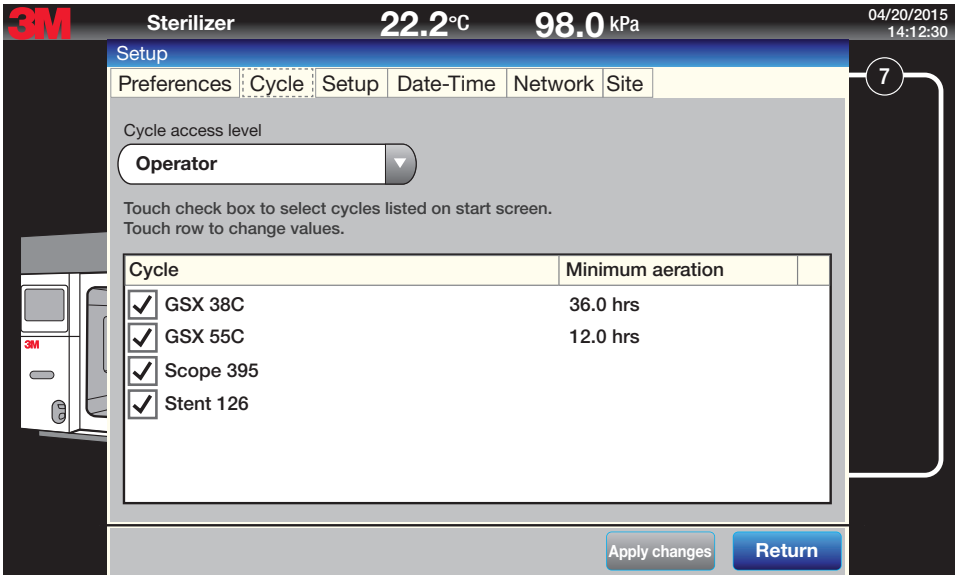


Figure 57.
Imported Cycles Stored in Menu>Setup >Site Setup>Cycle

2. Imported custom cycles that were selected in **Menu>Setup>Site Setup>Cycle** now appear in the Cycle Start Screen. Custom cycles have the 'gears' logo next to the file name to distinguish them from the preprogrammed cycles (Figure 58).

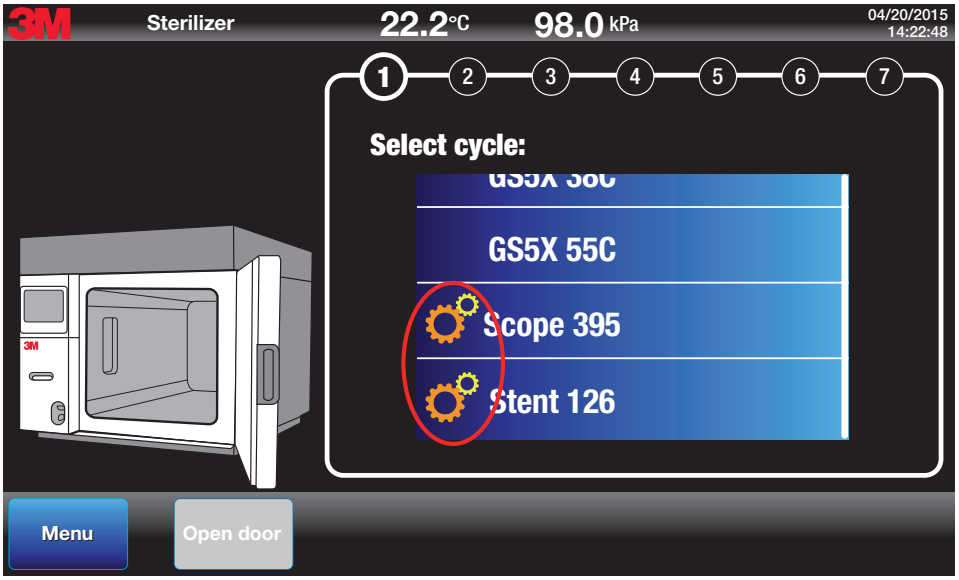


Figure 58.
Cycle Start Screen with Custom Cycles

3. Assure Operator Cycle Start Screen (Figure 58) on the GSX Series sterilizer, displays a minimal number of custom cycles to help assure Operator selects and starts the correct cycle for the intended use.
4. Start the cycle per Chapter 13.

11.8. Managing Custom Cycles on the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series

Only one cycle with the same name can be loaded onto the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. The GSX Series sterilizer will check the cycle names before allowing the cycles to be imported. If a custom cycle has the same name as a cycle already on the GSX Series sterilizer there are four choices:

a. Replace the current cycle on the GSX Series sterilizer (Figure 59).
b. Select not to Import the new custom cycle.
c. Stop the import process, delete the cycle with the same name on the GSX Series sterilizer, and restart the import process.
d. Stop the import process, change the custom cycle name to be imported, and restart the import process.

11.9. Replacing Cycles on the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series With the Same Name

Figure 59 illustrates that the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series has detected a custom cycle to be imported has the same name as a cycle already on the GSX Series sterilizer. The sterilizer requests confirmation to replace the custom cycle on the sterilizer.

Figure 59.
Example of Replacing a Custom Cycle on the GSX Series Sterilizer

1. To replace the custom cycle on the sterilizer, select **OK**.
2. A red "X" will appear next to the cycle to be deleted and a green check mark will appear next to the cycle to be imported (Figure 60). Press **Import cycles** to proceed.
3. Press **Return** to go back to the main screen.

Figure 60.
Final Confirmation of Custom Cycle Replacement

11.10. Removing Custom Cycles from the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series

1. To remove a custom cycle on the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series, the cycle can be deleted with the **Delete cycle** button and/or the cycle can be copied to a USB drive. To copy to a USB drive, place a USB drive into one of the GSX Series sterilizer USB ports.
2. Press **Browse** to search for valid Folders on the USB drive. Choose the desired USB Folder by pressing the name, then **OK**.
3. The GSX Series sterilizer will automatically create a valid USB folder on the USB drive to store the exported cycle(s) (e.g. "\ USBDisk \ Custom Cycles GS5X \ EA343434 Export cycles") (Figure 61).
4. Select single file for export from the right window and click ("<"). To export all files, click ("<<"). The selected files will move to the left window (Figure 61).
5. A green check mark next to the file name indicates the custom cycles are ready to be exported (Figure 61). Select **Export cycles**.
6. The sterilizer will ask for confirmation of the Folder designation before exporting.
7. Press **Return** to go back to the main screen.

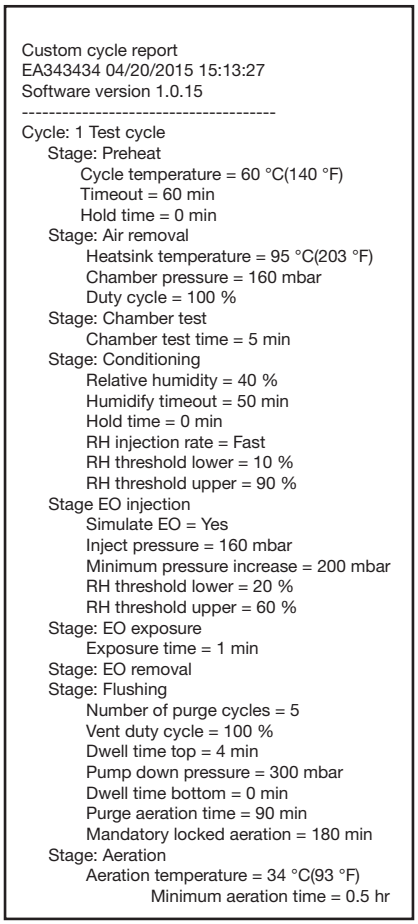
Figure 61.
USB Folder for Exporting

11.11. Cycle Reports

11.11.1. Custom Cycle Set Points

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series allows users to view and print parameter values for custom cycles installed on the GSX Series sterilizer. The report will display programmed custom cycle set-points for each parameter.

1. To view or print custom cycle set points go to **Menu>Reports>Custom cycle set points**.
2. Select the desired cycle and then **View** or **Print**. Figure 62 is an example custom cycle set point report.
3. Press **Cancel** to return to the main screen.



```
Custom cycle report
EA343434 04/20/2015 15:13:27
Software version 1.0.15
---------------------------------------
Cycle: 1 Test cycle
    Stage: Preheat
        Cycle temperature = 60 °C(140 °F)
        Timeout = 60 min
        Hold time = 0 min
    Stage: Air removal
        Heatsink temperature = 95 °C(203 °F)
        Chamber pressure = 160 mbar
        Duty cycle = 100 %
    Stage: Chamber test
        Chamber test time = 5 min
    Stage: Conditioning
        Relative humidity = 40 %
        Humidify timeout = 50 min
        Hold time = 0 min
        RH injection rate = Fast
        RH threshold lower = 10 %
        RH threshold upper = 90 %
    Stage EO injection
        Simulate EO = Yes
        Inject pressure = 160 mbar
        Minimum pressure increase = 200 mbar
        RH threshold lower = 20 %
        RH threshold upper = 60 %
    Stage: EO exposure
        Exposure time = 1 min
    Stage: EO removal
    Stage: Flushing
        Number of purge cycles = 5
        Vent duty cycle = 100 %
        Dwell time top = 4 min
        Pump down pressure = 300 mbar
        Dwell time bottom = 0 min
        Purge aeration time = 90 min
        Mandatory locked aeration = 180 min
    Stage: Aeration
        Aeration temperature = 34 °C(93 °F)
                Minimum aeration time = 0.5 hr
```

Figure 62.
Example Custom Cycle Set Point Report

11.11.2. Export Cycle Data

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series allows Supervisors or Service to export one or more condensed cycle data files to a USB drive. The GSX Series sterilizer can export up to 100 of the most recent cycle data files within 60 minutes. The sterilizer also automatically keeps the last 100 condensed cycle data files in a read-only folder accessible on the sterilizer's local area network (LAN) by Supervisor or higher access level users.

1. To export cycle data go to **Menu>Reports>Export cycle data**.
2. Enter a Supervisor or Service PIN.
3. Place a USB drive into one of the GSX Series sterilizer USB ports.
4. Press **Browse** to search for valid Folders on the USB drive. Choose the desired USB folder by touching the name, then **OK**.
5. The GSX Series sterilizer will automatically create a valid USB folder on the USB drive to store the exported cycle(s) data (e.g. "\ USBDisk \ Custom Cycles GS5X \ EA343434 Export cycle data").
6. Display screen will display up to 100 stored cycles for selection.
7. Choose **Export selected cycles** or **Export all cycles** (Figure 63).
8. Wait momentarily for the export process to complete, and then press **OK** on the "Save Completed" screen to return to the main screen.

Figure 63.
USB Folder and Cycles Selection for Export Cycle Data

9. The exported cycle data will be saved in a .csv file. The file name will include the sterilizer serial number, the date the cycle was run, and the cycle name.
10. Open the cycle data file in Excel.

12. Medical Device Packaging and Loading

12.1. Preparing Medical Devices for Sterilization

For reusable device sterilization, clean devices for sterilizing according to the device manufacturer's instructions for use before processing in the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series.

Thorough cleaning is essential to achieve sterilization efficacy.

⚠ **DANGER: To reduce risks associated with exposure to ethylene oxide:**
For reusable device sterilization, always follow the device manufacturer's instructions for use (IFU), including device cleaning, drying, packaging, sterilizing, and aerating.
Only sterilize medical devices that are manufactured with materials compatible with ethylene oxide sterilization processes. Do not sterilize leather, liquids, or materials that are reactive to ethylene oxide.

⚠ **WARNING: To reduce risks associated with fire and explosion:**
Do not sterilize devices with energy sources which could create a spark in the sterilization chamber during the sterilization cycle.
For reusable device sterilization, always follow device manufacturer's instructions for use (IFU), including device cleaning, drying, packaging, sterilization, and aeration.

⚠ **CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures:**
For reusable device sterilization, always follow device manufacturer's instructions for use (IFU), including device cleaning, drying, packaging, sterilization, and aeration.
Only sterilize medical devices that are manufactured with materials compatible with ethylene oxide sterilization processes. Do not sterilize leather, liquids, or materials that are reactive to ethylene oxide.

12.2. Packaging Medical Devices

Non-compatible packaging and/or incorrect loading of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series may compromise the sterility of the processed devices.

For reusable device sterilization, before packaging, ensure that the medical devices are clean and dry per manufacturer's instructions for use.

12.2.1. Recommended Packaging

The following packaging is recommended for use with ethylene oxide (EO) sterilization:

- Polyethylene plastic bags (designed for use as a sterile package and are not more than 5 mils thick)
- Peel pouches:
  - Spun-bonded olefin polyethylene-polyester laminate
  - Paper/polyethylene-polyester laminate
  - Paper/polypropylene-polyester laminate
- Wraps:
  - Woven textile
  - Nonwoven textile
  - Nonwoven polypropylene
  - Paper, coated and uncoated
- Rigid sterilization container systems
- Plastic trays with paper or spun-bonded olefin lids

12.2.2. Non-compatible Packaging

The following packaging is not compatible and is not recommended for use in ethylene oxide (EO) sterilization processes:

Do not use packages made entirely of any of the following materials:

- Foil
- Cellophane
- Polyvinylchloride (PVC)
- Impervious polypropylene film
- Polyester (polyester film made from stretched polyethylene terephthalate (PET))
- Polyamide (nylon)
- Polyvinylidene chloride

12.2.3. Package Medical Devices

1. Place the device in ethylene oxide (EO) compatible packaging.
2. If applicable per your facility's procedures, place one or more EO chemical indicators (CI) inside each container, wrapped tray, or sterilization pouch (Chapter 14: Process Monitoring, Load Release, and Sterilizer Qualification).
3. When sterilizing pouched items, seal the sterilization pouch using a heat sealer set to the appropriate time and temperature.
4. Wrap non-containerized trays with EO compatible wrapping material and secure with EO indicator tape.
5. For containerized items, ensure an external chemical indicator for EO is present.

NOTE: When loading devices inside a container or tray, leave sufficient space between the instruments to enable the sterilant to circulate. The containers used must be prepared and sealed according to the procedures recommended by their respective manufacturers.

12.3. Loading the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series

Loading baskets are recommended to facilitate loading the sterilization chamber. Loading baskets are designed with skids to avoid scratching the chamber floor. A transport cart can be used to easily load, unload, and move loading baskets to and from the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series.

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide,

do not overload the sterilization chamber. Use good practices for loading the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series chamber.

⚠ CAUTION: To reduce the risk of injury,

follow good ergonomic practices. Loading baskets should not be overfilled requiring excessive force in pulling and pushing loaded baskets in and out of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series chamber. Reference facility policies and procedures for appropriate ergonomic practices.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures:

Always use chemical indicators and biological indicators for monitoring the performance of sterilization cycles as described in this manual. Always use chemical indicators and biological indicators per the device manufacturer's instructions for use (IFU).

Do not overload the sterilization chamber. Use good practices for loading the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series chamber.

12.3.1. Loading Recommendations

3M™ Attest™ Biological Indicator in a ***routine*** biological indicator process challenge device (PCD, also known as a Test Pack or BI PCD) should be used in every load. A BI PCD should be placed in the center of the load (Chapter 14: Process Monitoring, Load Release, and Sterilizer Qualification).

- Always use loading baskets when loading the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series.
- Do not overload the GSX Series sterilizer. Arrange items in the loading baskets to ensure that water vapor and ethylene oxide (EO) can circulate freely between them.
- Place peel pouches on their edges, if possible.
- Arrange sterilization pouches so that the transparent side of a pouch faces the opaque side of the adjacent pouch.
- Ensure no devices are touching the GSX Series sterilizer chamber walls.

12.3.2. Loading Medical Devices and Instruments

Sterilization pouches should be placed on their edges if possible. If a sterilization pouch is placed on its side or flat on the shelf, do not place any item on top of the pouch.

To the extent practical, the Operator should attempt to sterilize full loads of items having a common aeration time.

A full load can be comprised of sterilization pouches, wrapped trays, and containers or a combination of various packs.

13. Operating Instructions

13.1. Starting a Cycle

The Operator controls the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series via a touch screen. A fingertip, stylus, or ball tip pen can be safely used to navigate the touch screens. There are seven (7) programming steps to start a cycle.

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide,

inspect the display screen and cycle reports for errors and listen for audible notifications (if enabled). Always take action for errors as indicated in this manual.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,

inspect the display screen and cycle reports for error codes and listen for audible notifications (if enabled). Always take action for error codes as indicated in this manual.

1. Select Cycle

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series has two validated preprogrammed cycle options: GSX 38C (100.4°F) and GSX 55C (131.0°F). Select the appropriate cycle.

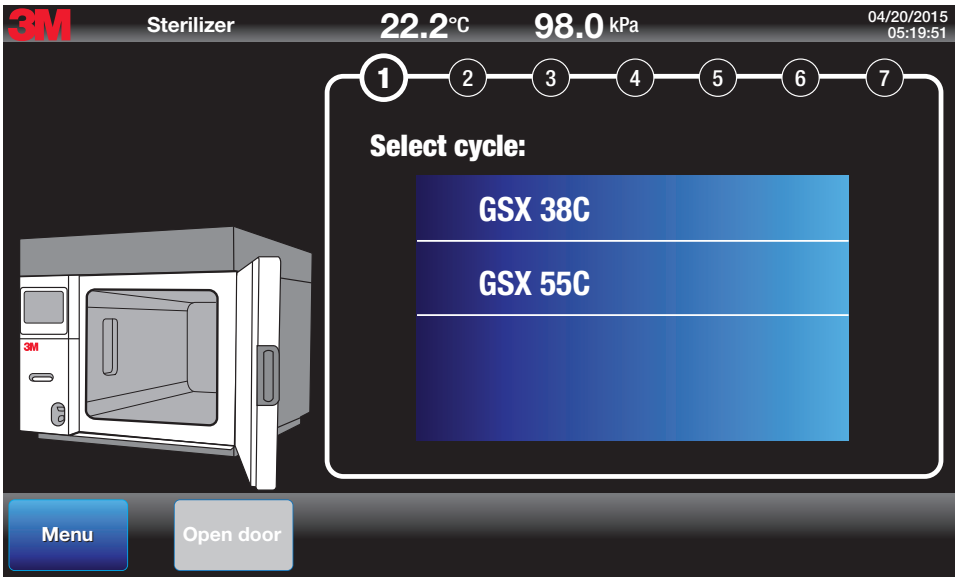


Figure 64.
Step One: Select Cycle

2. Select Aeration Time

Use the aeration time iWheel to select the appropriate aeration time. Aeration times can be set in intervals of 30 minutes. Press **Next** to continue.

The minimum default aeration time can be changed for the validated preprogrammed GSX 38C and GSX 55C cycles. Minimum aeration times cannot be changed in this view for custom cycles, however, additional aeration time can be added for custom cycles.

Custom cycle minimum aeration times must be changed in the 3M™ Cycle Programmer and imported back to the GSX Series sterilizer.

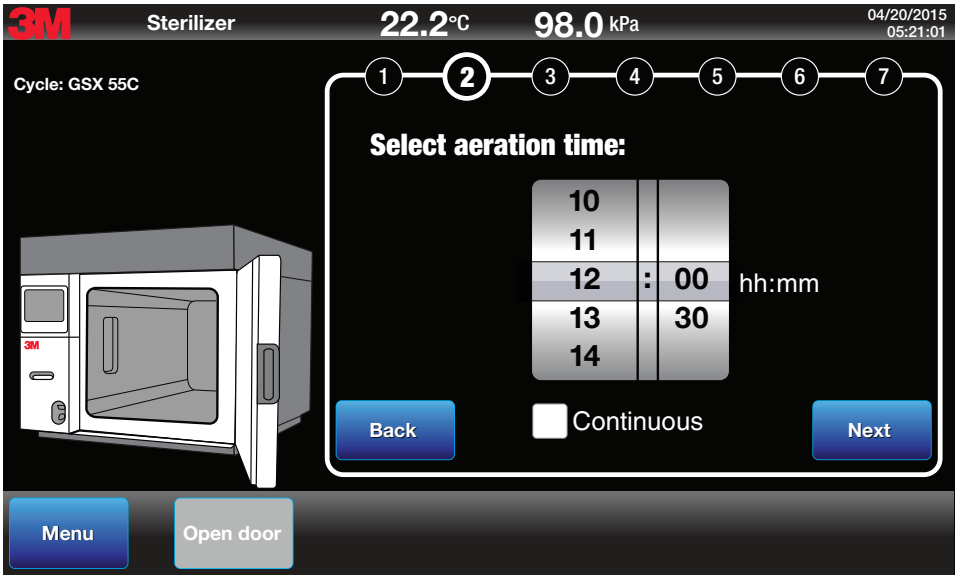


Figure 65.
Step Two: Select Aeration Time

3. Enter Load ID (Optional)

The Load ID is optional. The Load ID can be a combination of up to 20 characters. The system will accept 'A –Z', 'a-z', 0-9, space, period, and dash ("-"). Caps lock can be activated by double tapping the shift (up arrow) button. Touch the white data entry field to activate the keyboard. Enter the Load ID. Press **Next** to continue.

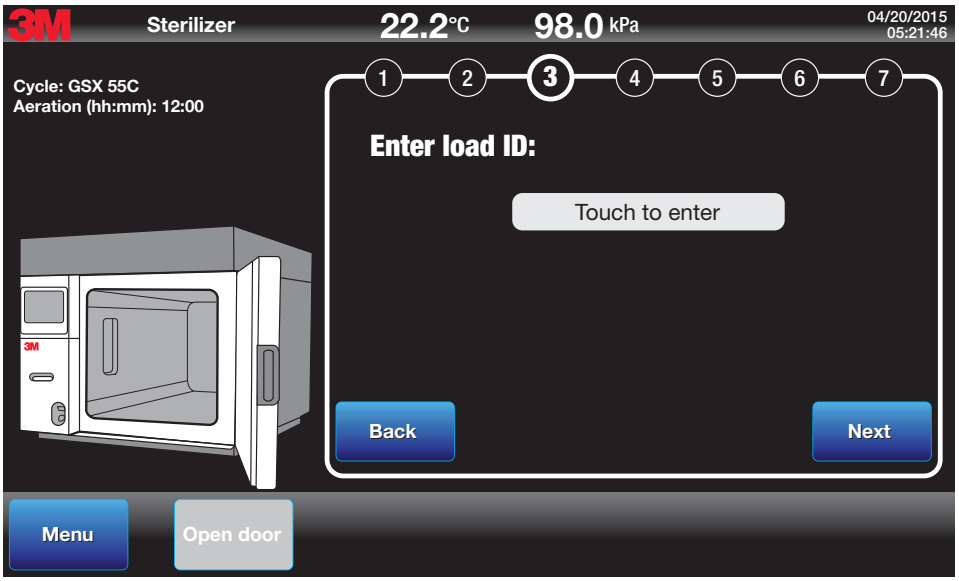


Figure 66.
Step Three: Enter Load ID

Figure 67.
Load ID Entry by Keyboard

4. Scan 3M™ Steri-Gas™ Ethylene Oxide (EO) Gas Cartridge Barcode

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide:

Only use 3M™ Steri-Gas™ EO Gas Cartridges as listed in this manual. Do not use other brands or types of sterilant cartridges.

Do not use damaged 3M™ Steri-Gas™ EO Gas Cartridges.

If an individual 3M™ Steri-Gas™ EO Gas Cartridge is ever dropped, the cartridge should be used immediately or disposed of as described in the cartridge disposal section.

⚠ WARNING: To reduce the risks associated with fire and explosion,

use care when handling 3M™ Steri-Gas™ EO Gas Cartridges as they contain 100% Ethylene Oxide (EO) which is an extremely flammable gas and liquid under pressure. Do not use near flame, electrical sparks, or hot surfaces, or allow sources of ignition near the cartridges. Do not puncture cartridge outside the sterilization chamber. Do not incinerate cartridges. Exposure to temperatures above 150ºF (65.5ºC) may cause cartridges to burst.

3M™ Steri-Gas™ EO Gas Cartridge Catalog Number	3M™ Steri-Vac™ GSX Series Model	Nominal Net Weight of EO
4-100	GS5X or GS8X	EO net wt. 100 g. (3.52 oz.)
8-170	GS8X	EO net wt. 170 g. (5.99 oz.)
4-134	GS5X or GS8X	EO net wt. 127 g. (4.47 oz.)
4-60	GS5X or GS8X	Custom EO net wt.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,

only use 3M™ Steri-Gas™ EO Gas Cartridges as listed in this manual. Do not use other brands or types of sterilant cartridges.

Put on personal protective equipment (PPE) consisting of indirect vented safety goggles, long sleeves, and butyl rubber gloves when handling full Ethylene Oxide (EO) Gas Cartridges. The barcode is a small square, located on the top of the cartridge, in the area of the black stripe. To scan, place the barcode under the red light of the cartridge scanning bay on the front of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series (Figure 69). The barcode scanner will remain active for 10 seconds once scanning begins. After a successful scan, the 3M™ Steri-Gas™ EO Gas Cartridge lot number will appear in the cycle parameters section of the GSX Series sterilizer display screen.

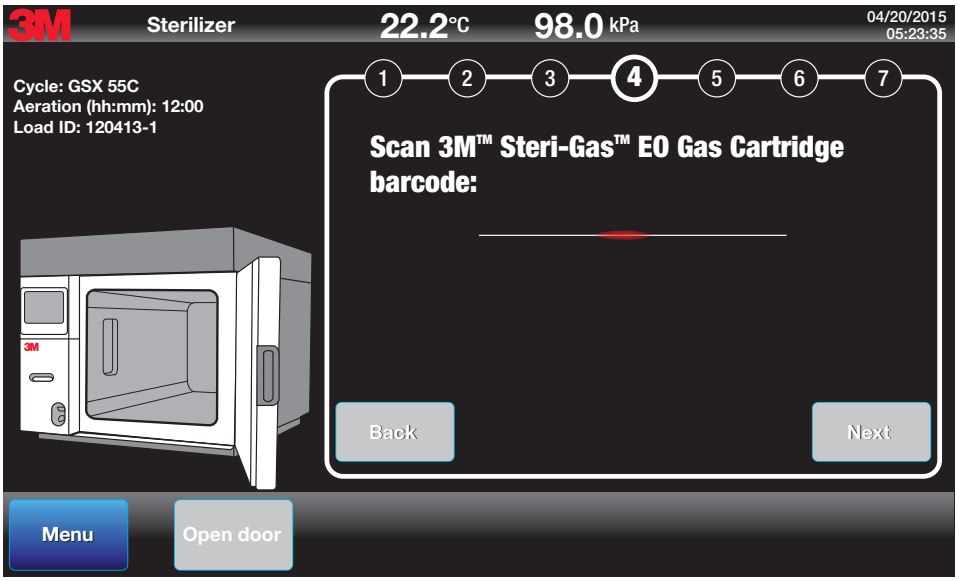


Figure 68.
Step Four: Scan the 3M™ Steri-Gas™ EO Gas Cartridge Barcode

Only valid 3M Steri-Gas EO Gas Cartridges will be accepted by the sterilizer. See Figure 70 for an example display message of an invalid gas cartridge.

Invalid cartridges include:

- A used cartridge
- An expired cartridge
- An invalid barcode
- An unreadable barcode
- Incorrect cartridge size for the GSX Series sterilizer

Figure 69.
Scanning the 3M™ Steri-Gas™ EO Gas Cartridge Barcode

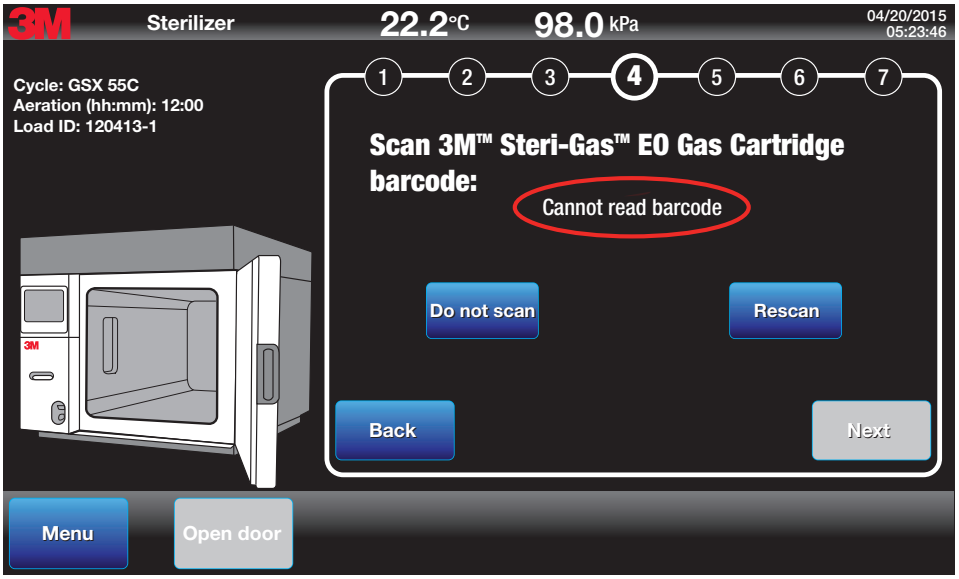


Figure 70.
Example Display Message for an Invalid 3M™ Steri-Gas™ EO Gas Cartridge

If a valid Steri-Gas EO Gas Cartridge has a damaged barcode, the Operator has the option to bypass the scan. However **THIS OPTION CAN ONLY BE PERFORMED FIVE TIMES**, after which a 3M Health Care service personnel or authorized 3M service personnel must be contacted to re-set the override (Figure 71).

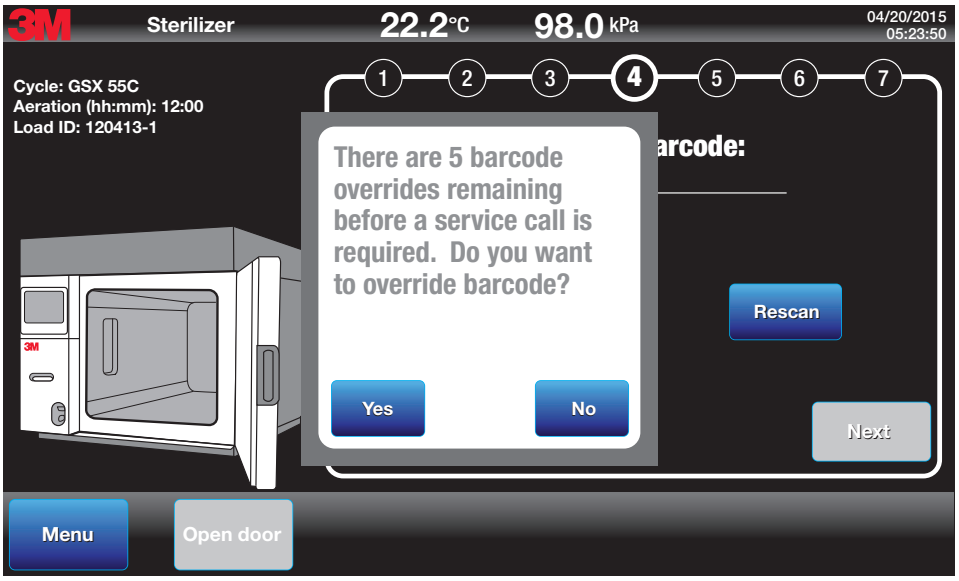


Figure 71.
Steri-Gas EO Gas Cartridge Barcode Override Message

5. Insert 3M™ Steri-Gas™ EO Gas Cartridge, Load Chamber, and Close Door

Insert the 3M™ Steri-Gas™ EO Gas Cartridge into the cartridge bay located inside the GSX Series sterilizer chamber (Figures 73). Push the green lever down over the Steri-Gas EO Gas Cartridge to secure in place (Figure 74).

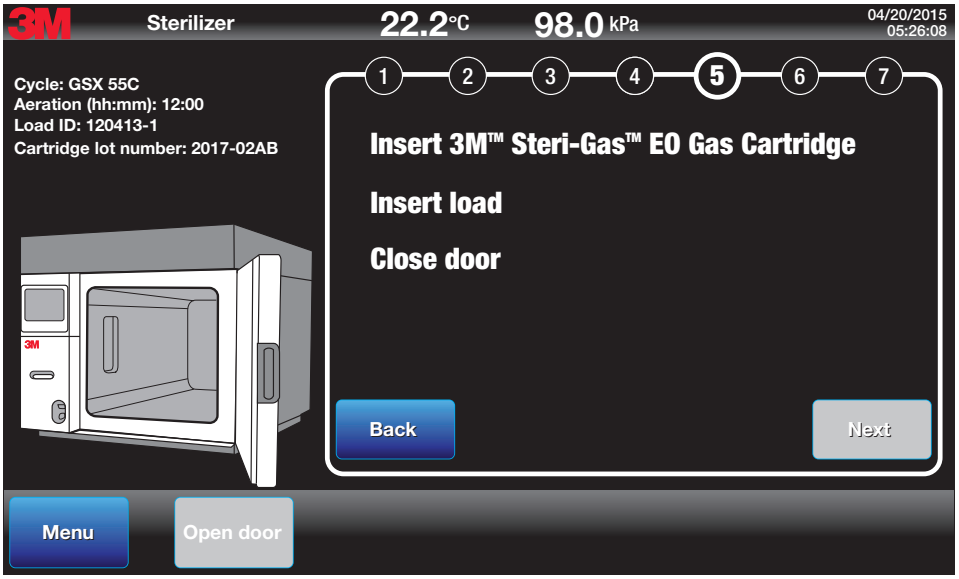


Figure 72.
Step Five: Insert Steri-Gas EO Gas Cartridge, Insert Load, Close Door

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide,

do not force the 3M™ Steri-Gas™ EO Gas Cartridges into the cartridge holder as excessive force could damage the cartridge and result in a cartridge leak.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,

do not force the 3M™ Steri-Gas™ EO Gas Cartridges into the cartridge holder; excessive force could damage the cartridge and result in a cartridge leak.

Figure 73.
Steri-Gas EO Gas Cartridge in Cartridge Bay

Figure 74.
Green Lever Securing Steri-Gas EO Gas Cartridge

Insert the load into the GSX Series sterilizer chamber.

Close the sterilizer door by gently pressing the door to the chamber seal. The sterilizer will engage a physical latch to secure and lock the door.

Press **Next** to continue.

A green filled cartridge icon will appear in the cartridge bay area of the sterilizer image on the display screen.

6. Enter Operator ID (Optional)

The Operator ID is optional. The Operator ID can be a combination up to 20 characters. The system will accept 'A –Z', 'a-z', 0-9 space, period, and dash ("-"). Caps lock can be activated by double tapping the shift (up arrow) button. Touch the white data entry field to activate the keyboard then enter the Load ID (Figures 75 and 76). Press **Next** to continue.

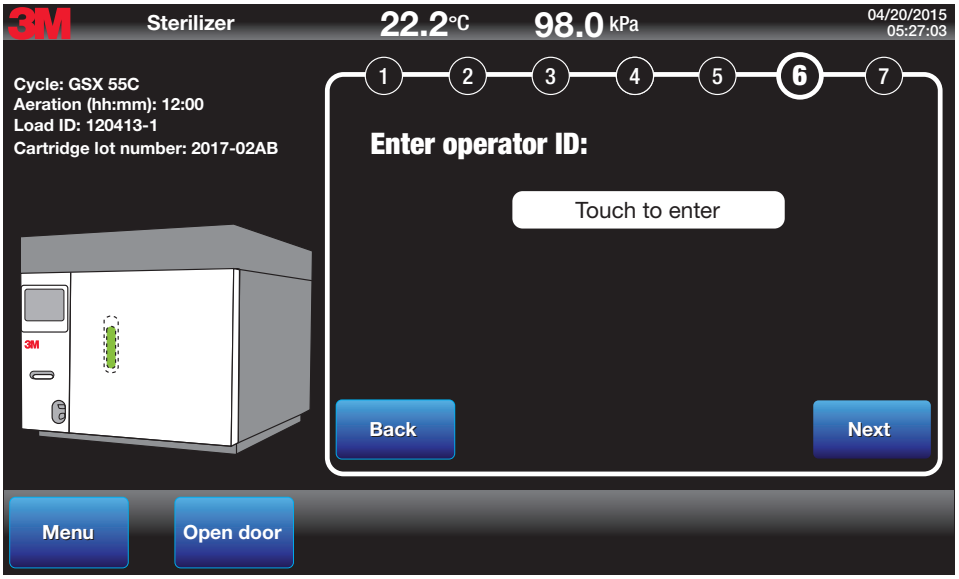


Figure 75.
Enter Operator ID

Figure 76.
Operator ID Entry by Keyboard

7. Review and Start Cycle

Review the selected cycle (Figure 77). Press **Start** to proceed and initiate the cycle. Select **Back** to change previously selected parameters of the cycle. Press **Cancel** to clear the cycle and return to the main screen.

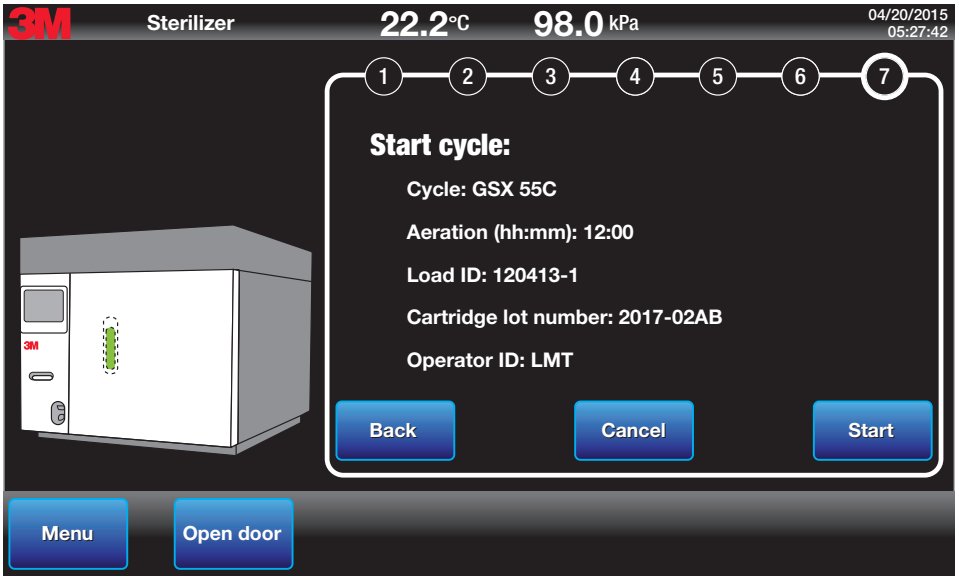


Figure 77.
Review and Start Cycle

After the cycle is started, the GSX Series sterilizer proceeds to the Preheat stage, the first of nine active stages of an EO sterilization cycle. Figure 78 is the display screen of a cycle in the Preheat stage.

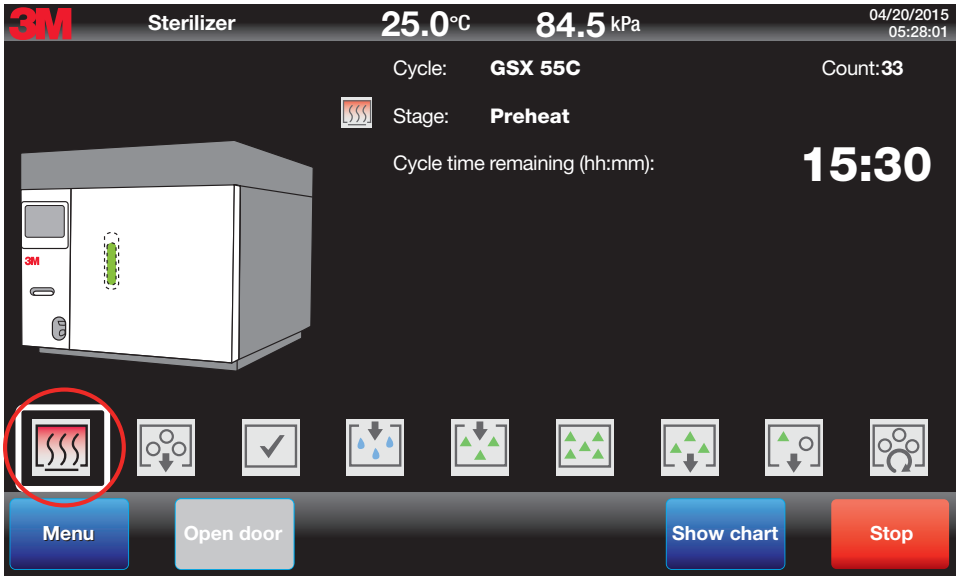


Figure 78.
Preheat Stage Display Screen

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide,

call 3M Health Care service personnel or authorized 3M service personnel immediately if there is a failure of the display or backlight and the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series continues to operate.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,

call 3M Health Care service personnel or authorized 3M service personnel immediately if there is a failure of the display or backlight and the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series continues to operate.

13.2. Display Screen Indications

Figure 79 illustrates the important information presented on the display screen while the sterilization cycle is running. Table 5 explains each indication.

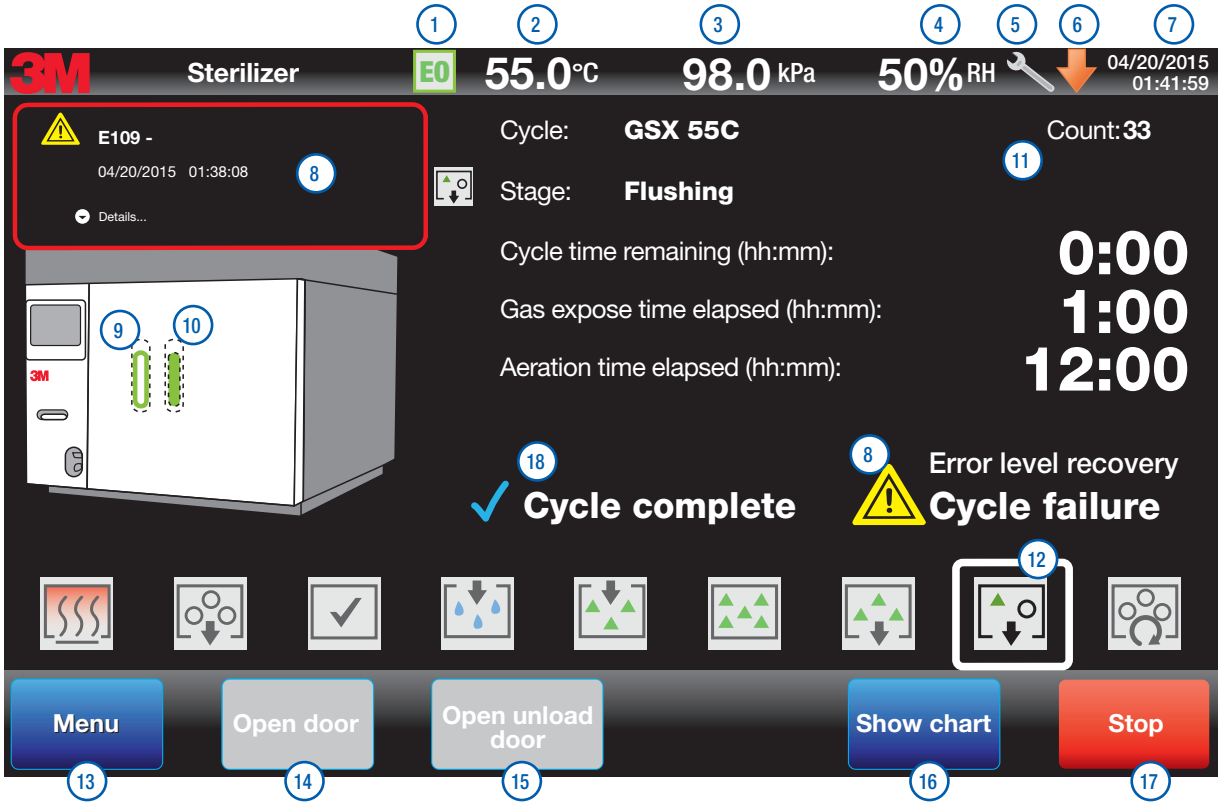


Figure 79.
Display Screen Indications

Indication Number	Indication Description
1	**EO Icon.** Indication ethylene oxide (EO) is in the chamber.
2	Shows current chamber temperature.
3	Shows current chamber pressure.
4	Shows current chamber percent relative humidity (%RH). %RH is only measured and displayed during the Conditioning stage.
5	Indication that Maintenance is due and Service should be notified.
6	An orange, downward arrow symbol will appear on the display screen task bar to remind the user that a pending software update is available for installation.
7	Shows current date and time.
8	**Error Message.** Indicates a fault has occurred. See Chapter 16: Cautions, Error Messages and Troubleshooting for specific errors and corrections.
9	Indication that a **used** 3M™ Steri-Gas™ EO Gas Cartridge is in the chamber.
10	Indication that an **unused** 3M™ Steri-Gas™ EO Gas Cartridge is in the chamber.
11	**Counter.** This is the sterilizing cycle counter that indicates the cumulative number of all cycles started, including those cycles in which a fault occurred.
12	**Cycle stage icons.** While a sterilization cycle is running, the icons on the bottom of the display screen indicate the current stage of the cycle (indicated by a white border around the icon). Each icon and the corresponding sterilization cycle stage are described in the section Overview of the GSX Series EO Sterilization Cycle.
13	**Menu** button is used to access GSX Series sterilizer options (e.g. cycle reports, setup variables)
14	**Open Door** button (the word "load "is only used for double door or pass through sterilizer models). During the sterilization process, the Operator cannot open the door; therefore, the button is colored gray.
15	**Open Unload Door** button is used on double door pass through GSX Series sterilizer models. During the sterilization process, the Operator cannot open the door; therefore, the button is colored grey.
16	**Show Chart** button displays a running graph of the current cycle in process.
17	**Stop** button cancels the cycle in progress. There are times during the sterilization process when the Operator cannot cancel the GSX Series sterilizer; therefore, the button is colored grey.
18	**Cycle Complete** signifies the Operator programmed cycle is successfully complete.

Table 5. Explanations of Display Screen Indications

13.3. Overview of GSX Series Ethylene Oxide (EO) Sterilization Cycle

13.3.1. Cycle Stages and Descriptions

3M™ Steri-Vac™ Sterilizer/Aerator GSX Series ethylene oxide (EO) sterilization cycles consist of ten stages. After the sterilization cycle is complete, an aeration cycle is required to remove any residual EO from the medical devices per the manufacturers' instructions for use (IFUs).

While a sterilization cycle is running, icons on the bottom of the display screen indicate the current stage of the cycle (both with a white box around them and in the stage indicator). Each icon, and the corresponding sterilization cycle stage, is described below.

Stage 1: Preheat

The temperature of the sterilizer chamber is controlled to attain the pre-set operating temperature.

Stage 2: Air Removal

A vacuum is created to remove air from the chamber and load. The vacuum rate is dependent upon the nature of the sterilization load, environmental conditions and preprogrammed vacuum rate.

Stage 3: Chamber Test

The Chamber Test measures the integrity of the sealed system and chamber. The test is carried out prior to the start of both the EO Injection stage and Conditioning stage at a pre-set vacuum level. Once the vacuum level is obtained, the pressure rise in the chamber is monitored for the set point duration, after an appropriate equilibration time that allows for pressure stabilization. During this period, the final chamber pressure measurement minus the initial chamber pressure measurement must be less than 18 mBar (1.8 kPa).

Stage 4: Conditioning

The Conditioning stage involves treatment of the product load within the sterilization cycle, prior to EO admission, in order to attain a predetermined temperature and relative humidity. This part of the sterilization cycle is carried out completely under vacuum in the GSX Series sterilizer.

Stage 5: EO Injection

When the 3M™ Steri-Gas™ EO Gas Cartridge is punctured, EO is vaporized and pulled into the chamber by the pre-injection chamber vacuum level.

Stage 6: EO Exposure

EO Exposure is the pre-set time period between the end of EO Injection and the beginning of EO Removal when EO is sterilizing the load.

Stage 7: EO Removal

During this stage, EO is removed from the sterilizer chamber but not necessarily removed from the sterilization load.

Stage 8: Flushing

During the Flushing stage of the sterilization cycle, the EO is removed from the load and the open chamber space of the sterilization chamber.

Stage 9: Aeration

During Aeration, EO desorbs from the product load and devices until predetermined levels of EO are reached. Aeration in the GSX Series sterilizer begins automatically after the sterilization cycle is complete. Aeration duration is based on the selection made by the Operator, either a specific time or continuous aeration.

[No Icon] Stage 10: Air Admission Stage

Filtered air is admitted into the chamber to allow the chamber pressure to equilibrate with ambient pressure. An "Opening door…" message will appear on the display screen during the Air Admission stage.

13.3.2. Cycle Reports

There are five (5) standard sections of a cycle report: Header, Graph, Table, Set-points, and Footer. The contents for each of the five report sections are illustrated in Figures 80 - 84. There are three options for assembling a cycle report: Graph, Table and Detailed. Table 6 explains the sections included in each cycle report option.

		Header	Graph	Table	Set-points*	Footer
Cycle Reports Option	Graph	Included	Included	N/A	N/A	Included
	Table	Included	N/A	Included	N/A	Included
	Detailed	Included	Included	Included	Included	Included

*Reference Section 11.13 for a obtaining a detailed report of set points for custom cycles.

Table 6. Options for Standard Cycle Reports

Navigate to **Menu>Reports>Cycle Reports** to save or print a cycle report.

Note: The print record will fade over time. Photocopy or electronically export reports for long-term storage.

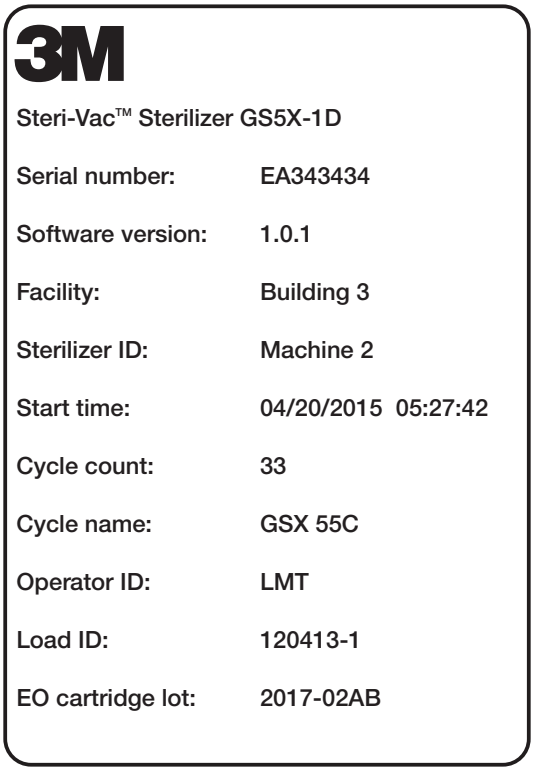


Figure 80.
Example Cycle Report - Header

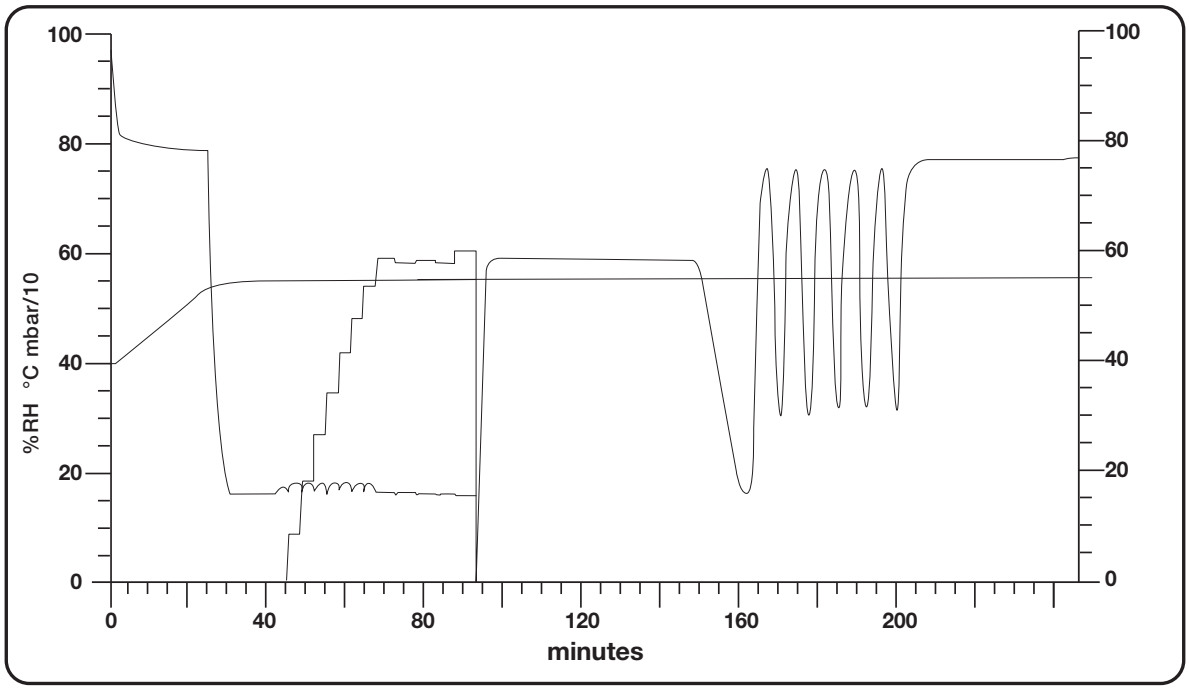
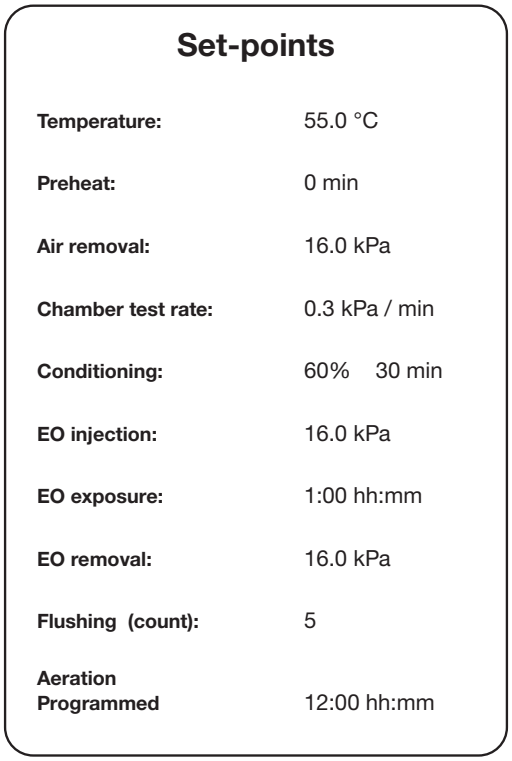


Figure 81.
Example Cycle Report – Graph Option

Stage	Start time	Tc (C)	Tm (C)	Tld (C)	Tmd (C)	Tul (C)	Pc (kPa)	Pm (kPa)	HS (C)	RHc (%)	RHm (%)
Preheat	03:10:05	21.2	21.2	21.0	21.1	21.1	97.06	97.14	31.0		
Air removal	03:39:19	54.0	54.0	54.2	53.5	54.3	77.49	77.60	54.9		
Chamber test	03:49:19	54.6	54.6	54.7	54.0	54.9	15.95	15.98	94.7		
Conditioning	03:55:22	54.7	54.7	54.9	54.2	55.1	16.22	16.25	94.7	5.2	5.1
EO injectin	05:03:28	55.0	55.0	55.1	54.4	55.3	15.38	15.41	94.9	59.1	56.4
EO exposure	05:05:00	56.0	56.1	56.1	54.4	558.3	61.58	61.64	61.7		
EO removal	06:05:02	55.0	55.0	55.0	54.4	55.2	60.02	60.12	54.9		
Flushing	06:18:54	55.0	55.0	55.0	54.4	55.2	16.79	16.78	55.0		
Aeration	08:40:43	55.0	55.0	54.9	54.5	55.1	79.70	19.85	54.9		

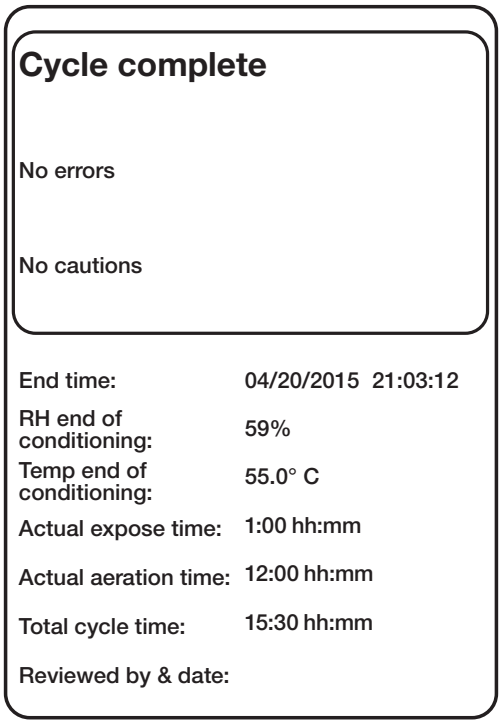
Figure 82.
Example Cycle Report – Table Option



Set-points

Temperature:	55.0 °C
Preheat:	0 min
Air removal:	16.0 kPa
Chamber test rate:	0.3 kPa / min
Conditioning:	60% 30 min
EO injection:	16.0 kPa
EO exposure:	1:00 hh:mm
EO removal:	16.0 kPa
Flushing (count):	5
Aeration Programmed	12:00 hh:mm

Figure 83.
Example Cycle Report - Set-points Option



Cycle complete

No errors

No cautions

End time:	04/20/2015 21:03:12
RH end of conditioning:	59%
Temp end of conditioning:	55.0° C
Actual expose time:	1:00 hh:mm
Actual aeration time:	12:00 hh:mm
Total cycle time:	15:30 hh:mm
Reviewed by & date:	

Figure 84.
Example Cycle Report – FootertReference Section 11.13 for a obtaining a detailed report of set points for custom cycles.

The definitions for the column headings in the Table cycle report (Figure 82) are as follows:

- **Tc (C)** is the chamber temperature (°C) read by the control sensor
- **Tm (C)** is the chamber temperature (°C) read by monitor sensor
- **Tld (C)** is the load zone temperature (°C) of the chamber heating blankets
- **Tmid (C)** is the middle load zone temperature (°C) of the chamber heating blankets
- **Tul (C)** is unload zone temperature (°C) of the chamber heating blankets
- **Pc (mBar)** is the chamber pressure (mBar) read by the control sensor
- **Pm (mBar)** is the chamber pressure (mBar) read by monitor sensor
- **HS (C)** is heatsink (vaporizer) temperature (°C)
- **RHc (%)** is the chamber percent relative humidity (%RH) read by the control sensor
- **RHm (%)** is the chamber percent relative humidity (%RH) read by monitor sensor

13.4. Cartridge Dispose Cycle for 3M™ Steri-Gas™ EO Gas Cartridges

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series is designed with a specialized dispose cycle for full, damaged, expired, or excess 3M™ Steri-Gas™ EO Gas Cartridges. **Cartridge Dispose** is a custom abbreviated cycle to safely empty and aerate Steri-Gas EO Gas Cartridges, one per cycle. This cycle cannot sterilize devices. The cycle time for a Cartridge Dispose cycle is estimated to be less than four (4) hours. Dispose cycles are Supervisor cycles and require a Supervisor PIN.

13.5. Ethernet Connection

Connecting to the Ethernet port provides 3M Health Care service personnel or authorized 3M service personnel with a means to access diagnostic information on the 3M™ Steri-Vac™ Sterilizer/ Aerator GSX Series from a desktop located on-site within the facility network. The system is intended for use in a server-based network.

13.5.1. Network Connections

The 3M™ Steri-Vac™ Sterilizer/Aerators GSX Series software application **will introduce a minimal amount of** active network traffic when connected to a local area network (LAN). Adding the GSX Series sterilizer to a LAN allows the ability for 3M Health Care service personnel or authorized 3M service personnel to map to read-only, shared network folders on the sterilizer from a client workstation within the LAN to access diagnostic information. The GSX Series sterilizers allow users with Supervisor or Service level access (already set up on the sterilizer) to map to read-only, shared network folders on the sterilizer, from a client workstation within the LAN, to access cycle data.

3M™ Steri-Vac™ Sterilizer/Aerators GSX Series come equipped with a preinstalled remote management device agent. The device agent manages communications between your sterilizer and a 3M server, providing 3M Health Care service personnel or authorized 3M service personnel with the ability to access diagnostic information on your sterilizer via a secured Manager Console. The device agent also allows 3M to provide software and firmware updates to your system remotely.

The Operating System (OS) uses the NDIS (Network Device Interface Specification) to communicate with the Ethernet hardware. TCP/IP and DNS protocols are supported. Device configuration HTML server has been disabled. Access to shared drives is read-only.

The device agent maintains a persistent connection to the 3M server by sending a small heartbeat (approx. 32 bytes) every 60 to 180 seconds. At two hour intervals, the 3M™ Steri-Vac™ Sterilizer/Aerators GSX Series performs a full check in, exchanging all new pending updates via TCP/IP. Port 5494 is the 3M system's primary and preferred communications port. On average, with no large updates, expect to see up to 20 MB of traffic per month for analytics reporting.

There are no known hazardous situations resulting from a failure of the IT-NETWORK to provide the characteristics required to meet the purpose of the GSX Series sterilizer connection to the IT-NETWORK. All service information can be accessed directly from the machine. The system autonomously identifies and reacts to faults regardless of the network connectivity state.

Devices connected to the Ethernet port must be 60950-1 (General Requirements for Information Technology Safety) compliant. Do not connect devices that are not compliant to 60950-1.

13.5.2. IP Addresses

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series software application supports IPv4 (32 bit IP addresses). Both static and dynamic IP addresses are supported. There are no means to forcibly renew the sterilizer's dynamic host configuration protocol (DHCP) address.

The MAC address of the GSX Series sterilizer single board computer can be viewed in the "MAC address" field of the **Menu>Site Setup>Setup>Network** tab (Figure 85).

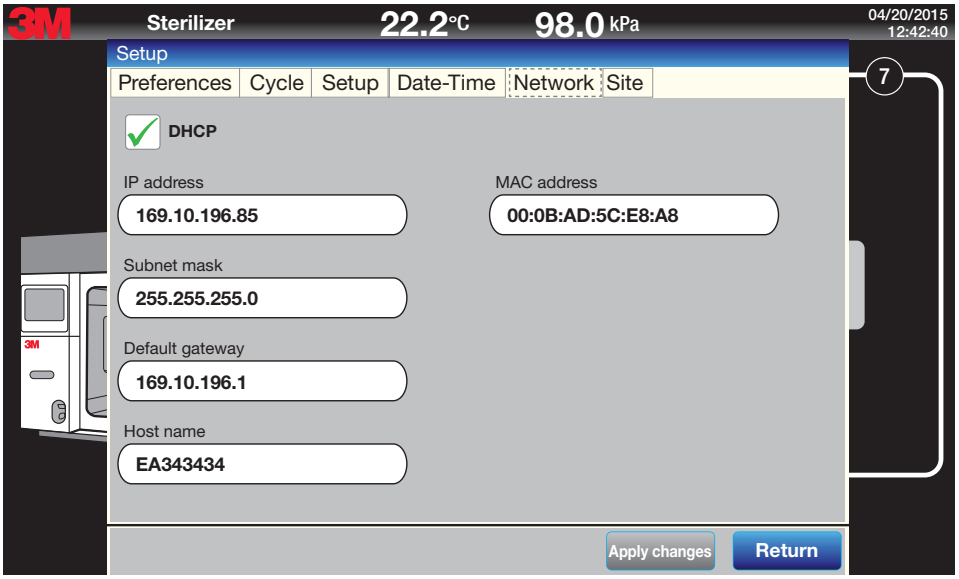


Figure 85.
Menu>Site Setup>Setup>
Network Information

13.5.3. Software Security

The customized Operating System (OS) utilized on the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series system employs a trusted platform that only allows applications signed with the 3M digital certificate to be executed. The system does not allow execution of unknown applications or applications with uncertified modules.

The system automatically loads the 3M application on boot up and users are restricted from leaving this application and executing applications that may be vulnerable to malware or viruses. System folders on the system that are accessible to the user are read-only, preventing introduction of malicious applications.

The systems only allow data transfer from external sources when accepting custom cycles from a USB drive. In this process, the system only allows importing of validated .eto files. Custom cycle files are in a proprietary and encrypted format and must be correctly formatted for the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series to accept for import. This check and confirmation by the GSX Series sterilizer ensures that the stored cycle is acceptable. 3M recommends that the 3M Cycle Programmer software be installed and run on a computer that contains up-to-date anti-virus software and up-to-date OS patches.

13.5.4. Software Updates

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series will monitor for software updates uploaded from a 3M server if appropriate access to the server through the Ethernet connection is enabled. When a pending software update is available, the following screen will be displayed (Figure 86). The update software prompt will only display when the GSX Series sterilizer transitions to Idle mode (Main Screen) and no pending errors exist. The sterilizer screens will guide the user through the update process.

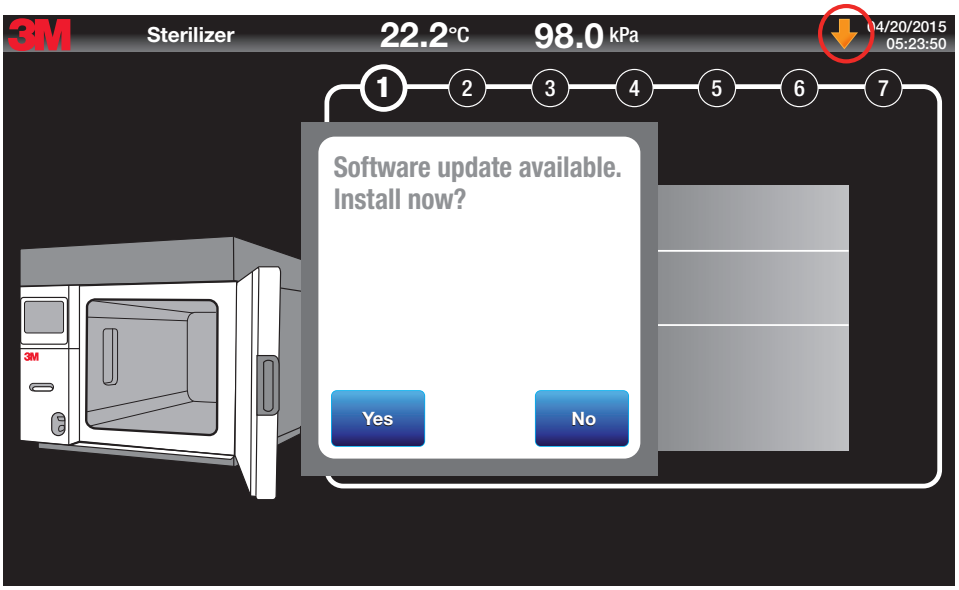


Figure 86.
Prompt of Software Update Available

If the software update is deferred, an orange downward arrow symbol will appear on the display screen task bar to remind the user that a pending software update is available for installation. Software can be updated by Supervisor level users by selecting the **Update software** button on the Site tab (**Menu>Setup>Site Setup>Site**).

Notifications of pending software updates will also be sent to registered users via the email address used to register the GSX Series sterilizer on www.3M.com//SteriVacServiceLSS. The user's facility 3M Health Care service personnel or authorized 3M service personnel can assist with completing software updates after communication with the user's facility management.

13.5.5. Firmware Updates

3M™ Steri-Vac™ Sterilizer/Aerator GSX Series firmware updates will be completed by the user's facility 3M Health Care service personnel or authorized 3M service personnel after communication with the user's facility management.

13.6. Distilled Water Reservoir

Distilled water is used for humidification during the ethylene oxide (EO) sterilization process. Ensure the distilled water reservoir is adequately filled. The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series will display a caution message if the distilled water level is too low to run a sterilization cycle. Do not overfill the water reservoir. Figures 3, 6, and 7 illustrate the distilled water reservoir location.

13.7. Printer Overview

The built-in printer provides easy-to-read information on each sterilization cycle. The cycle report is essential in analyzing the 3M™ Steri-Vac™ Sterilizer/Aerators GSX Series performance and can be retained to meet cycle verification policies.

To load printer paper, install the roll in the feed mechanism (Figure 87). Once the paper is fed into the mechanism, the printer will automatically advance the paper through the printer rollers. Manually place the paper through the slot in the access door. To avoid damage to the print head, only use the paper intended for this printer.

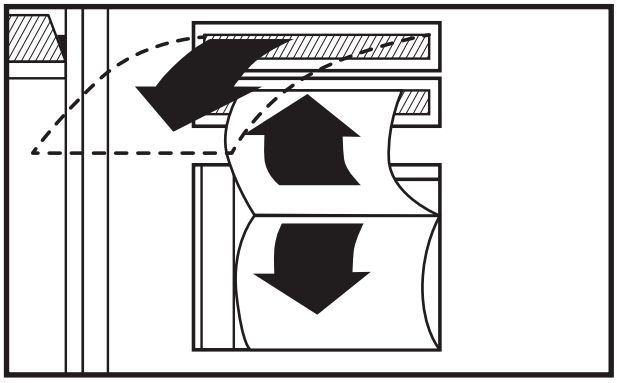


Figure 87.
Loading Printer Paper

13.8. Unloading the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide:
Short term exposure limits (STEL) or long term exposure limits (LTEL) or immediately dangerous to life or health (IDLH) levels could be exceeded during NORMAL use. Operators and staff must use protective measures (e.g. engineering controls, work practices, or personal protective equipment (PPE)) in accordance with United States 29 CFR 1910.134 and 29 CFR 1910.1047 under NORMAL use conditions until the user's facility management completes an exposure assessment on each custom cycle that validates facility protective measures meet national, state, and local requirements for short term exposure limits (STELs) and long term exposure limits (LTELs).
Inspect the display screen and cycle reports for errors and listen for audible notifications (if enabled). Always take action for errors as indicated in this manual.
Always review the elapsed aeration time on 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series display prior to opening GSX Series sterilizer door.
Never use force to access the inside of the sterilization chamber.

⚠ WARNING: To reduce the risks associated with fire and explosion:
Inspect the display screen and cycle reports for errors and listen for audible notifications (if enabled). Always take action for errors as indicated in this manual.
Do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. Operators should not service the sterilizer as there are no user serviceable parts.

⚠ CAUTION: To reduce the risk of injury,
follow good ergonomic practices. Loading baskets should not be overfilled requiring excessive force in pulling and pushing loaded baskets in and out of the sterilizer chamber. Reference facility policies and procedures for appropriate ergonomic practices.

⚠ **CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,**
inspect the display screen and cycle reports for errors and listen for audible notifications (if enabled). Always take action for errors as indicated in this manual.

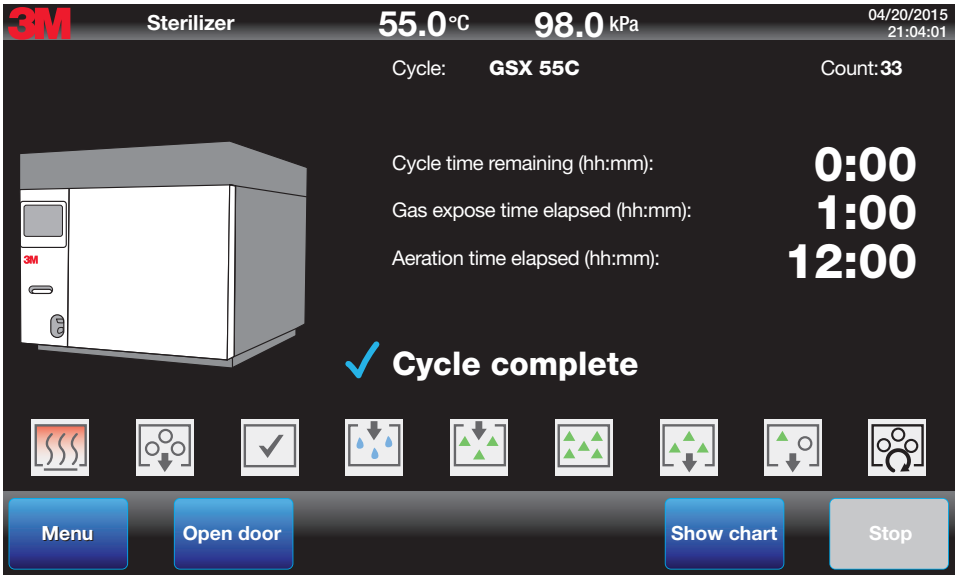


Figure 88.
Cycle Complete Screen

1. Press the **Open Door** button on the touch screen (Figure 88). On double door units, press the **Open Unload Door** button.
2. Allow chamber pressure to equilibrate to room pressure; this typically requires 60-90 seconds.
3. Open the GSX Series sterilizer door.
4. Remove the load from the chamber. Remove the empty 3M™ Steri-Gas™ EO Gas Cartridge.
5. Press the **Stop** button to generate a printout of the cycle report (Figure 89). The display screen will return to the main screen.
6. Follow the Process Monitoring and Quality Control procedures described in Chapter 14.

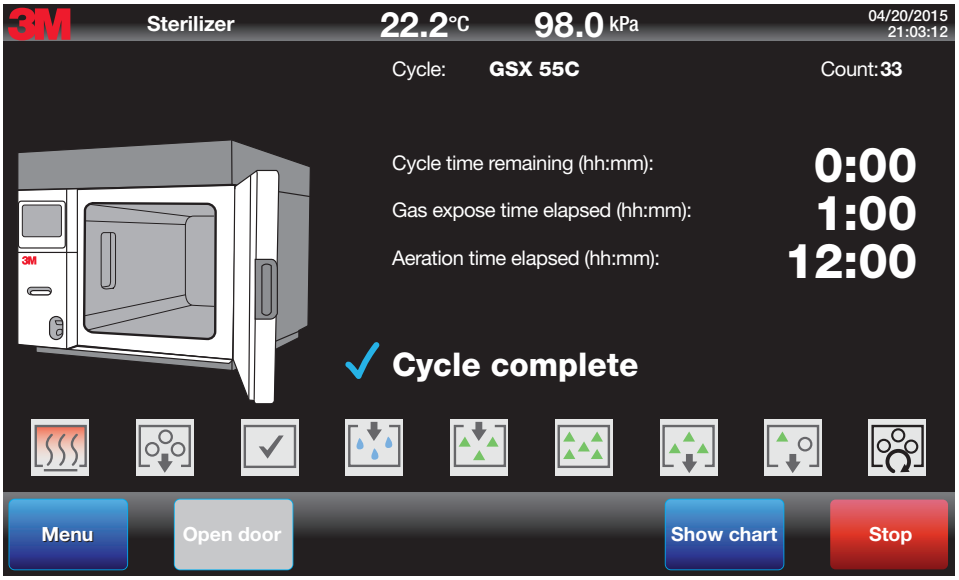


Figure 89.
Command to Obtain Cycle Report Printout

13.9. Accessing the Chamber – Aeration Not Complete

During user programmed aeration, the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series door can only be opened with a Supervisor PIN (Figures 90 and 91). Aeration timing will be interrupted if the door is opened. Once the door is closed and aeration temperature is reached, aeration timing will continue.

The vent hood (i.e. exhaust hood) is monitored for appropriate air flow in standard cubic feet per minute (SCFM). If the GXS Series sterilizer detects the air flow is too low, the sterilizer door will remain locked until a minimum of three hours of aeration is fulfilled.

1. To access the chamber when aeration is not complete, press the **Open Door** button on the touch screen. On double door units, press the **Open Unload Door** button.
2. Enter the Supervisor or Service PIN.
3. Close the GSX Series sterilizer door to continue aeration.

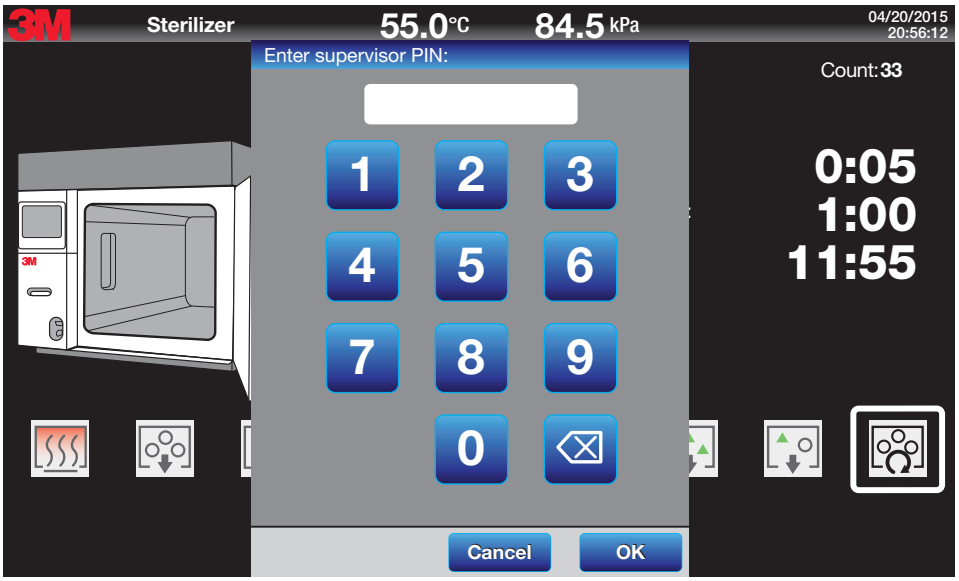


Figure 90.
Supervisor PIN Required to Pause Aeration

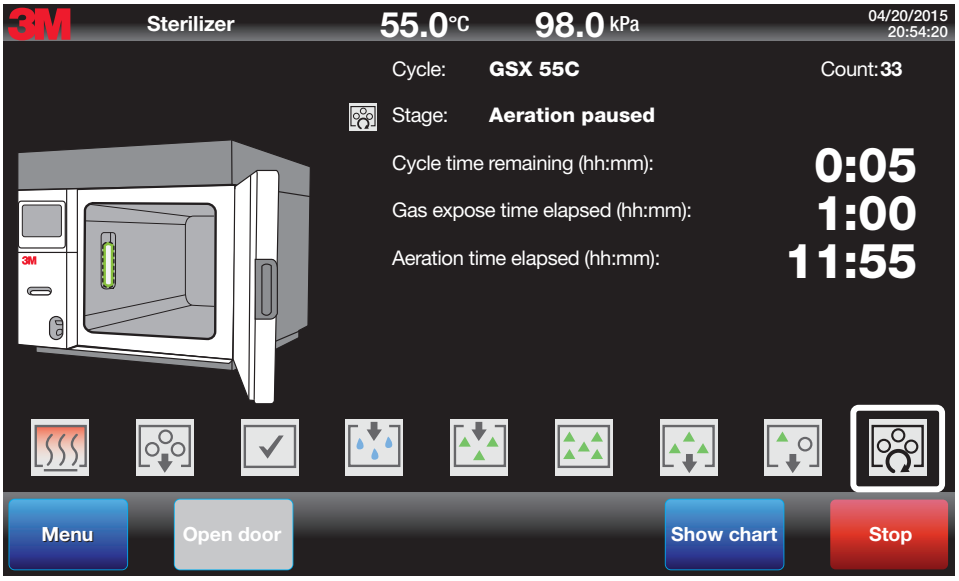


Figure 91.
Aeration Stage Paused

13.10. Empty 3M™ Steri-Gas™ Ethylene Oxide (EO) Gas Cartridges

The 3M™ Steri-Gas™ Ethylene Oxide (EO) Gas Cartridge should be aerated for a minimum of two hours before disposal. Cycles with two or more hours of aeration time will provide sufficient aeration as required for a Steri-Gas EO Gas Cartridge. An empty cartridge will aerate while located inside the 3M™ Steri-Vac™ Sterilizer/Aerators GSX Series chamber cartridge bay. After aeration is complete, remove the cartridge from the holder and dispose of the cartridge in a non-incinerated waste receptacle or recycle the cartridge per your facility's requirement.

13.11. Aeration of a Biological Indicator Process Challenge Device (BI PCD)

The components of the biological indicator (BI) process challenge device (PCD, also known as a Test Pack) should also be aerated prior to disposal. A 3M branded BI PCD will normally be sufficiently aerated with a load with two hours or greater aeration time. For other brands of BI PCDs, contact the manufacturer for recommended aeration time. Dispose of the BI PCD components per manufacturer's instructions for use (IFUs).

13.12. Sterilization Cycle Cancellations

13.12.1. Manual Cycle Cancellation

The Operator can manually interrupt a cycle at any time prior to ethylene oxide (EO) gas injection. If the sterilization cycle is manually cancelled any time after EO gas injection, the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series will automatically proceed to or repeat EO Removal and Flushing stages to clear the chamber of EO gas before the door is unlocked. A manual cycle interruption error message will appear on the display screen and cycle reports. Refer to Chapter 16: Cautions, Error Messages, and Troubleshooting for error codes and their respective corrective actions.

13.12.2. Automatic Cycle Cancellation

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series may automatically cancel a cycle and progress to a safe error recovery stage if a fault condition is detected by the sterilizer. An error message will be evident on the display screen and cycle reports. Refer to Chapter 16: Cautions, Error Messages, and Troubleshooting for error codes and their respective corrective actions.

13.13. Power Outages

If a power outage occurs while a cycle is in progress, the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series will remain in a safe state.

When the power resumes, if critical cycle parameters are still within acceptable limits, the cycle will continue and a caution indication will appear on both the display screen and the cycle report to notify the user that a power outage occurred.

When the power resumes, if the critical parameters are outside acceptable limits, the cycle will automatically proceed to an error recovery state. A cycle error indication will appear on both the display screen and the cycle report to notify the user. Refer to Chapter 16: Cautions, Error Messages, and Troubleshooting for error codes and their respective corrective actions.

14. Process Monitoring and Load Release

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,

always use chemical indicators and biological indicators for monitoring the performance of sterilization cycles as described in this manual. Always use chemical indicators and biological indicators per the device manufacturer's instructions for use (IFU).

All sterilization processes require a comprehensive quality control program that includes sterility assurance monitoring. Comprehensive monitoring of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series consists of three essential elements:

1. Monitoring of physical parameters (sterilizer cycle reports).
2. Use of biological indicators (BIs) within the appropriate process challenge device (PCD) or Test Pack.
3. Use of chemical indicators (CIs).

14.1. Physical Parameters and Requirements

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide,

always inspect cycle reports (printout or electronic file) to ensure the total aeration time matches the device manufacturer's instructions for use (IFU).

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures:

Always inspect cycle reports (printout or electronic file) to ensure the Operator's programmed parameters or the device manufacturer's instructions for use (IFU) matches:

- %RH at the End of Conditioning,
- Temperature at the End of Conditioning,
- Actual Gas Exposure Time.

Documentation for physical parameters is provided on the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series cycle reports (printout and electronic file). Under normal operating conditions, the paper cycle report produced at the end of the cycle will be similar to the one shown in Figures 80 - 84.

Each cycle report should be reviewed prior to load release per facility policies. Critical parameters for the preprogrammed cycles are contained in Table 7. Verification of these parameters on the printed cycle report is illustrated in Figures 92 and 93. Verification of custom cycle performance should be conducted per facility policies. For all cycles confirm final status contains **Cycle Complete** on the printout footer (Figure 93). There is space on the cycle report for a signature and date.

End time on the cycle report footer is the date and time (month/day/4-digit year + hh:mm:ss) when the Stop button was pressed after cycle is complete.

Total cycle time on the cycle report footer is the actual total elapsed time in hours and minutes (hh:mm) of the selected programmed cycle. The Total cycle time is the duration between touching the cycle Start button and when the Cycle Complete text appears on the display screen. If continuous aeration was selected, the Total cycle time is the duration between touching the cycle Start button and touching the Stop button.

Cycle Selected	Final Status	End of Conditioning Temp (°C)	End of Conditioning (%RH)	EO Exposure Time (hr + min)	Aeration Temp (°C)	Aeration Time (min)
GSX 38C	'Cycle Complete' + 'No Errors'	38 ± 3	40 - 80	4.5 hr ± 5.4 min	As Programmed	As Programmed
GSX 55C	'Cycle Complete' + 'No Errors'	55 ± 3	40 - 80	1.0 hr ± 1.2 min		

Table 7. Preprogrammed GSX Series Cycle Report Physical Parameter Requirements

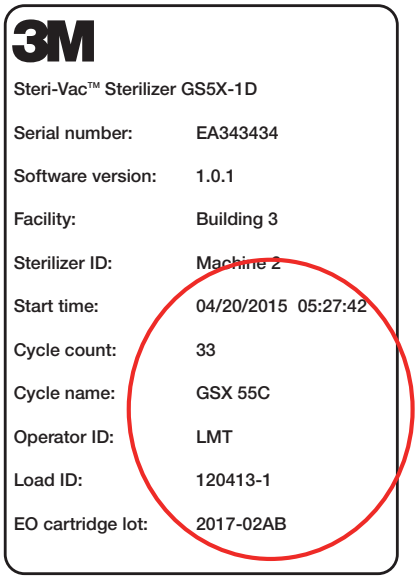


Figure 92.
Verifying Cycle Report – Header

⚠ WARNING: To reduce the risks associated with fire and explosion:

Inspect the display screen and cycle reports for errors and listen for audible notifications (if enabled). Always take action for errors as indicated in this manual.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures:

Inspect the display screen and cycle reports for errors and listen for audible notifications (if enabled). Always take action for errors as indicated in this manual.

Always inspect cycle reports (printout or electronic file) to ensure the Operator's programmed parameters or the device manufacturer's instructions for use (IFU) matches:

- %RH at the End of Conditioning,
- Temperature at the End of Conditioning,
- Actual Gas Exposure Time.

For reusable device sterilization, always follow device manufacturer's instructions for use (IFU), including device cleaning, drying, packaging, sterilization, and aeration.

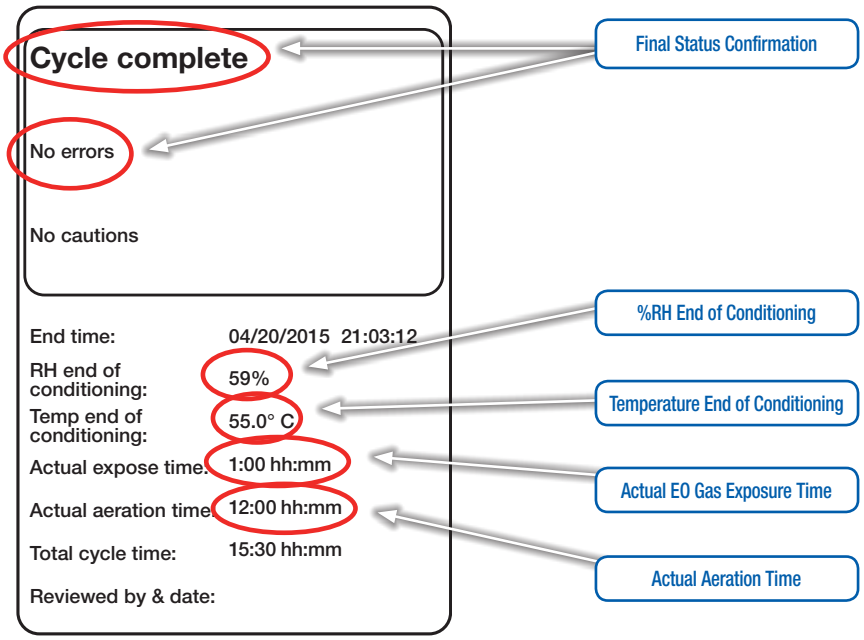


Figure 93.
Verifying Cycle Report - Footer Information

14.2. Biological Indicators and Process Challenge Devices

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,

always use chemical indicators and biological indicators for monitoring the performance of sterilization cycles as described in this manual. Always use chemical indicators and biological indicators per the device manufacturer's instructions for use (IFU).

Biological indicators (BIs) consist of viable spores in or on a carrier, sometimes (as in the case of self-contained BIs) accompanied by incubation media. BIs provide the only direct measure of the lethality of the sterilization process. BIs must be incubated for various periods of time (depending on the specific product) until it is determined whether the microorganisms grow (i.e. they survived the sterilization process) or fail to grow (i.e. they were killed by the sterilization process).

For routine monitoring of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series EO sterilization process, use 3M™ Attest™ Biological Indicators for EO which contain spores of Bacillus atrophaeus or a biological indicator defined by the user.

3M Attest Biological indicators for EO:

- comply with applicable clauses of ISO 11138-2
- should be placed within an appropriate process challenge device (PCD)

The appropriateness of the BI PCD used for process definition, validation or routine monitoring and control should be defined and determined by the user. Additional information for defining the appropriateness of a PCD can be found in ISO 11135.

A minimum of three (3) appropriate PCDs with BIs should be used in every load. The BI PCDs should be placed in the worst case location to achieve sterilization conditions inside the chamber and load.

BIs should be used in accordance with the biological indicator manufacturer's instructions.

Use a positive control each day a BI is processed. This helps ensure:

- Correct incubation temperatures are met.
- Viability of the spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals.
- Capability of media to promote growth.
- Proper functioning of the BI incubator.

Failure of the positive control test may invalidate the processed indicator results. Refer to the instructions for use for BIs for additional information.

15. Routine Maintenance

⚠ WARNING: To reduce the risks associated with fire and explosion,

do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. Operators should not service the sterilizer as there are no user serviceable parts.

⚠ WARNING: To reduce the risk of shock due to hazardous voltage:

Do not attempt to access any internal mechanisms of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. Operators should not service the sterilizer as there are no user serviceable parts.

Use only 3M Health Care service personnel or authorized 3M service personnel for installation and maintenance.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures,

complete maintenance at routine scheduled intervals of a maximum of every six months. There are no user-serviceable parts; use only 3M Health Care service personnel or authorized 3M service personnel for maintenance.

15.1. Daily Cleaning

Using a soft cloth dampened with mild detergent and warm water, clean the following parts of the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series daily (if applicable).

- Chamber walls and floor
- Outer lip of the chamber
- Inside surface of the chamber door
- Outer surface of the cabinet
- Door gasket

Do not use alcohol or any other anti-bacterial cleaning agents as these could damage the door seal gasket and potentially falsely activate an ethylene oxide (EO) area monitor (if installed).

After cleaning, use a clean soft cloth dampened with distilled water to wipe away and reduce the potential of accumulation of residues from cleaning products. Allow the equipment to air dry before using.

The display screen of the GSX Series sterilizer is made of glass. Use a soft cloth dampened with a common glass cleaner to remove debris and foreign matter from the display screen.

15.2. Air Supply Line Filters

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide,

ensure the compressed air supply is clean with a maximum allowable dirt particle size of 0.5 microns, and is also free of oil. Ensure air filters on the compressed air supply contain a water trap and are cleaned daily (if applicable) and maintained properly.

It is the user's facility management's responsibility to daily inspect the air supply line filters for water or visible contaminate (e.g. oil) and clean the air supply line filters if applicable.

15.3. Preventative Maintenance

Performing preventative maintenance, at scheduled intervals, is a critical part of ensuring the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series continues to function properly. Complete maintenance at routine scheduled intervals of a maximum of every six (6) months. A wrench icon will appear on the display screen when maintenance is due (Figure 94). There are no user-serviceable parts; use only 3M Health Care service personnel or authorized 3M service personnel for maintenance.

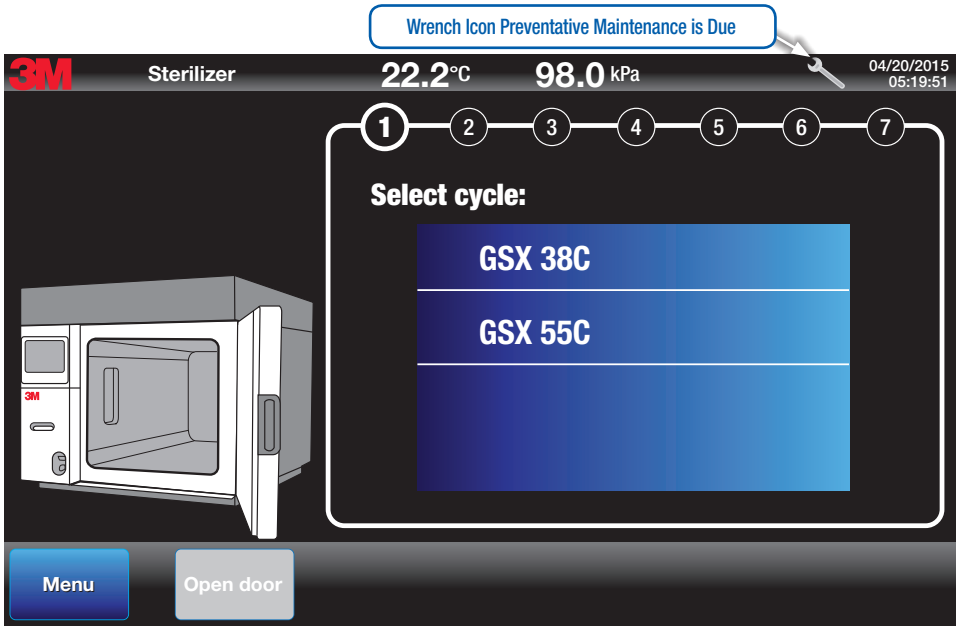


Figure 94.
Wrench Icon - Preventative Maintenance is Due

It is the user's facility management's responsibility to complete appropriate decontamination in case of spillage of hazardous material on or inside of the equipment. Reference the appropriate Safety Data Sheet (SDS) for decontamination procedures. If there are questions regarding the appropriate cleaning procedures and/or cleaning agents, contact your local 3M Health Care service personnel or authorized 3M service personnel.

16. Cautions, Error Messages, and Troubleshooting

⚠ DANGER: To reduce the risks associated with exposure to ethylene oxide:
Never use force to access the inside of the sterilization chamber.
Inspect display screen and cycle reports for errors and listen for audible notifications (if enabled). Always take action for errors as indicated in this manual.
Call 3M Health Care service personnel or authorized 3M service personnel immediately if there is a failure of the display or backlight and the sterilizer continues to operate.

⚠ WARNING: To reduce the risks associated with fire and explosion,
inspect the display screen and cycle reports for errors and listen for audible notifications (if enabled). Always take action for errors as indicated in this manual.

⚠ CAUTION: To reduce patient risks associated with exposure to potentially non-sterile devices or inadequate sterilization procedures.
inspect the display screen and cycle reports for errors and listen for audible notifications (if enabled). Always take action for errors as indicated in this manual.

The 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series is designed with embedded software that automatically controls, monitors and regulates the mechanical functions of the GSX Series sterilizer and the sterilization process.

16.1. Caution Messages

If the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series detects a fault condition that does not adversely affect the performance of the sterilization cycle, a caution message will appear on both the display screen and cycle report to notify the Operator (Figure 95).

The cycle can complete successfully when a caution message is asserted. Document all caution messages per facility procedures.

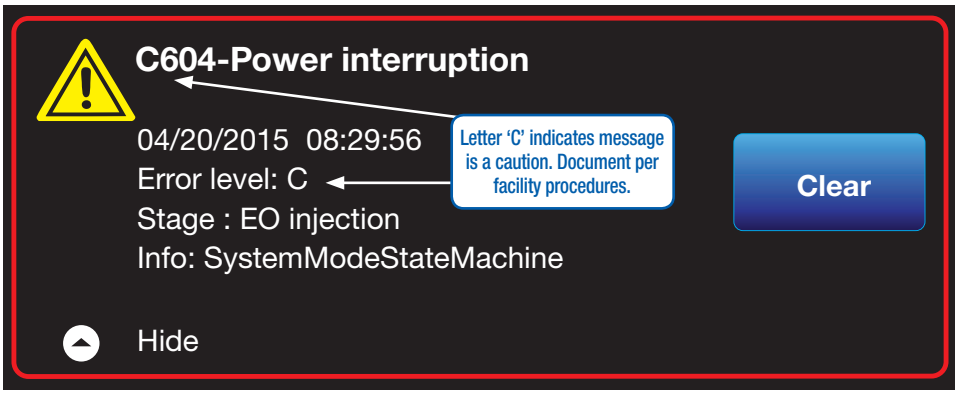


Figure 95.
Example of a Caution Message

16.2. Error Messages

If the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series detects a fault condition that adversely affects the performance of the cycle, an error message will appear on the display screen and cycle report to notify the Operator. Additionally, an optional audible notification will accompany the error message if the audible notification option is enabled. Immediately after an error is detected, the sterilization cycle will cancel and the GSX Series sterilizer will automatically complete an error recovery to bring the sterilizer to the safest state possible.

There are seven error levels that could occur during a sterilization cycle and two error levels that could occur during the Aeration stage. The seven error levels, descriptions and their respective corrective actions are detailed in Table 8. Some errors must be cleared by your 3M Health Care service personnel or authorized 3M service personnel with a Service PIN.

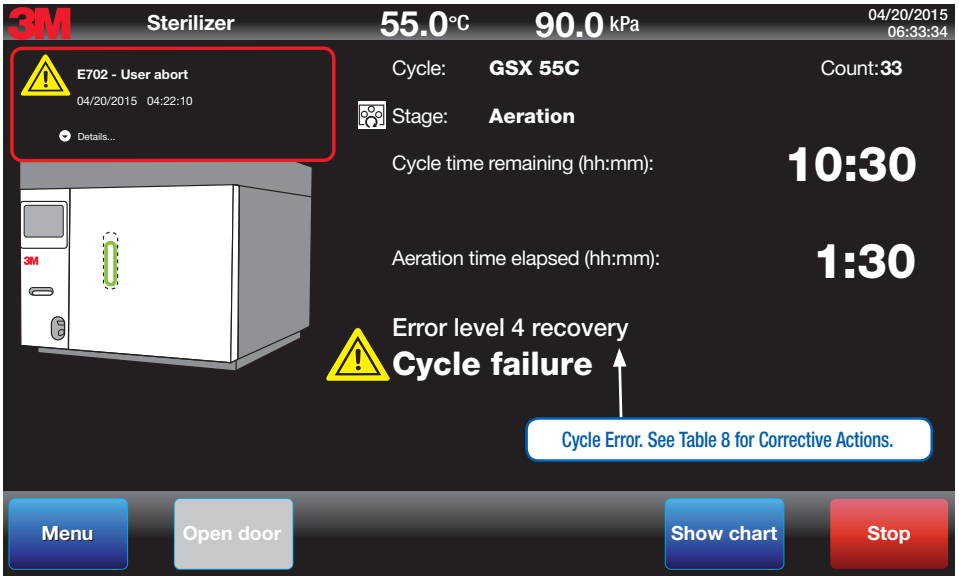


Figure 96.
Example of a Level 4 Error Message

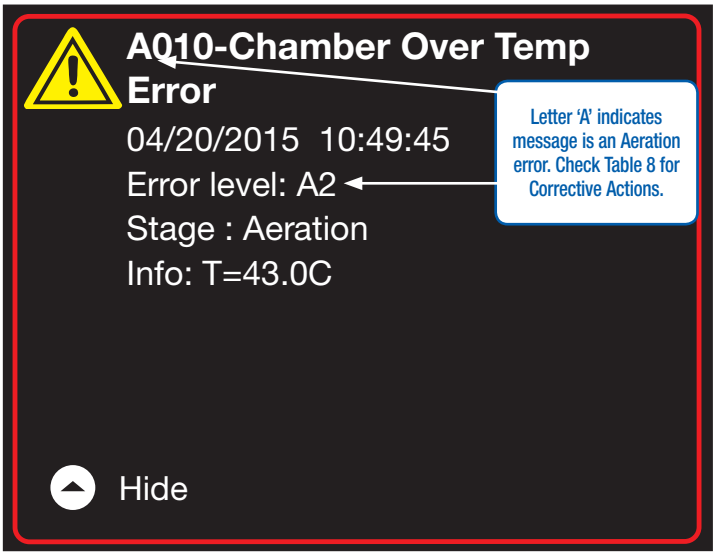


Figure 97.
Example of an Aeration Error Message

16.3. Error Levels and Corrective Actions

Error Level	Description	Example Error	Corrective Action
L1	Errors that occur before ethylene oxide (EO) gas is in the chamber and does not require immediate Service attention.	– Chamber too hot to start a new cycle – Timeout attempting to reach target – %RH setpoint	Operator can clear error and access load. Wait until **Open Door** or **Open Load Door** button is blue. Press **Open Door**. Press **Clear** to clear the error. Document per facility procedures. Restart cycle per facility procedures.
L2	Errors that occur before EO gas is in the chamber and require Service attention. Operator can open load door before Service arrives.	– Cooling fan failure before EO Injection – 12V/24V power supply failure before EO Injection	Operator can access load. Wait until **Open Door** or **Open Load Door** button is blue. Press **Open Door**. **Call Service. Service must clear the error.** Document per facility procedures. Restart cycle per facility procedures.
L3	Errors that occur before EO gas is in chamber and requires Service attention before Operator can open load door.	– Puncture pin not detected in home position (pin deployed) in idle state – Service aborted cycle	**Call Service.** **Service must access load and clear the error.** Document per facility procedures. Restart cycle per facility procedures.
L4	Errors that occur after EO gas is in the chamber. Pressure and temperature sensors can return system to a safe state. Supervisor or individual with higher access must clear error. System will then return to main screen where door can be opened.	– Monitoring sensor failures after EO Injection	Supervisor or Service must clear the error. Wait until the **Stop** button is red. Supervisor or Service press **Stop Cycle** and enter PIN. Supervisor or Service press **Clear** and enter PIN to clear the error. Document per facility procedures.
L5	Errors that occur after EO is in the chamber. Pressure and temperature sensors can return system to a safe state; however, Service is required to open load door.	– Leak detected in EO Expose stage – Puncture pin not detected as retracted in Gas Injection stage	**Call Service.** **Service must access load and clear error.** Document per facility procedures.
L6	Errors that occur after EO is in the chamber. Pressure sensors can return system to a safe state but temperature sensors cannot. Service attention is required.	– Chamber over temperature and under temperature failures after EO Injection	**Call Service.** **Service must access load and clear error.** Document per facility procedures.
L7	Errors that will require 3M Service. EO may or may not be present in the chamber. Errors that occur during an Error Recovery stage will be elevated to L7. Service attention is required.	– Failure in controller pressure sensor after EO Injection – Exhaust line blockage detected	**Call Service.** **Service must clear error.** Document per facility procedures.
A1	Not Used	Not applicable	Not applicable
A2	Errors in temperature control that occur during programmed aeration. Service attention is required.	– Chamber over temperature or under temperature during aeration	**Call Service.** **Service must access load and clear error.** Document per facility procedures.
A3	Errors that occur during programmed aeration and require Service attention.	– Loss of compressed air during aeration – Power supply failures during aeration	**Call Service.** **Service must access load and clear error.** Document per facility procedures.

Table 8. Descriptions for Error Levels and Corrective Actions

Once the automatic error recovery cycle is complete, a larger message will appear on the display screen as illustrated in Figures 98 and 99.

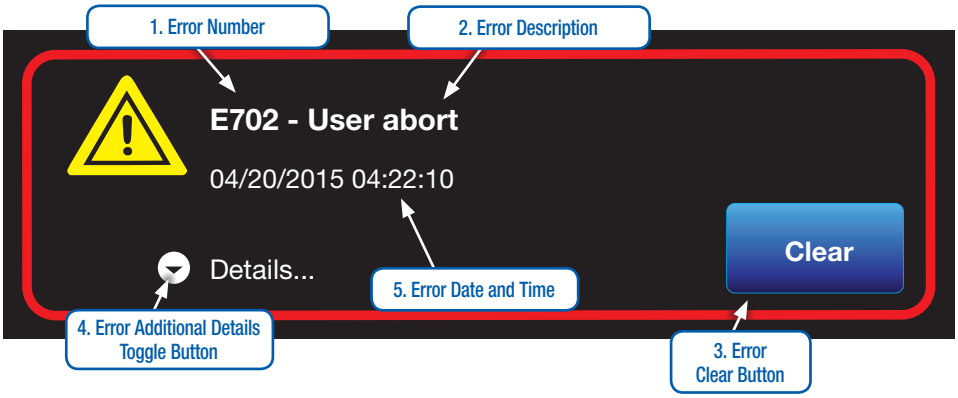


Figure 98.
Error Message –Details Hidden

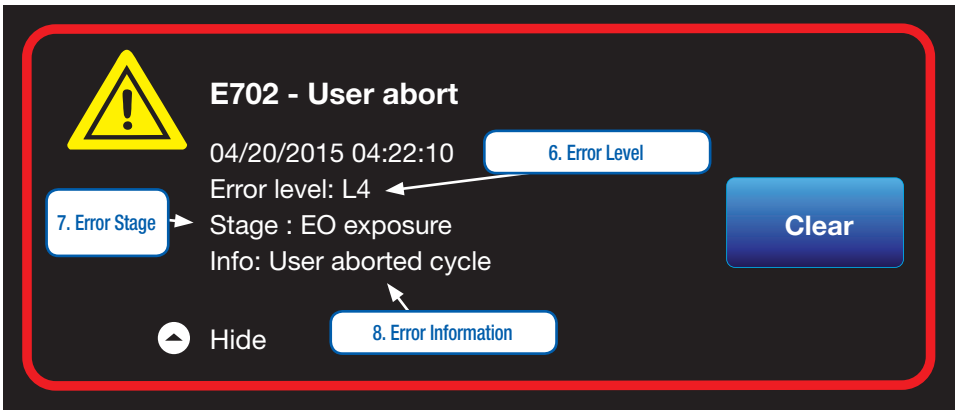


Figure 99.
Error Message – Details Revealed

Item Number	Error Name	Error Item Description
1	Error Number	Alpha-numeric designator of the error
2	Error Description	Text description of the error. This description will be helpful information for 3M Health Care service personnel or authorized 3M service personnel.
3	Error Clear Button	Press this button to acknowledge and clear the error. Some errors must be cleared by 3M Health Care service personnel or authorized 3M service personnel with a Service PIN. See Table 8 – Descriptions for Error Levels and Corrective Actions for more details.
4	Error Additional Details Toggle Button	Press toggle button to reveal the Error Level, sterilization cycle stage, and additional information regarding the error.
5	Error Date and Time	The date and time the error occurred.
6	Error Level	Error is divided into levels. Each level has distinct automatic safe recovery actions and Operator corrective actions. See Table 8 - Descriptions for Error Levels and Corrective Actions for more details.
7	Error Stage	Stage of the sterilization cycle or aeration stage when the error occurred.
8	Error Information	Additional information regarding the error which will be helpful 3M Health Care service personnel or authorized 3M service personnel.

Table 9. Explanation of Error Messages

17. Repair and Replacement

3M Health Care has established a worldwide service organization to provide trained technicians to maintain and repair 3M™ Steri-Vac™ equipment. For servicing information or warranty claims in the U.S., contact the local 3M Service Representative or the 3M Health Care Service Center at the following address:

3M Health Care Service Center
Suite 200, Bldg. 502
3350 Granada Avenue North
Oakdale, MN 55128
1-800-292-6298
Fax: 1-800-770-8016

In Canada, contact:
3M Health Care
3M Canada, Inc.
P.O. Box 5757
London, Ontario N6A 4T1
1-800-268-6235 (English)
1-800-567-3193 (French)

Outside of the U.S., contact your local 3M Subsidiary for warranty claims or for contacting your 3M Health Care service personnel or authorized 3M service personnel.

Service Contact:

18. Preventative Maintenance

3M provides preventative maintenance services for purchase with the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. Contact your local 3M Health Care service representative or the 3M Health Care Service Center for information regarding preventative maintenance contracts.

19. Ordering Accessories and Supplies

One set of upper and lower loading baskets are provided with each new 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series. Additional baskets are available for purchase. Table 10 provides order information for products used with the 3M™ Steri-Vac™ Sterilizer/Aerator GSX Series.

Accessories		
Name	**Catalog Number**	**Packaging**
Stainless Steel Stackable Basket for use in Model GS8X – 47 x 95 x 20cm (18.5 x 37.5 x 8 in.)	78-8078-8313-3	1 Basket
Stainless Steel Upper Half Basket for use in Model GS8X – 47 x 47 x 20cm (18.5 x 18.5 x 8 in.)	78-8078-5399-5	1 Basket
Stainless Steel Basket Cover GS8X	78-8078-6251-7	1 Cover
Stainless Steel Lower Basket for use in Model GS5X Sterilizer – 39 x 80 x 18cm (15.5 x 31.5 x 7 in.)	78-8055-6040-2	1 Basket
Stainless Steel Upper Basket for use in Model GS5X Sterilizer – 39 x 80 x 18cm (15.5 x 31.5 x 7 in.)	78-8055-6039-4	1 Basket
3M™ Steri-Gas™ Ethylene Oxide (EO) Cartridge Adaptor	78-8083-3965-5	1 Adaptor
Name	**Catalog Number**	**Packaging**
3M™ Steri-Gas™ 100% Ethylene Oxide (EO) Gas Cartridges	4-134* EO net wt. 127 g. (4.47 oz.)	12 units/box
3M™ Steri-Gas™ 100% Ethylene Oxide (EO) Gas Cartridges	4-100* EO net wt. 100 g. (3.52 oz.)	12 units/box
3M™ Steri-Gas™ 100% Ethylene Oxide (EO) Gas Cartridges	8-170 EO net wt. 170 g. (5.99 oz.)	12 units/box
3M™ Printer paper	1217	2 rolls/case
3M™ Attest™ Biological Indicator for Ethylene Oxide	1264-S	300 units/box/2 box/case
3M™ Attest™ Rapid Readout Biological Indicator for Ethylene Oxide	1294-S	300 units/box/2 box/case
3M™ Comply™ Ethylene Oxide (EO) Indicator Tape 1224	1224-0 1.25 cm x 55 m (1/2 in. x 60 yd) 1224-1 2.5 cm x 55 n (1 in. x 60 yds) 1224-6 1.9 cm x 55 m (3/4 in. x 60 yds)	36 rolls/case 18 rolls/case 24 rolls/case

* The use of a 4-100 and 4-134 catalog number in the GS8X requires a special adaptor. For more information, in the US contact 3M Health Care Helpline at 1-800-228-3957. Outside the US contact your local 3M office or to locate your local office go to www.3M.com.

Table 10. Accessories and Supplies

20. 3M™ Cycle Programmer Support and Software Updates

Help information is available in the 3M Cycle Programmer application under the **Help** command. Additional assistance is available through 3M. For assistance in programming or selecting cycles contact in the US 3M Technical Service – Tech Line at 1 800 441-1922 Option 2. For assistance in the US on installing the 3M™ Cycle Programmer on a personal computer or network, contact 3M Health Care Service Center at 1-800-292-6298, Option 0. Outside of the US, contact your local 3M office. Alternately, send inquires to healthcare@3M.com.

Contact Information

3M Health Care
Infection Prevention Division
2510 Conway Avenue
St. Paul, MN 55144-1000
U.S.A.
3M Health Care Helpline 1-800-228-3957
www.3M.com/infectionprevention

3M Health Care - 3M Canada
Post Office Box 5757
London, Ontario N6A 4T1
Canada
1-800-364-3577
www.3M.com/ca/healthcare

U.S. Ordering Information

Quotations and Orders for Equipment, Service Parts, and Accessories*

3M Health Care Service Center

Telephone Orders

1- 800-292-6298 Select “2”

Fax Orders

1-800-770-8016

Mail Orders

3M Health Care Service Center
Building 502-1W-01 Suite 200
3350 Granada Ave N
Oakdale, MN 55128

Orders for Supplies (e.g. 3M™ Steri-Gas™ EO Gas Cartridges, 3M™ Attest™ Biological Indicators, 3M™ Printer Paper)*

3M Health Care Customer Service

Telephone Orders

1-800-592-3979

Fax Orders

1-800-772-2547

Mail Orders

3M Health Care Customer Service
3M Center, Building 275-5E-08
P.O. Box 33275
St. Paul, MN 55133-3275

* Outside of the United States, contact the local 3M Subsidiary. In Canada, contact your local 3M sales representative or 3M Canada office.

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Infection Prevention Division
3M Health Care
3M Center, Building 275-4E-01
St. Paul, MN 55144-1000
(U.S.A.) 1-800-228-3957
www.3M.com/healthcare

CE

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