

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



Operator's Manual



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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.



UL Listed to U.S. and Canadian Safety Standards. EO GAS STERILIZER E160704



0086 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.



Unique Device Identification (UDI) barcode (located on the sterilizer serial plate).

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 GS 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 GS Series has a unique serial number printed on the serial label (e.g. AA121212) 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/Aerators GS Series is for use in health care, industrial sterilization, research labs, veterinary surgical and other appropriate settings. 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. 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 GS 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.

Sterilizers have two preprogrammed sterilization cycles, 38 °C and 55 °C. Critical cycle parameters are detailed in Table 1.

The GS Series sterilizer EO sterilization cycles consist of ten (10) 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 GS Series EO sterilization cycle.

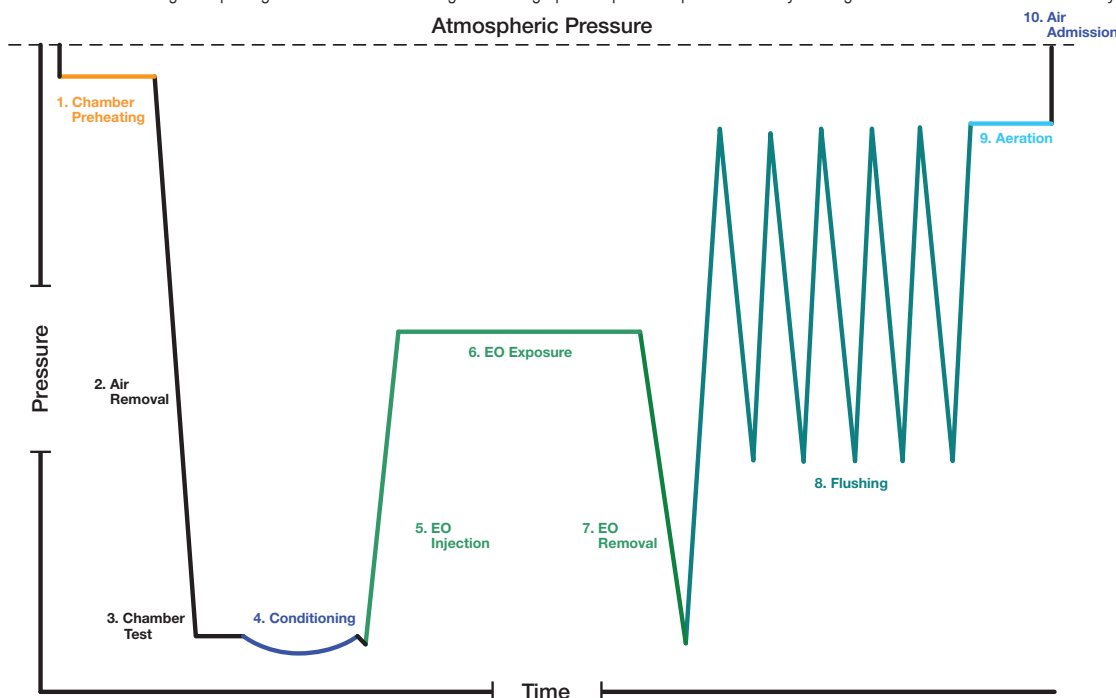


Figure 1.
Pressure Profile GS Series EO Sterilization Cycle

2. Intended Use

The 3M™ Steri-Vac™ Gas Sterilizer/Aerator is a compact unit designed to sterilize heat- and/or moisture-sensitive devices in the following cycles:

Model	Cycle	Gas Expose Time (min.)	Temperature (°C)	EO Concentration (mg/L)	Relative Humidity (%)
GS5	Cool	270	38	736	40-80
	Warm	60	55	736	40-80
GS8	Cool	270	38	759	40-80
	Warm	60	55	759	40-80

Table 1. GS Series Critical Cycle Parameters

Single or dual channel rigid and flexible scopes can be sterilized with non-lumened medical instruments in any of the GS sterilizer cycles provided the cycle parameters match the instrument’s sterilization instructions. The load per cycle should not exceed 20 lumens.

CAUTION: To reduce the risk of injury,

always follow the procedures described in this manual.

3. Safety

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

- Hardware and mechanical components of the GS Series sterilizers meet or exceed the compliance requirements of current, recognized national and international safety standards including applicable sections of IEC 61010-1 (2010), IEC 61010-2-010 (2014), IEC 61010-2-040 (2015) and 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.
- GS 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 GS 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 GS 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 GS Series sterilizer will automatically complete an error recovery process to bring the sterilizer to a safe-state prior to further action.
- GS Series sterilizers are designed with a state-of-the-art proprietary humidification process. In the Conditioning stage of the sterilization cycle, GS 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. GS 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 GS 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 GS 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.

In addition, recommended practices for the safe and effective use of EO are also contained in the Association for the Advancement of Medical Instrumentation ANSI/AAMI ST41: *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*.

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.

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

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 and may exist in your country or region as well.

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:

Ensure a minimum of ten (10) air exchanges per hour (ACH's) for the room in which the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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.

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.

Never use force to access the inside of the sterilization chamber.

Always review the elapsed aeration time on the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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).

Do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 150°F (65.5°C) may cause cartridge to burst.

3M™ Steri-Gas™ Cartridge Catalog Number	3M™ Steri-Vac™ Sterilizer GS Series Model	Nominal Net Weight of EO
4-100	GS5 Series	EO Net wt. 100 g. (3.52 oz.)
8-170	GS8 Series	EO Net wt. 170 g. (5.99 oz.)

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

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 GS Series. Operators should not service the GS 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 GS Series. Operators should not service the GS 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 use a detachable cord rated less than 15A.

Do not operate the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 GS 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:

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 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.

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 GS 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 GS 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 GS Series Structural Specifications

	GS5	GS8
Shipping Weight	163 kg (359 lbs.) single door 169 kg (373 lbs.) double door	355 kg (782 lbs.) single door 362 kg (799 lbs.) double door
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 Levels

The average decibel level of an active GS5 or GS8 sterilizer is <60 dBA. For more information on sound levels, 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

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. Do not use a detachable cord rated less than 15A.

⚠ 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
GS5 Current	10	Amps
GS8 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 7.0 kg/cm ² (4.7 standard cubic feet per minute at 100 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

The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series is an instrument, Class II medical device, per the U.S. Food and Drug Administration (FDA) classification scheme.

The 3M™ Steri-Vac™ Sterilizer/Aerator GS Series is a Class IIb medical device per the European Union Medical Device Directive (MDD 93/42/EEC) classification scheme.

The 3M™ Steri-Vac™ Sterilizer/Aerator GS 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, 2010, CSA 2nd Ed:2008, 2nd Ed:2013, 3rd Ed:2012) Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
- IEC / EN 61010-2-010 (2003, 3rd Ed:2014) 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, 2015) 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 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 GS 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 GS Series are certified as exempt from the scope of the ATEX Directive.

8.2. Electromagnetic Compatibility (EMC) Compliance

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

The 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 GS 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 GS 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 GS Series outside the environmental conditions as stated in this manual.

Environmental Condition	Operating Condition	Units
Altitude	2500 (max)	Meters
*Operating Temperature	15 - 35	°C
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 GS Series in a temperature environment that is close to the sterilization process temperature set point (e.g. 35°C operating environment and a 38°C 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 GS 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 10cm (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.

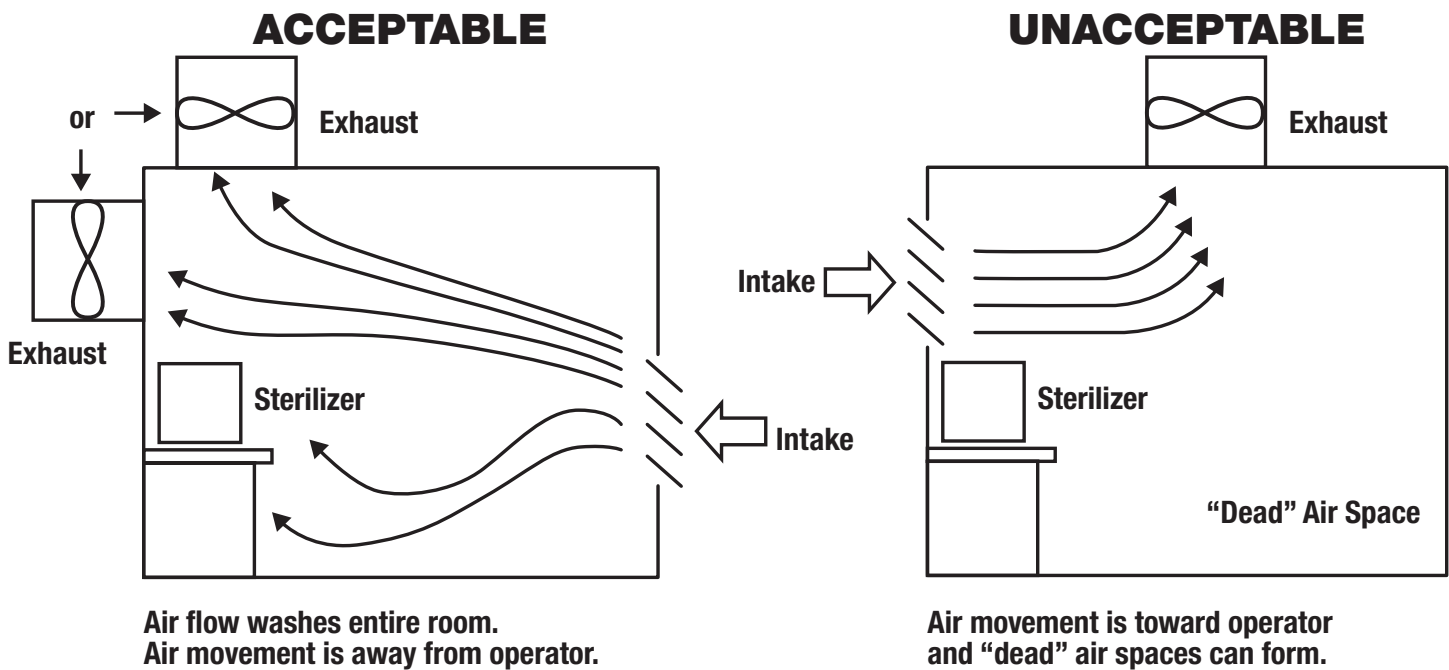


Figure 2.
Acceptable and Unacceptable Installation Air Flow

9.3. Set up and Connections

Figures 3 - 7 illustrate the components and connections for the 3M™ Steri-Vac™ Sterilizer/Aerator Series, Models GS5 and GS8. Table 2 contains additional details regarding specific components and connections for the GS Series Models GS5 and GS8.

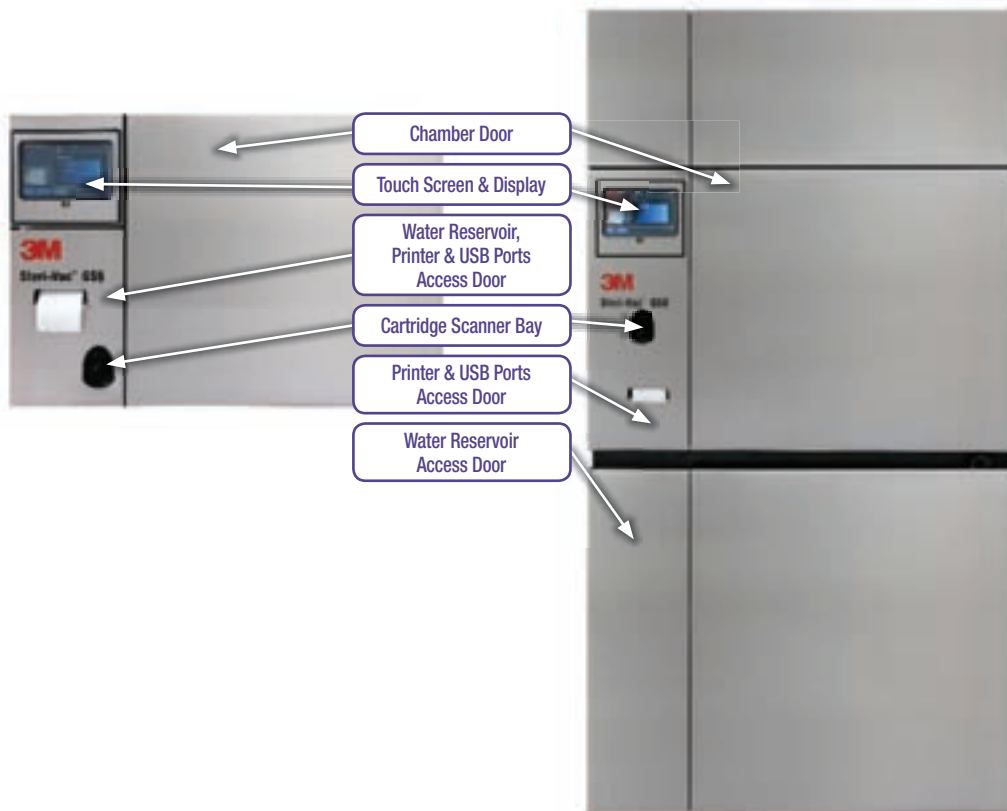


Figure 3.
Front View 3M™ Steri-Vac™
Sterilizer/Aerator GS Series,
Models GS5 & GS8

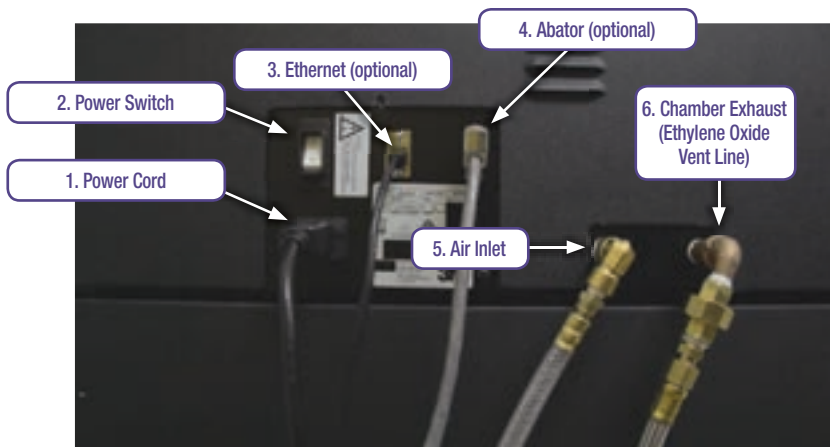


Figure 4.
Left Side Connections -
3M™ Steri-Vac™ Sterilizer/
Aerator GS Series



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

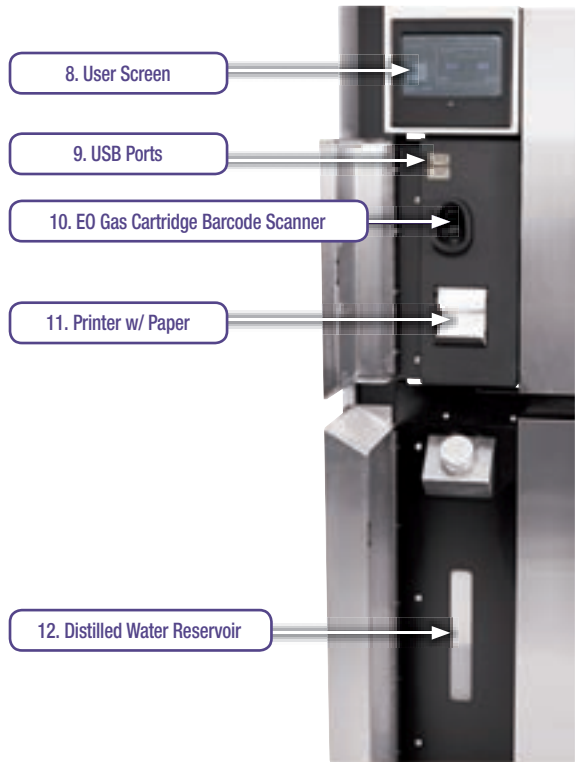


Figure 6.
Front Panel - 3M™ Steri-Vac™ Sterilizer/Aerator GS Series,
Model GS8

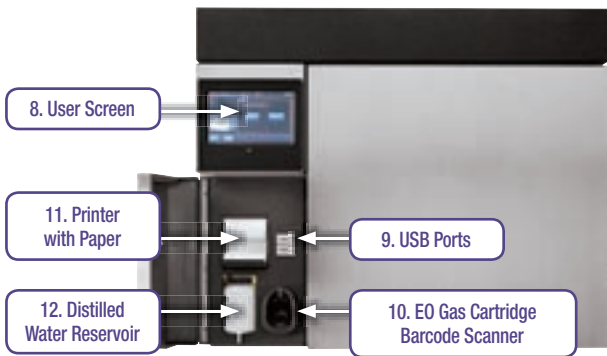


Figure 7.
Front Panel - 3M™ Steri-Vac™ Sterilizer/Aerator GS Series,
Model GS5

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. Do not use a detachable cord rated less than 15A.
2	Power Switch	The power switch turns power to the GS 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 GS 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 12 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 for use only by trained 3M Health Care service personnel or 3M authorized service personnel.
6	Chamber Exhaust (Ethylene Oxide Vent Line)	Connect the GS 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 GS 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. See Chapter 10 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 10 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 12 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 GS Series sterilizer performance and can be retained to meet cycle verification policies. See Chapter 12 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 GS 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 GS Series that appears after the power cycles ON. A double door sterilizer will have an additional button on the Main Screen for the option to open the Unload door.

The Operator controls the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series via a touch screen. A fingertip, stylus, ball tip pen or a computer mouse can be safely used to navigate the touch screens. To use a computer mouse, simply plug the mouse into one of the two USB ports (reference Figures 6 and 7) and the mouse arrow will appear on the touch screen.

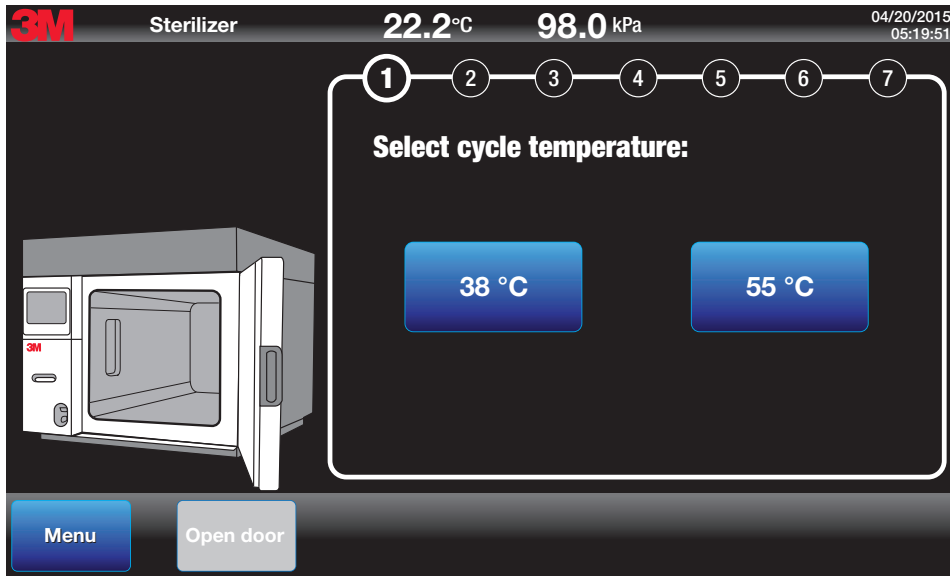


Figure 8.
GS Series Sterilizer Main Screen

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.

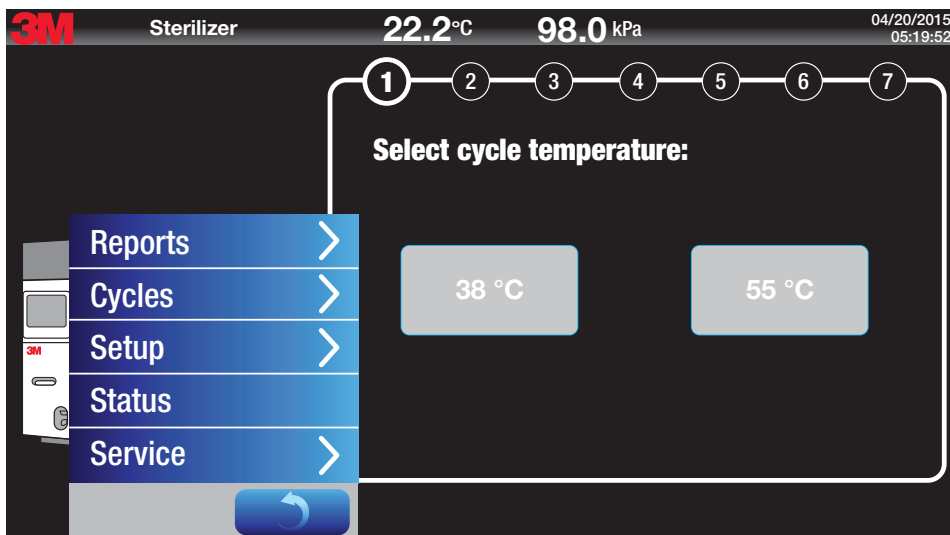


Figure 9.
GS Series Sterilizer Menu Options

10.3. Reports

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

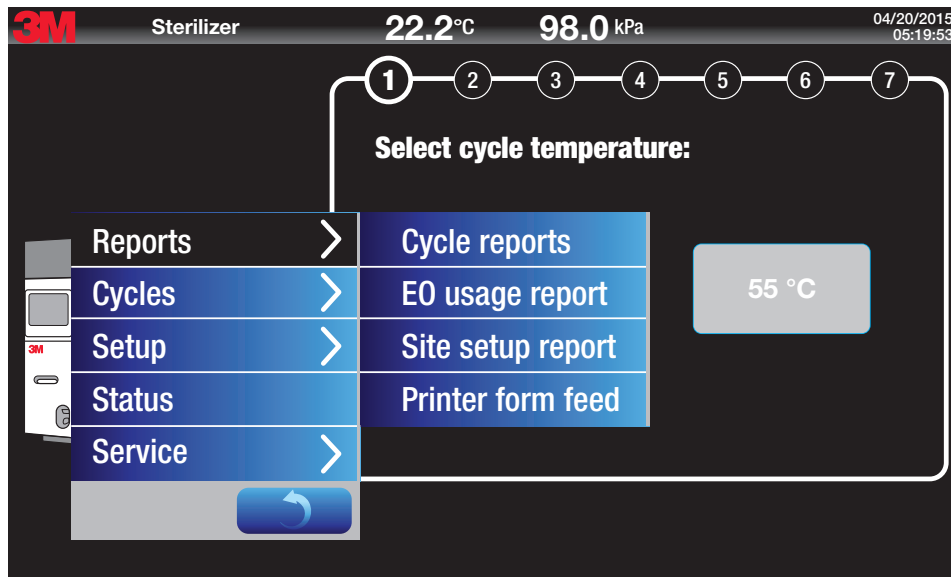


Figure 10.
Reports Menu

10.3.1. Cycle Reports

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

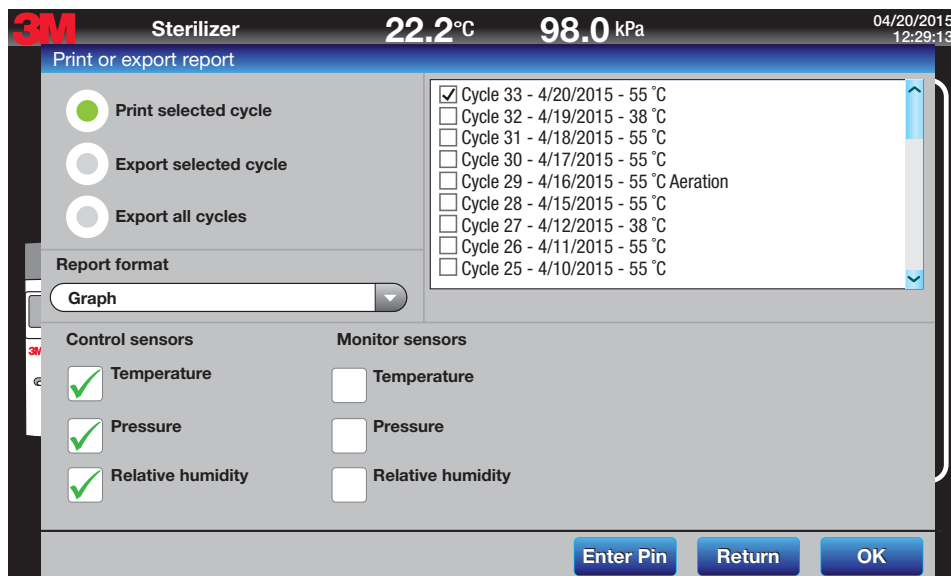


Figure 11.
Cycle Report Setup

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 GS 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 GS 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 12 in Table 5.

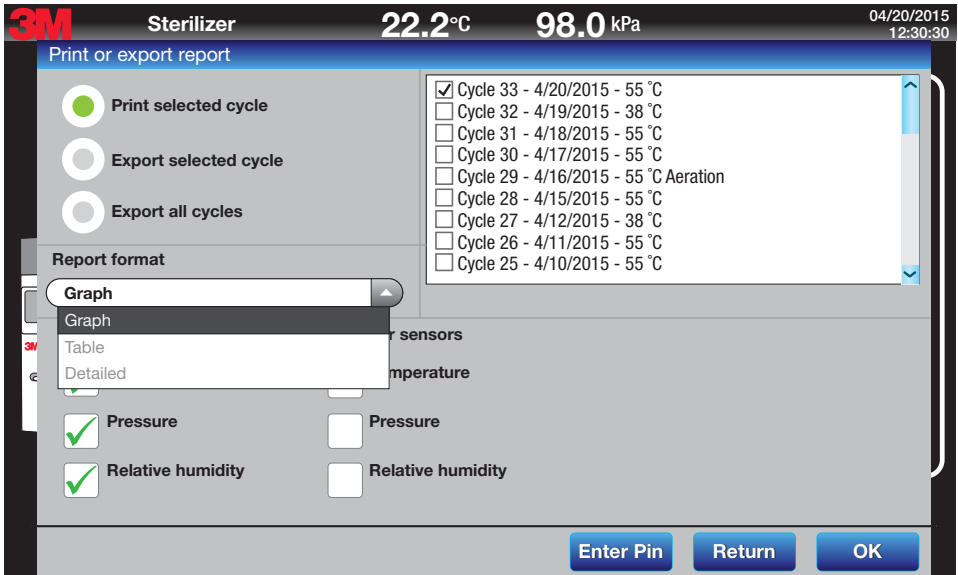


Figure 12. Selecting Report Formats

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.

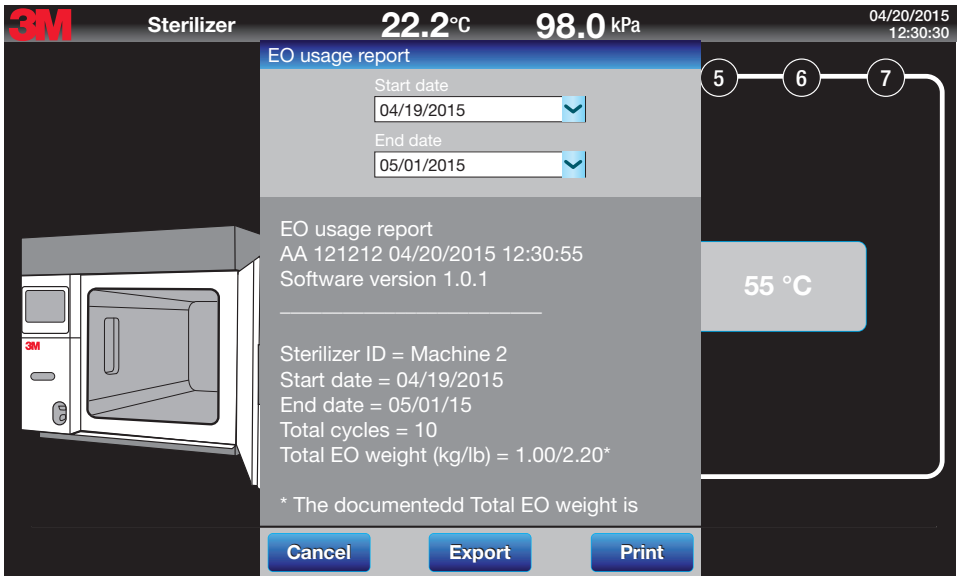


Figure 13. Selecting Dates for EO Usage Reports

EO usage report
AA 121212 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 GS 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.

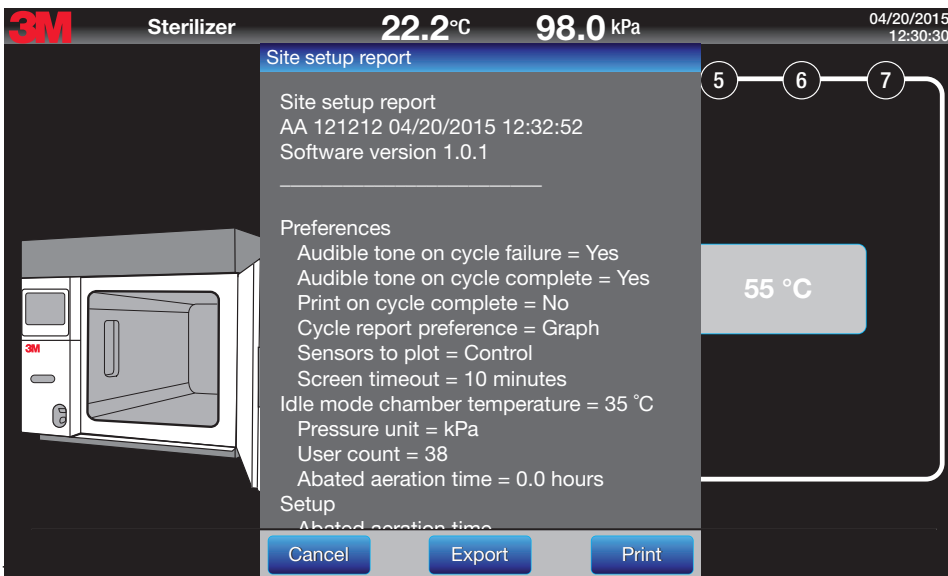


Figure 15.
Display Screen View of the Site
Setup Report

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.

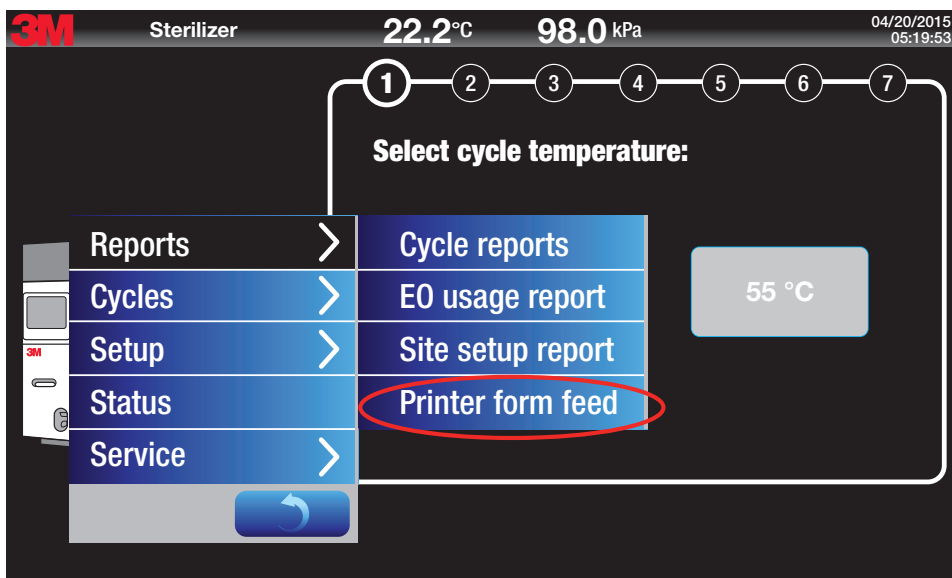


Figure 16.
Location of the Printer Form Feed Button

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).

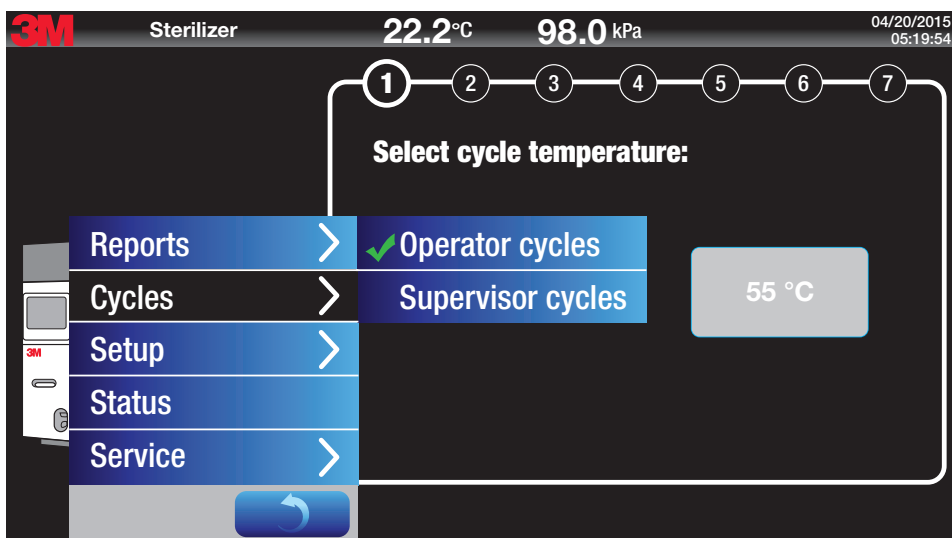


Figure 17.
Cycle Options Menu - Operator Cycles

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.

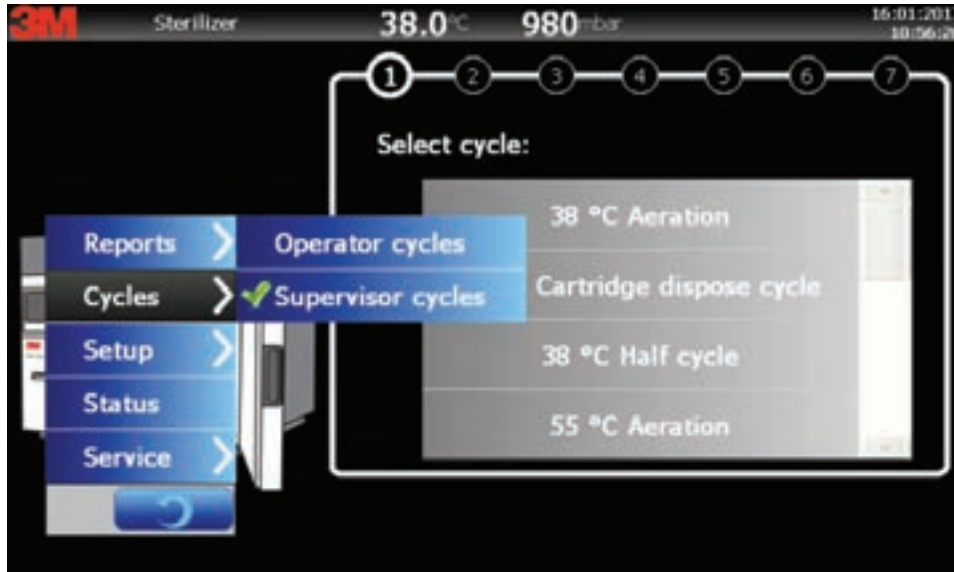


Figure 18.
Cycles Option Menu -
Supervisor Cycles

There are three (3) Supervisor Cycles: for each temperature of 38 °C and 55 °C. 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 cycle** 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.
3. **Half cycle** is a cycle with half the gas exposure time for the selected temperature cycle; 2 hours 15 minutes for 38 °C and 30 minutes for 55 °C. All other parameters for the half cycle are the same as a full cycle. Half cycles are used for sterilizer qualification testing after major redesigns or for specific customer studies.

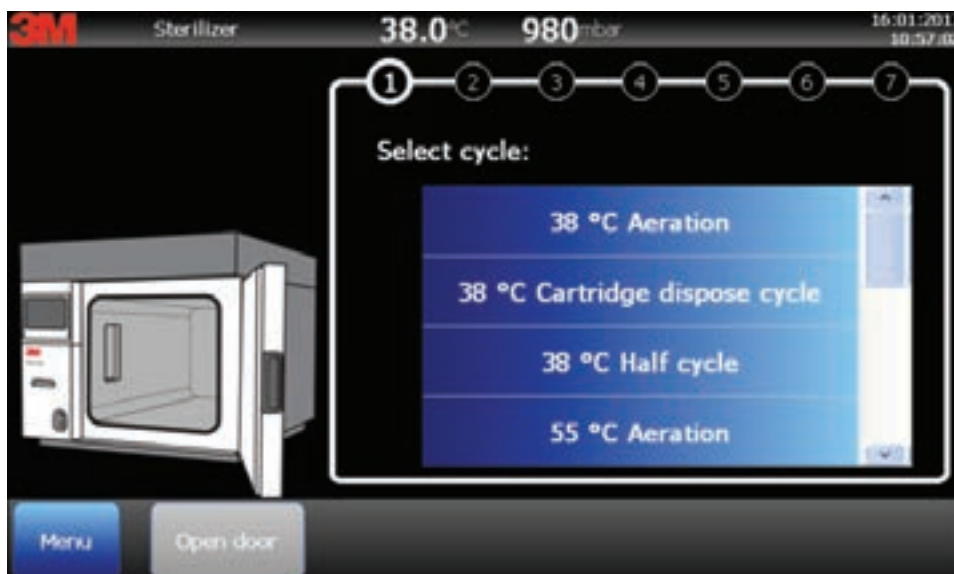


Figure 19.
Main Screen - Supervisor
Cycles Displayed

10.5. Setup Menu

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

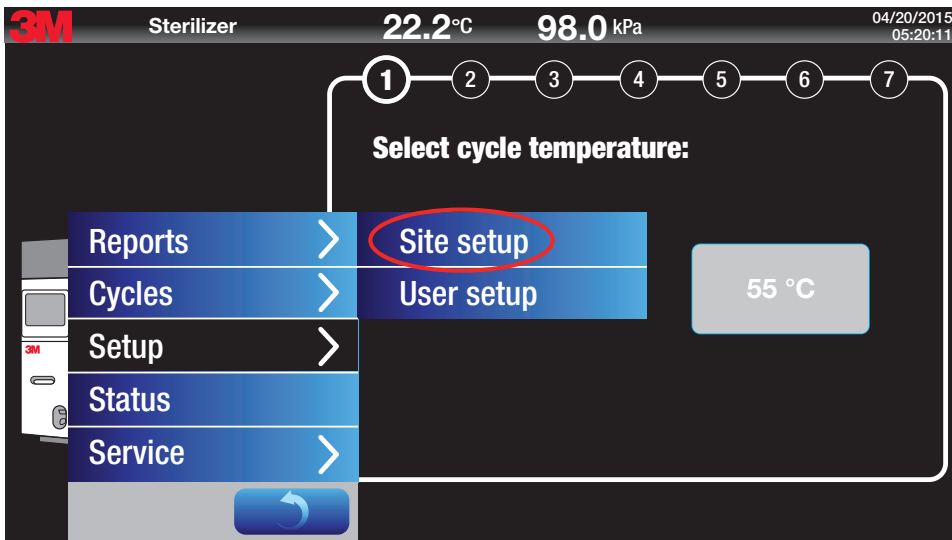


Figure 20.
Button to Access Site Setup Options

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
Enter PIN to bypass scan	When enabled the system will require a Supervisor PIN to bypass scanning the 3M™ Steri-Gas™ EO Gas Cartridge during the cycle programming stage.	Disabled, Enabled	Disabled	Supervisor
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, GS [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.

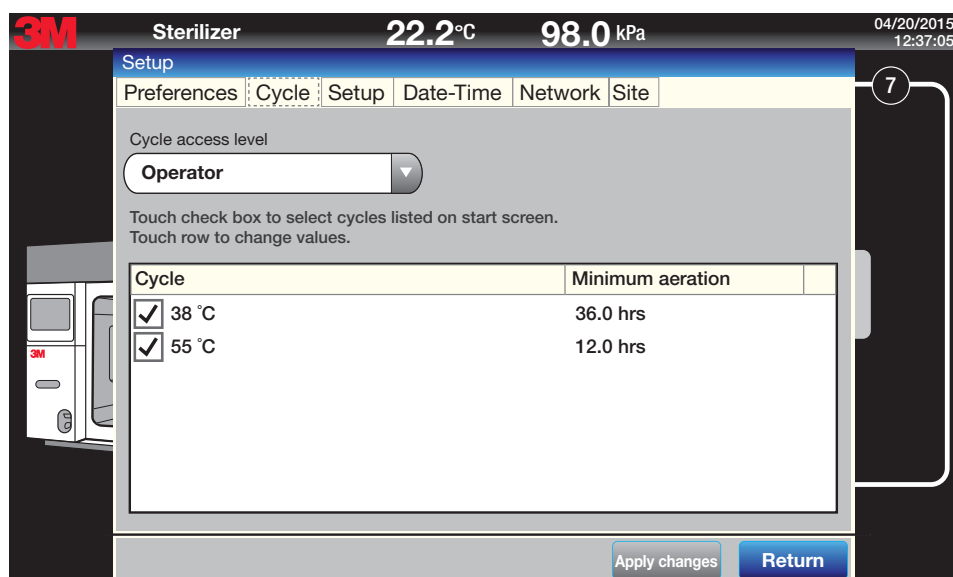


Figure 22.
Setup Cycle Options for Operator Cycles

The minimum default aeration time on the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series can be changed for the 38 °C and 55 °C 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.

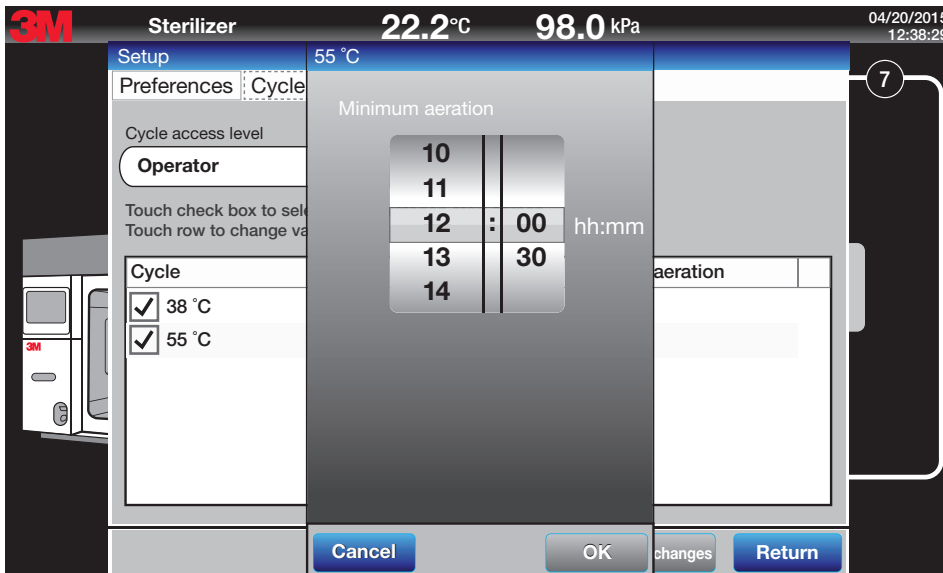


Figure 23.
Changing the Minimum Aeration Default Time

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.

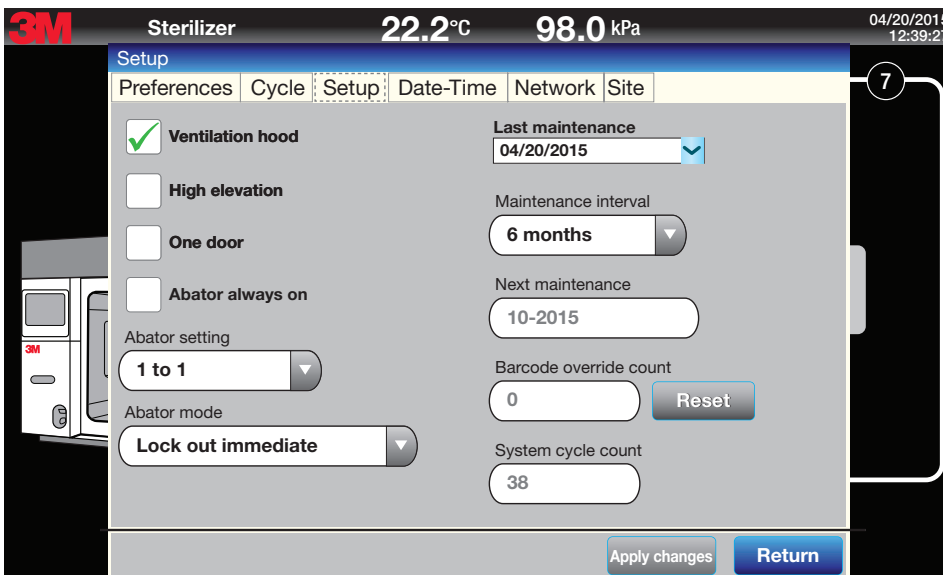


Figure 24.
Site Setup>Setup Tab - Options

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

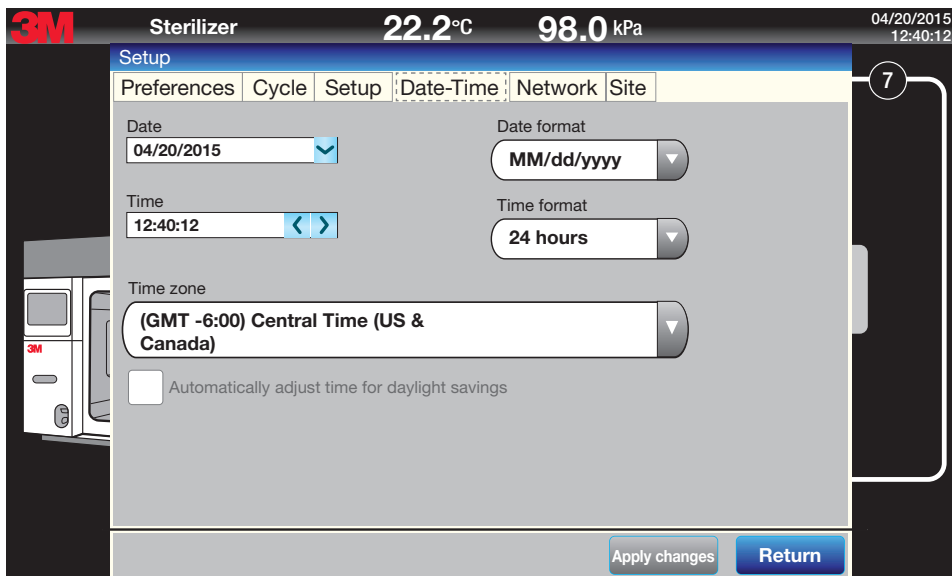


Figure 25.
Site Setup>Date-Time Options

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.

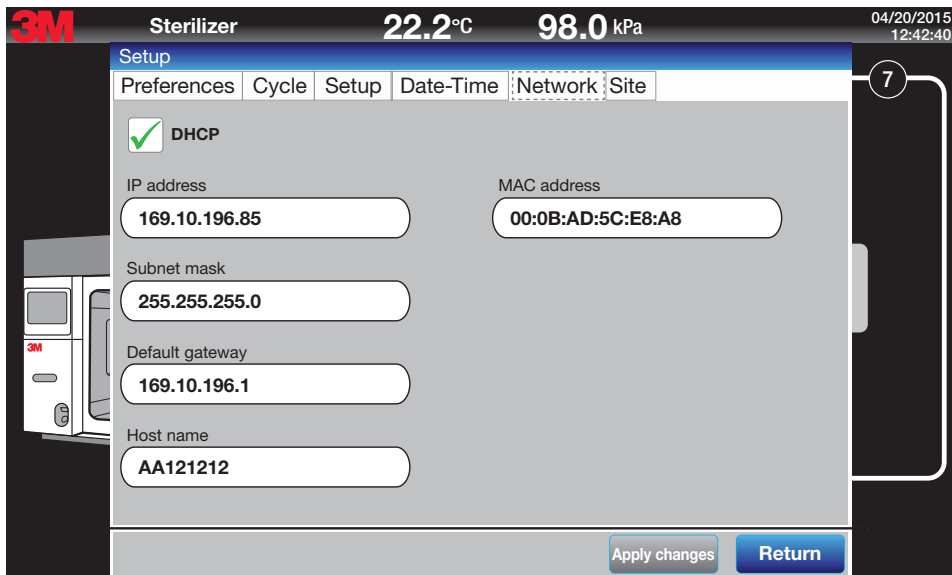


Figure 26.
Site Setup>Network Information

The **Site Setup>Site** tab (Figure 27) provides options for entering the facility name, naming the sterilizer, and setting the language. In addition, deferred or pending software updates can be installed from this screen when the **Update software** button is blue.

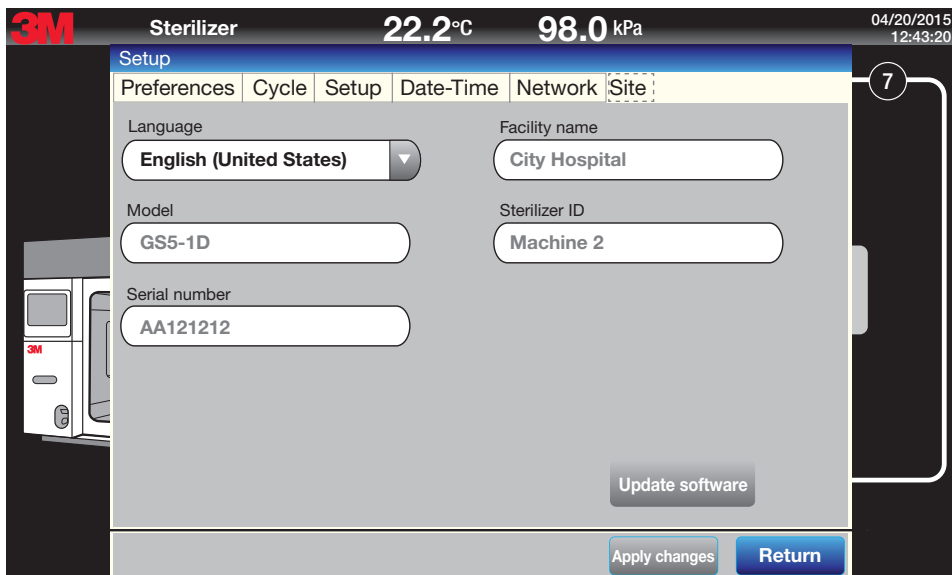


Figure 27.
Site Setup>Site Tab Fields

10.5.2. User Setup

Access the User Setup menu (Figure 28) to establish personal identification numbers (PINs) for Supervisors and Service. **3M Health Care service personnel or authorized 3M service personnel must create the first Supervisor user and PIN.** 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.

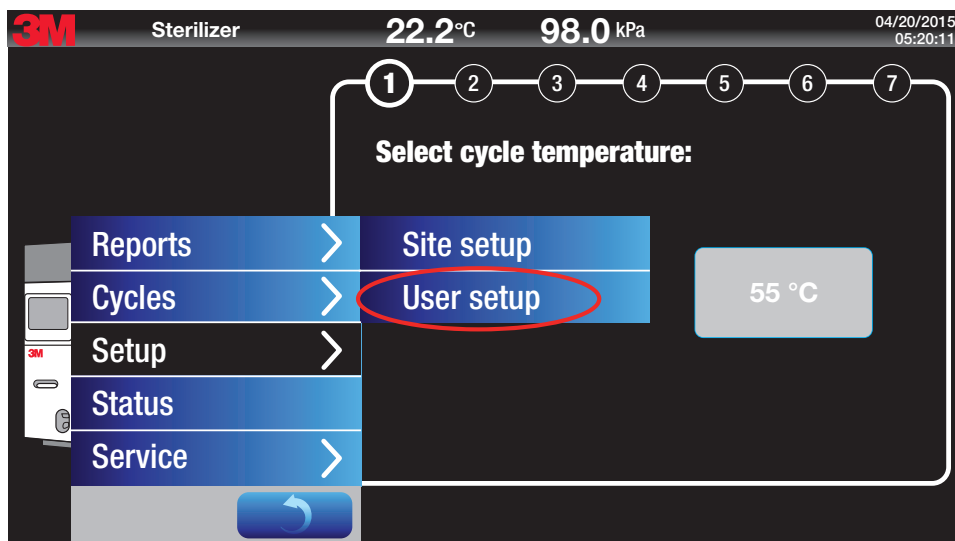


Figure 28.
User Setup Menu



Figure 29.
User Setup Menu – Enter
Supervisor PIN

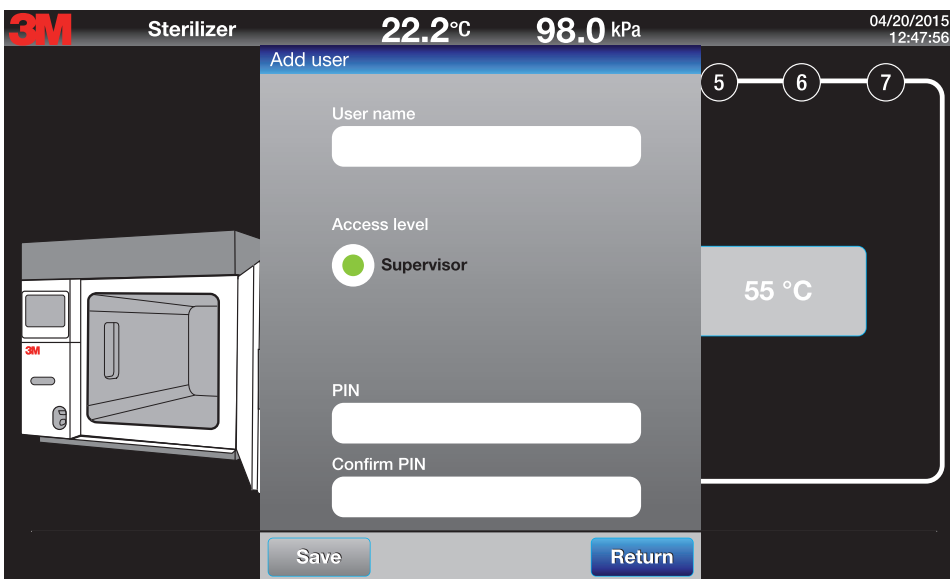


Figure 30.
User Setup Menu – Adding
a Supervisor

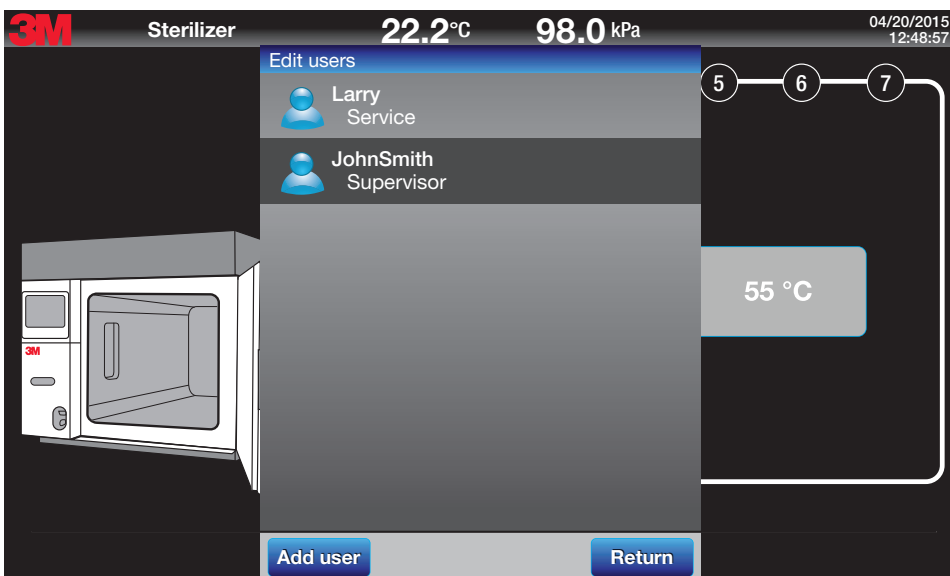


Figure 31.
User Setup Menu – Populated User List

10.6. Status

The **Status** button provides information on the current functional state of the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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.

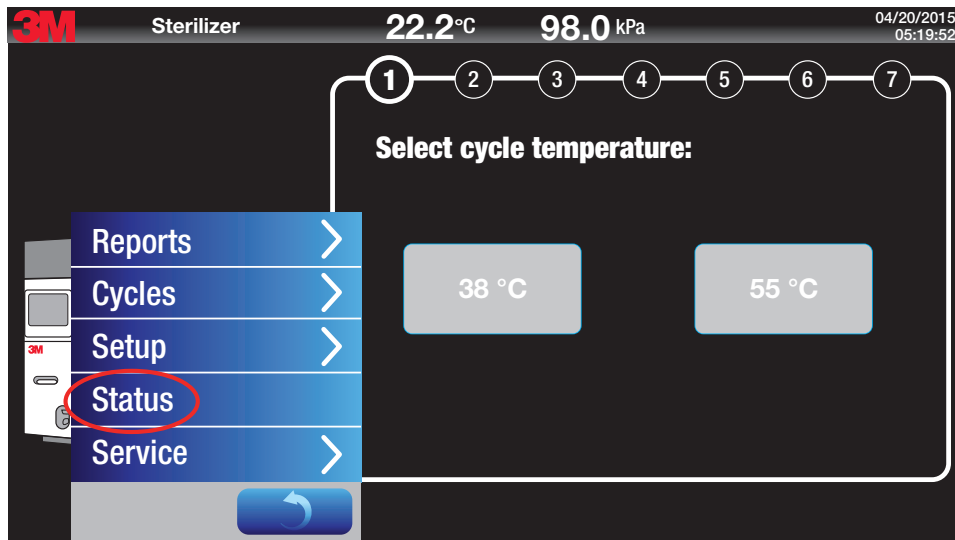


Figure 32.
Status Button

10.6.1. Control

The **Control** tab of the Status option provides information on the current state of the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 GS 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 GS Series is running a cycle. The Log is not saved and is overwritten as new data information appears.

11. Medical Device Packaging and Loading

11.1. Preparing Medical Devices for Sterilization

Clean devices for sterilizing according to the device manufacturer's instructions for use before processing in the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series.

Thorough cleaning is essential to achieve sterilization efficacy.

The definition of a lumen as noted in the cleared Intended Use statement, is an opening or pathway into a medical device. Lumens have several configurations. A lumen may have only 1 opening into the device that serves as both the entrance and exit for sterilant penetration and contact. These are worst case lumens for effective gaseous sterilization. A lumen may also have 1 opening and 1 exit. These configurations are counted as 1 lumen. A lumen may also have multiple openings and multiple exits into and out of the device. These configurations are also counted as 1 lumen. These configurations provide the sterilant multiple openings and exits for penetration and removal which allows for efficient gaseous sterilization. Per this definition, most common gastrointestinal endoscopes have 2 or 3 lumens.

11.1.1. Preparing Endoscopes for EO Sterilization

NOTICE: To reduce the risk of endoscope damage:

Always follow the endoscope manufacturer's instructions for use (IFU) for venting and preparing the endoscope for sterilization.

To prevent possible damage of the endoscope during the air removal or vacuum stages of the sterilization process, some models and brands of endoscopes require a method to vent the endoscope. Venting the endoscope allows a balance of internal and external pressures during the vacuum phases of the sterilization process (i.e. ensuring the pressure inside of the endoscope equilibrates with the vacuum of the chamber). Some brands and models of endoscopes may require:

- connecting a ventilation cap
- removal of the water resistant soaking cap
- both connecting a ventilation cap and removal of the water resistant soaking cap

In addition some brands and models require the removal of parts before packaging and sterilization. Always follow the endoscope manufacturer's instructions for use (IFU) for venting and preparing the endoscope for sterilization.

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

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.

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:

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.

11.2. Packaging Medical Devices

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

Before packaging, ensure that the medical devices are clean and dry per manufacturer's instructions for use.

11.2.1. Packaging Endoscopes for EO Sterilization

Each facility should verify appropriate packaging materials and procedures with the endoscope manufacturer(s) to ensure the endoscopes are suitably packaged for sterilization (i.e., endoscope positioning, bending radius). Including the factors noted above, there are many options available to optimize packaging and the load configuration for endoscopes (i.e. number of endoscopes placed in the chamber).

If the packaging is not specified by the endoscope manufacturer, best practices for packaging of endoscopes for EO sterilization include metal baskets and disposable sterilization wraps due to the smallest Volume to Vent (V-to-V) ratio. The V-to-V ratio is a measurement of the ability for the sterilant to flow into and out of the sterilization container or packaging. This ratio is defined as the interior volume of the sterilization container divided by the total cross-sectional area of the perforated vent holes. Metal baskets and disposable sterilization wraps or some brands of plastic trays wrapped in disposable sterilization wraps have a relatively small Volume to Vent (V-to-V) ratio.

11.2.2. 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

11.2.3. 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

11.2.4. Package Medical Devices

1. Place the device in ethylene oxide (EO) compatible packaging.
2. Place one or more EO chemical indicators (CI) inside each container, wrapped tray, or sterilization pouch (Chapter 13: 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 or seal with the self-adhesive tab per the pouch manufacturer's instructions per use (IFU).
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.

11.3. Loading the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 GS 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 GS 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 GS 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 GS Series chamber.

11.3.1. Loading Recommendations

Biological indicators, such as the 3M™ Attest™ Biological Indicators for ethylene oxide, 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 such as 3M™ Attest™ Biological Indicator Test Pack for EO or 3M™ Attest™ Rapid Readout Biological Indicator Test Pack for EO should be placed in the center of the load (Chapter 13: Process Monitoring, Load Release, and Sterilizer Qualification).

- Always use loading baskets when loading the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series.
- Do not overload the GS 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 GS Series sterilizer chamber walls.

11.3.2. 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.

NOTE: In the U.S., the Environmental Protection Agency (EPA) National Emission Standards for Hospital Ethylene Oxide Sterilizers requires hospitals that do not have an air pollution control device to adopt the management practice of running full loads except under medically necessary circumstances. The date and time of all EO sterilization cycles should be documented and any loads not containing a full load for medically necessary reasons should be noted. The rule does not require hospitals to purchase air pollution control devices. The use of an air pollution control device, however, is an acceptable alternative to the management practice.

12. Operating Instructions

12.1. Starting a Cycle

The Operator controls the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series via a touch screen. A fingertip, stylus, ball tip pen or a computer mouse can be safely used to navigate the touch screens. To use a computer mouse, simply plug the mouse into one of the two USB ports (reference Figures 6 and 7) and the mouse arrow will appear on the touch screen. 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 GS Series has two validated preprogrammed cycle options: 38 °C (100.4°F) and 55 °C (131.0°F). Select the appropriate cycle. On a double door sterilizer the Unload door must be closed to program a new cycle.

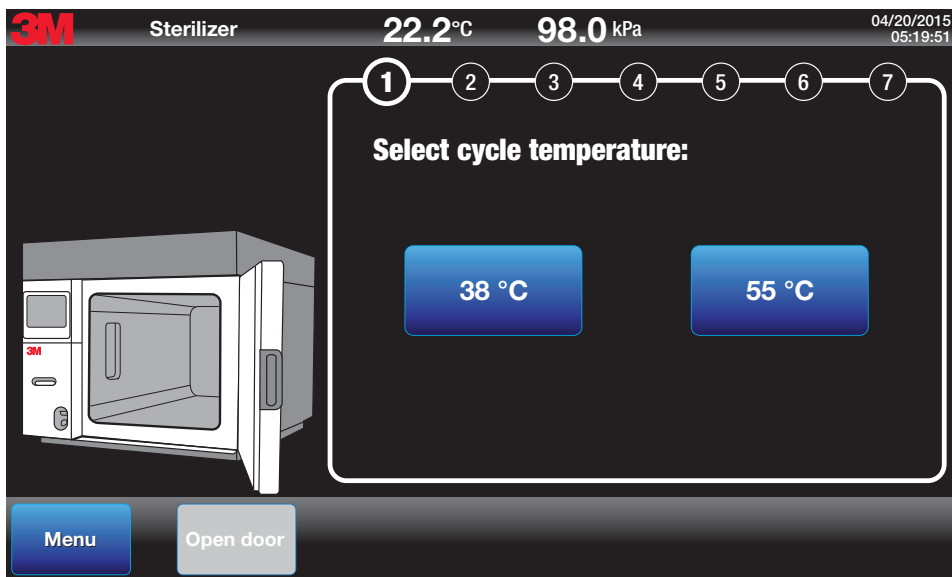


Figure 33.
Step One: Select Cycle

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.

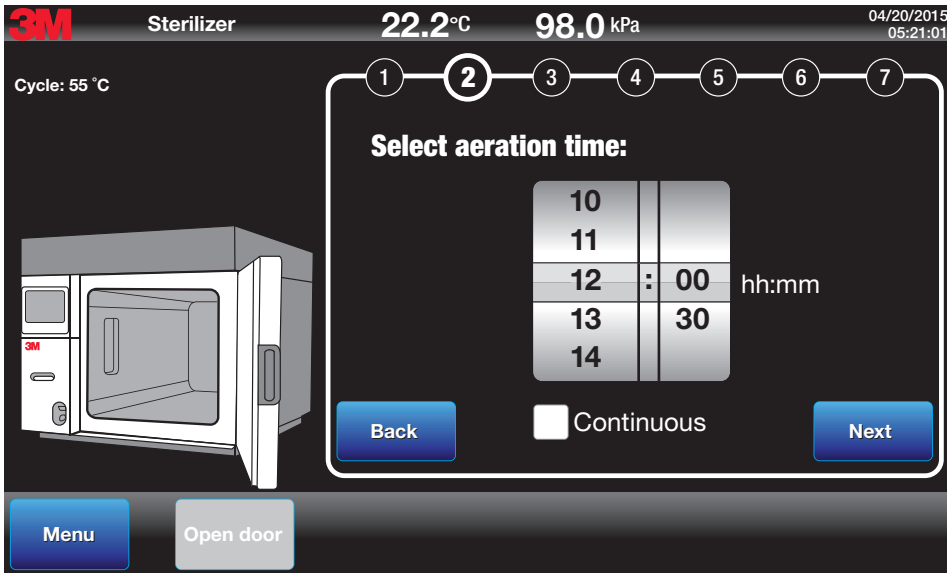


Figure 34.
Step Two: Select Aeration Time

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.

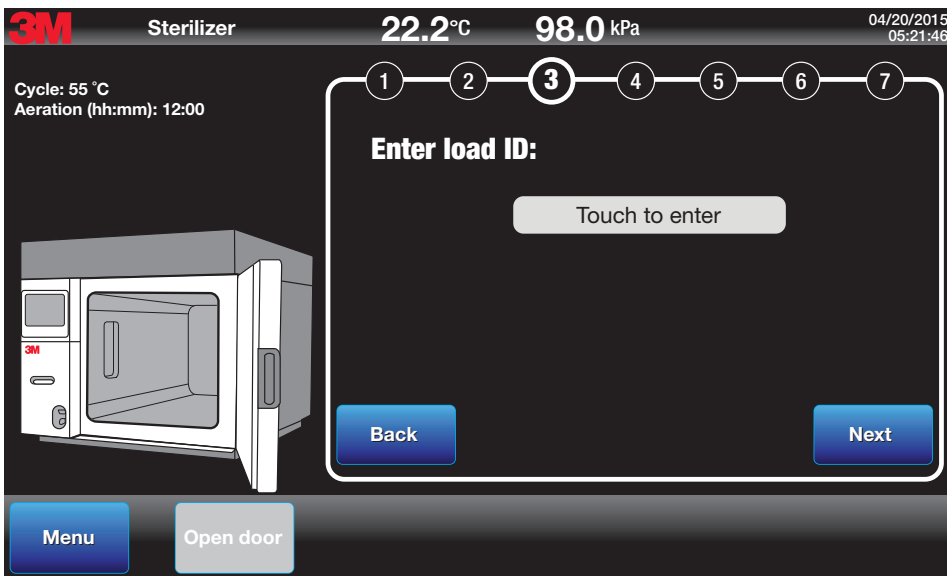


Figure 35.
Step Three: Enter Load ID

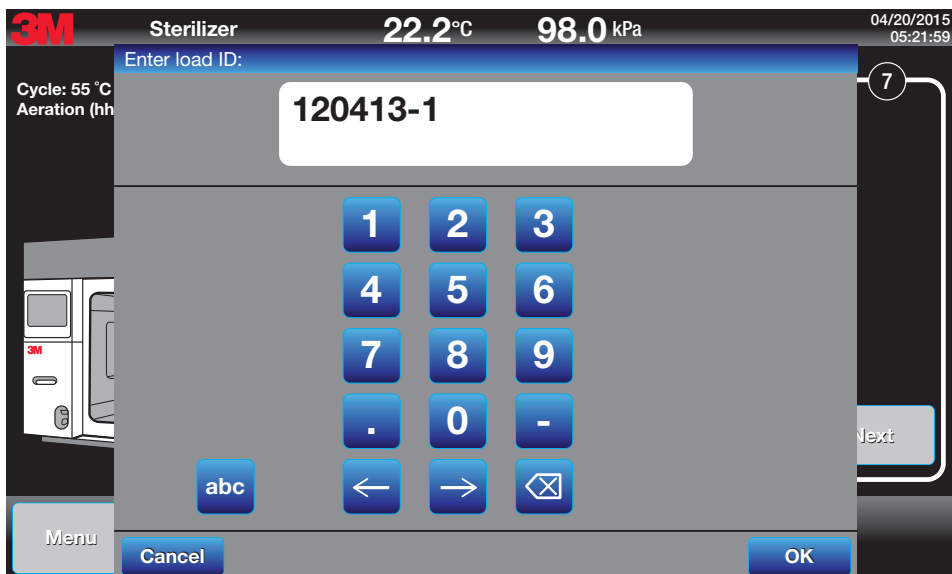


Figure 36.
Load ID Entry by Keyboard

4. Scan 3M™ Steri-Gas™ 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 150°F (65.5°C) may cause cartridges to burst.

3M™ Steri-Gas™ EO Gas Cartridge Catalog Number	3M™ Steri-Vac™ GS Series Models	Nominal Net Weight of EO
4-100	GS5 Series	EO Net wt. 100 g. (3.52 oz.)
8-170	GS8 Series	EO Net wt. 170 g. (5.99 oz.)

⚠ 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 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 GS Series (Figure 38). 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 GS Series sterilizer display screen.

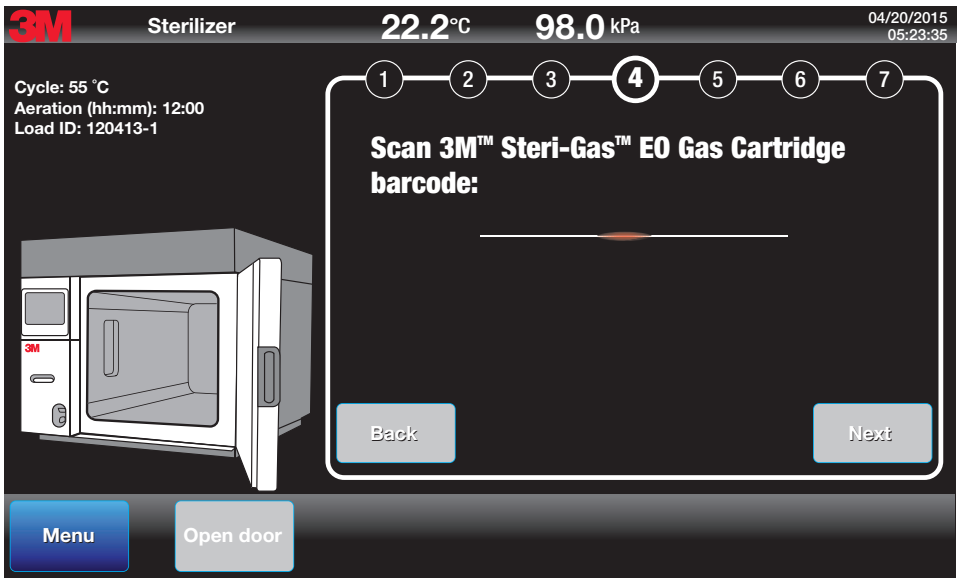


Figure 37.
Step Four: Scan the 3M™ Steri-Gas™ EO Gas Cartridge Barcode

Only valid 3M Steri-Gas EO Gas Cartridges will be accepted by the sterilizer. See Figure 39 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 GS Series sterilizer



Figure 38.
Scanning the 3M™ Steri-Gas™ EO Gas Cartridge Barcode

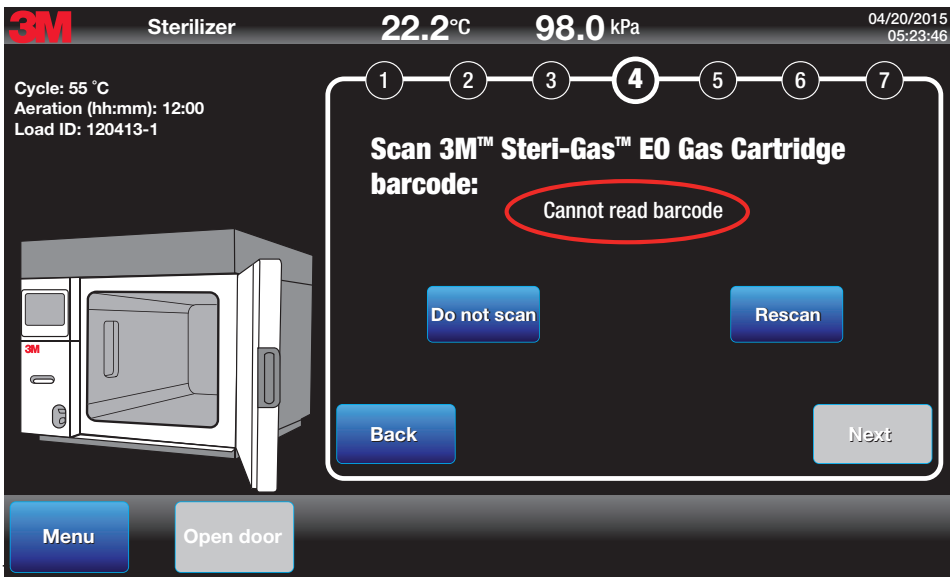


Figure 39.
Example Display Message for an Invalid 3M™ Steri-Gas™ EO Gas Cartridge

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 40).

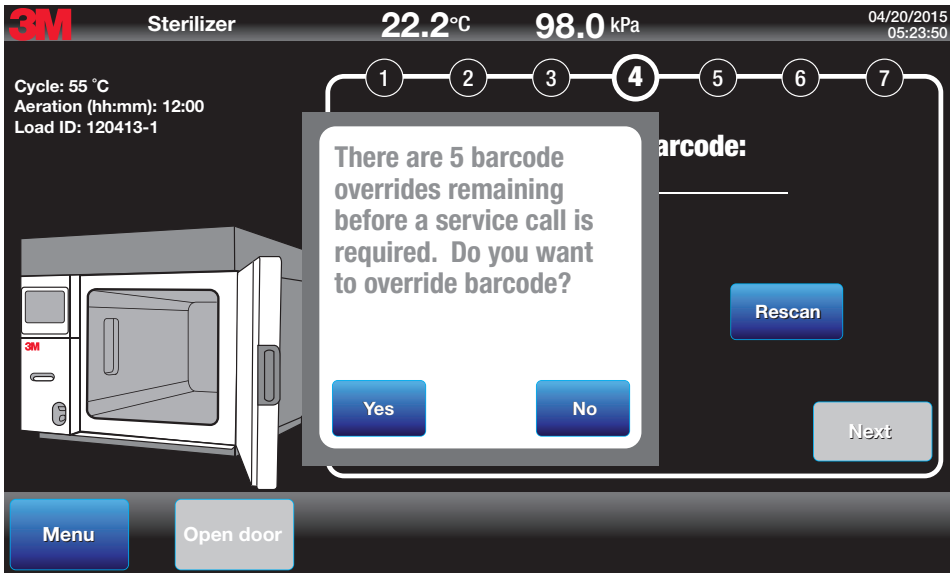


Figure 40.
Steri-Gas EO Gas Cartridge Barcode Override Message

If enabled the sterilizer will require a Supervisor PIN to bypass or override scanning of the 3M™ Steri-Gas™ EO Gas Cartridge. Reference the Site Setup Preferences menu (Figure 21).

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 GS Series sterilizer chamber (Figures 42). Push the green lever down over the Steri-Gas EO Gas Cartridge to secure in place (Figure 43).

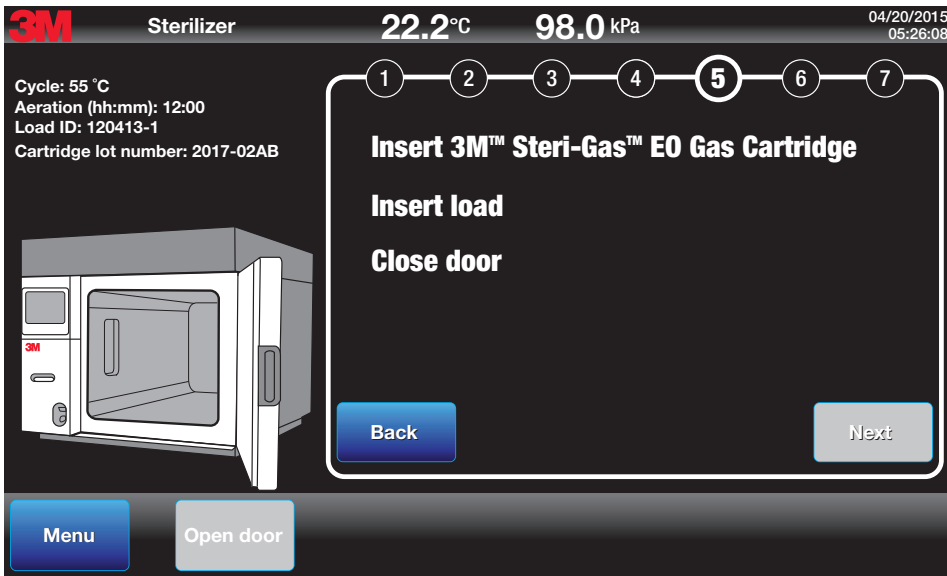


Figure 41.
Step Five: Insert Steri-Gas EO Gas Cartridge, Insert Load, Close Door

⚠ 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 42.
Steri-Gas EO Gas Cartridge in Cartridge Bay



Figure 43.
Green Lever Securing Steri-Gas EO Gas Cartridge

Insert the load into the GS 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. The display screen will automatically advance to the Operator ID screen.

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 44 and 45). Press **Next** to continue.

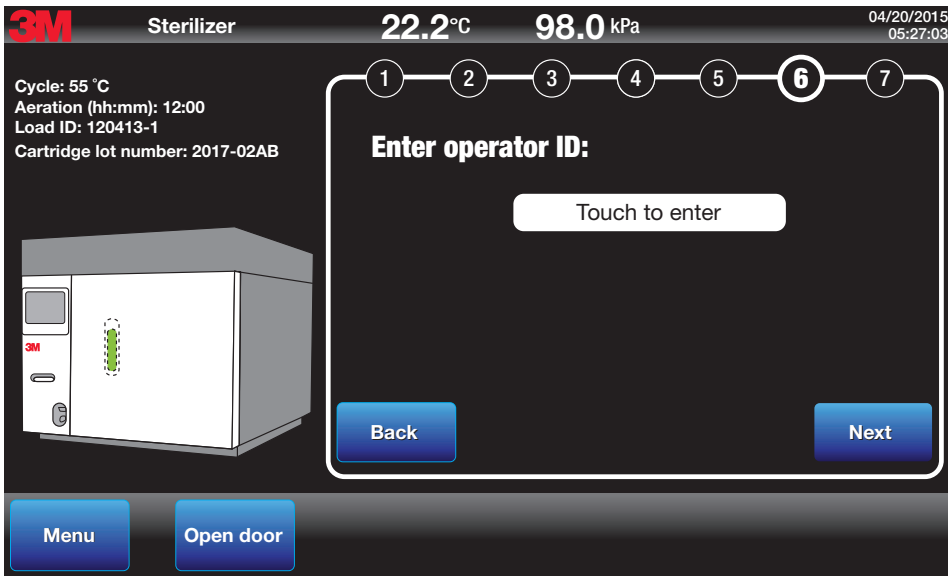


Figure 44.
Enter Operator ID



Figure 45.
Operator ID Entry by Keyboard

7. Review and Start Cycle

Review the selected cycle (Figure 46). 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.

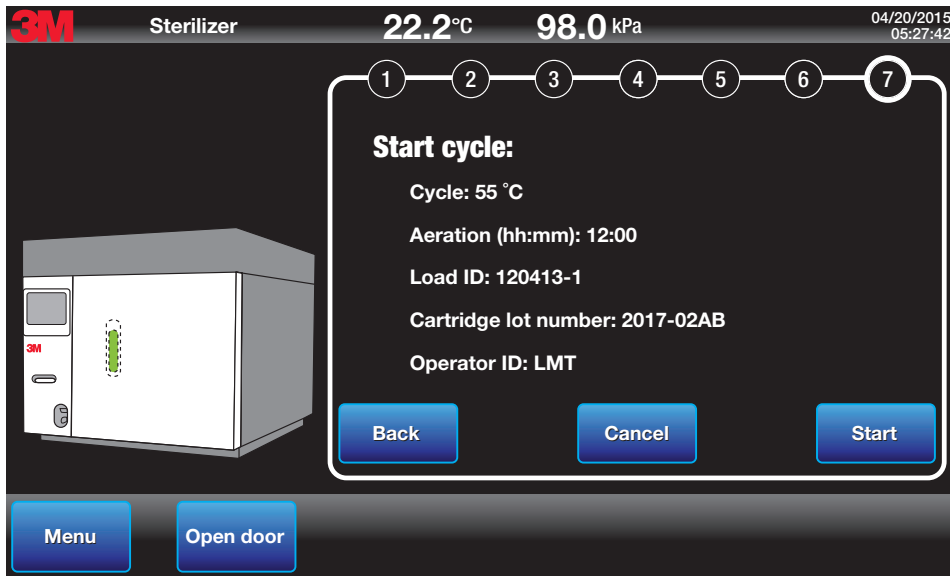


Figure 46.
Review and Start Cycle

After the cycle is started, the GS Series sterilizer proceeds to the Preheat stage, the first of nine active stages of an EO sterilization cycle. Figure 47 is the display screen of a cycle in the Preheat stage.

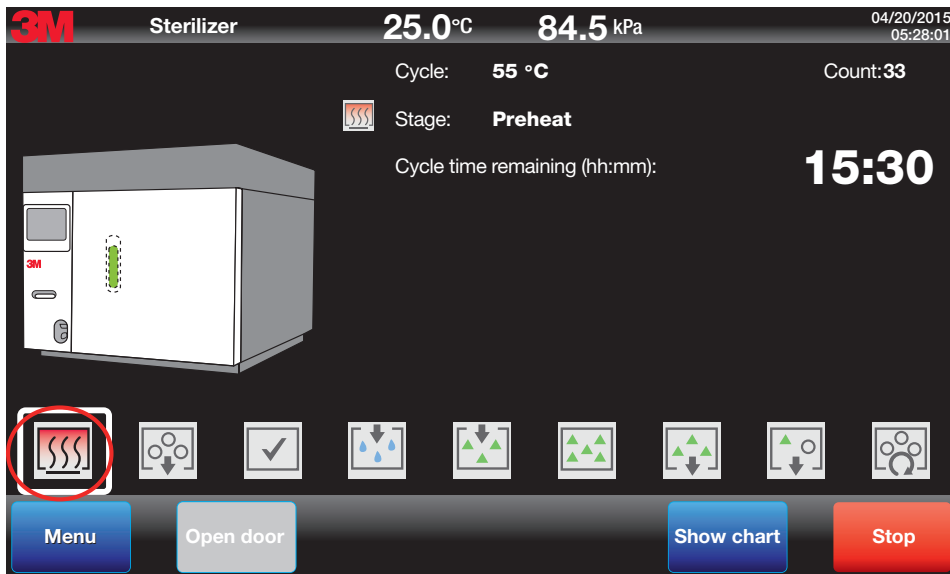


Figure 47.
Preheat Stage Display Screen

⚠ 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 GS 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 GS Series continues to operate.

12.2. Display Screen Indications

Figure 48 illustrates the important information presented on the display screen while the sterilization cycle is running. Table 4 explains each indication.

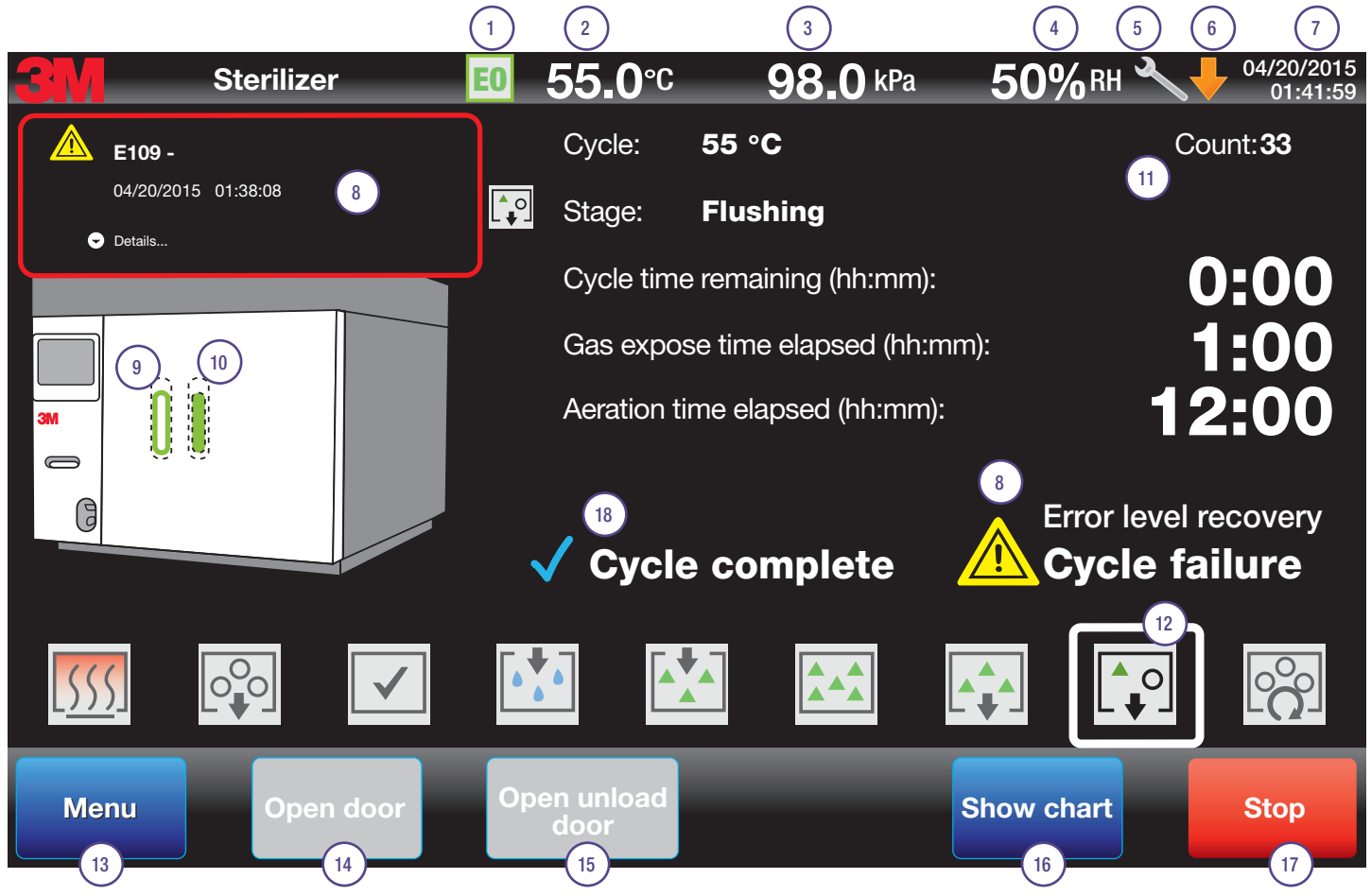


Figure 48.
Display Screen Indications

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 15: 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 GS Series EO Sterilization Cycle.
13	Menu button is used to access GS 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 grey.
15	Open Unload Door button is used on double door pass through GS 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 GS Series sterilizer; therefore, the button is colored grey.
18	Cycle Complete signifies the Operator programmed cycle is successfully complete.

Table 4. Explanations of Display Screen Indications

12.3. Overview of GS Series Ethylene Oxide (EO) Sterilization Cycle

12.3.1. Cycle Stages and Descriptions

3M™ Steri-Vac™ Sterilizer/Aerator GS 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. The time required to obtain the pre-set operating temperature will vary slightly from cycle to cycle, up to 40 minutes.



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 a 2 minute equilibration time allows for pressure stabilization, afterwards the pressure rise in the chamber is monitored for six (6) minutes. 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 GS 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. The chamber is repeatedly filled with filtered air and cleared by a vacuum.

The end of the Flushing stage contains 90 minutes of locked aeration. During this aeration period the chamber remains locked to all personnel (Operators, Supervisors, and Service). This aeration time will be included in the cycle report as part of the total aeration time elapsed. In addition, the vent hood (i.e. exhaust hood) is monitored for appropriate air flow in standard cubic feet per minute (SCFM). If the GS Series sterilizer detects the air flow in the vent hood is too low (< 125 SCFM) or if the vent hood option is disabled in the Site Setup Menu, the sterilizer door will remain locked in Flushing stage until a minimum of three hours of aeration is fulfilled during the Flushing stage. This aeration time will be included in the cycle report as part of the total aeration time elapsed.



Stage 9: Aeration

During Aeration, EO desorbs from the product load and devices until predetermined levels of EO are reached. Aeration in the GS 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.

The U.S. Environmental Protection Agency (EPA) requires U.S. healthcare facilities to complete full aeration within the sterilizer chamber prior to transferring the load. This practice eliminates the potential for EO exposure that might occur if the load were transferred to a separate aeration chamber prior to full 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.

12.3.2. 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 49 – 53. There are three options for assembling a cycle report: Graph, Table and Detailed. Table 5 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

Table 5. Options for 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.



Steri-Vac™ Sterilizer GS5-1D

Serial number: AA121212

Software version: 1.0.1

Facility: City Hospital

Sterilizer ID: Machine 2

Start time: 04/20/2015 05:27:42

Cycle count: 33

Cycle name: 55° C

Operator ID: LMT

Load ID: 120413-1

EO cartridge lot: 2017-02AB

Figure 49.
Example Cycle Report – Header

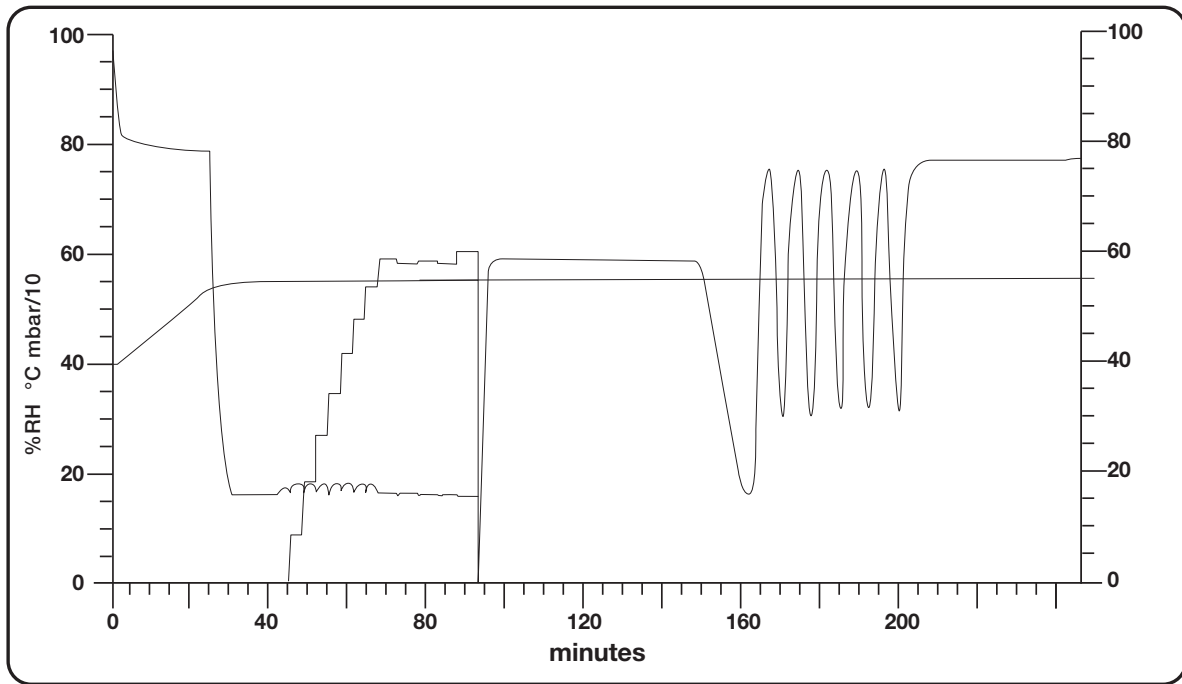


Figure 50.
Example Cycle Report – Graph Option

Stage	Start time	Tc(C)	Tm(C)	Td(C)	Tmid(C)	Tu(C)	Pc(mbar)	Pm(mbar)	H5(C)
Preheat	14:52:12	23.2	23.4	22.1	22.5	22.7	978.3	979.4	33.2
Air removal	15:17:22	54.0	54.2	49.8	53.0	49.9	797.3	798.9	54.8
Chamber test	15:27:43	55.6	55.7	53.7	54.0	54.1	159.4	160.3	94.8
Conditioning	15:33:46	55.3	55.5	53.5	53.6	53.7	162.5	164.1	94.8
EO injection	16:41:13	55.0	55.1	54.2	53.4	54.3	151.4	152.3	94.8
EO exposure	16:42:46	55.0	55.2	54.2	53.5	54.3	360.2	361.1	94.7
EO removal	17:43:46	55.0	55.2	54.3	53.5	54.3	360.2	361.8	56.0
Flushing	17:49:46	55.0	55.2	54.2	53.5	54.3	157.9	158.8	55.0
Aeration	20:16:18	55.1	55.2	54.2	53.7	54.4	807.6	809.6	54.9

RH end of conditioning: 12/20/2016 16:41:06 RHc (%): 57.8 RHm (%): 59.0

Figure 51.
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 52.

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 53.

Example Cycle Report – Footer

The definitions for the column headings in the Table cycle report (Figure 51) 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

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

The 3M™ Steri-Vac™ Sterilizer/Aerator GS 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.

12.5. 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 GS Series from a desktop located on-site within the facility network. The system is intended for use in a server-based network.

12.5.1. Network Connections

The 3M™ Steri-Vac™ Sterilizer/Aerators GS Series software application will introduce a minimal amount of active network traffic when connected to a local area network (LAN). Adding the GS 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 GS 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 GS 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 GS 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 GS 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.

12.5.2. IP Addresses

The 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 GS Series sterilizer single board computer can be viewed in the "MAC address" field of the **Menu>Site Setup>Setup>Network** tab (Figure 54).

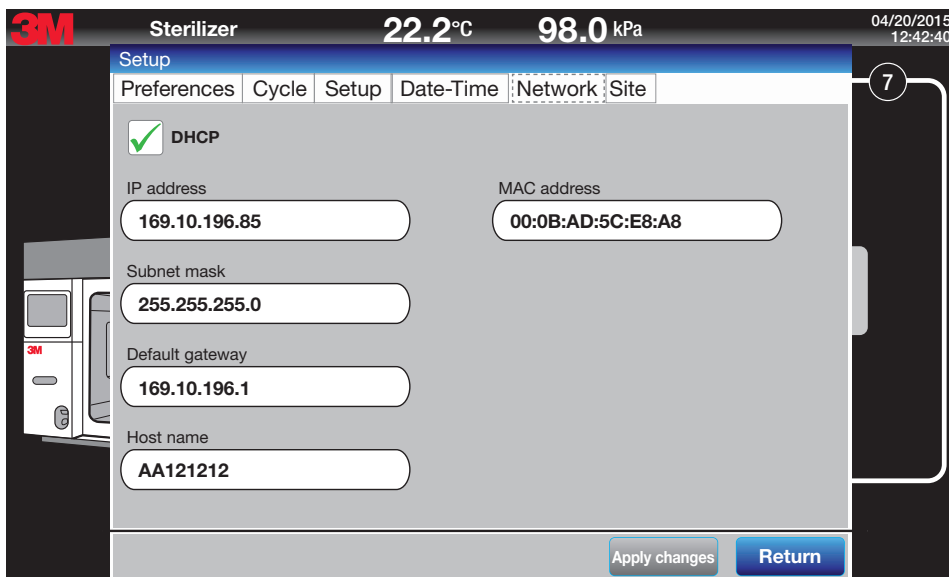


Figure 54.
Menu>Site Setup>
Setup>Network Information

12.5.3. Software Security

The customized Operating System (OS) utilized on the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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.

12.5.4. Software Update

The 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 55). The update software prompt will only display when the GS Series sterilizer transitions to idle mode (Main Screen) and no pending errors exist. The sterilizer screens will guide the user through the update process.

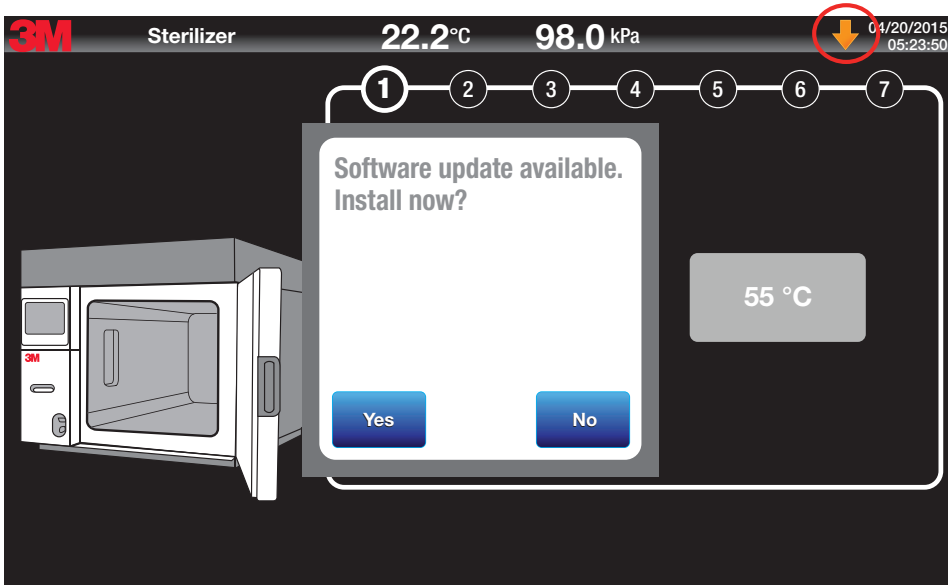


Figure 55.
Prompt of Software Update Available

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**) reference Figure 27.

Notifications of pending software updates will also be sent to registered users via the email address used to register the GS Series sterilizer on www.3M.com/SteriVacService. 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.

12.5.5. Firmware Updates

3M™ Steri-Vac™ Sterilizer/Aerator GS 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.

12.6. 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 GS 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.

12.7. 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 GS Series performance and can be retained to meet cycle verification policies.

To load printer paper, install the roll in the feed mechanism (Figure 56). 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.

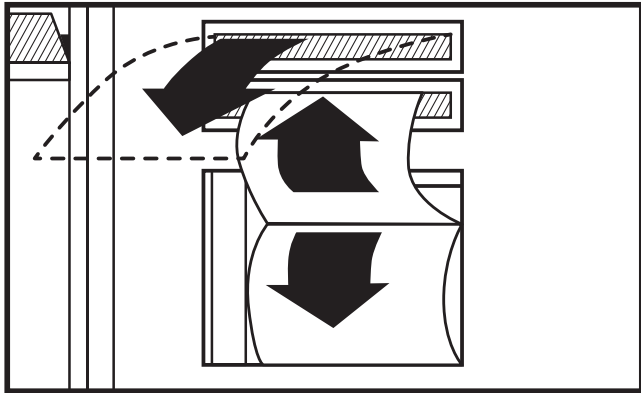


Figure 56.
Loading Printer Paper

12.8. Unloading the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series

⚠ 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.

Always review the elapsed aeration time on 3M™ Steri-Vac™ Sterilizer/Aerator GS Series display prior to opening GS 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 GS 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.

12.8.1. Unloading the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series – Cycle Complete

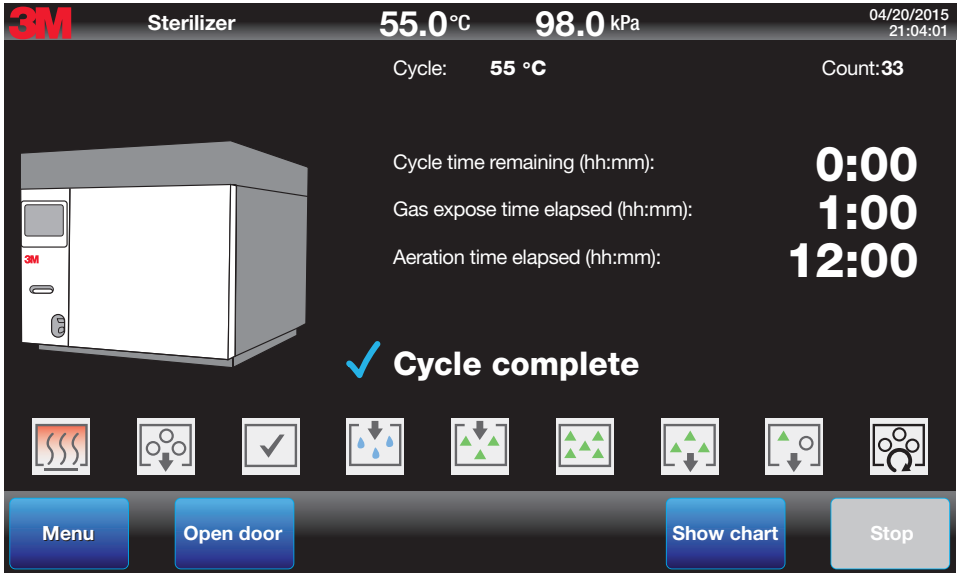


Figure 57.
Cycle Complete Screen

1. Press the **Open Door** button on the touch screen (Figure 57). On double door units, press the **Open Unload Door** button. The Load Door cannot be opened after the cycle has successfully completed on double door units.
2. Allow chamber pressure to equilibrate to room pressure; this typically requires 60-90 seconds.
3. Open the GS 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 58). The display will return to the main screen.
6. Follow the Process Monitoring and Quality Control procedures described in Chapter 13.

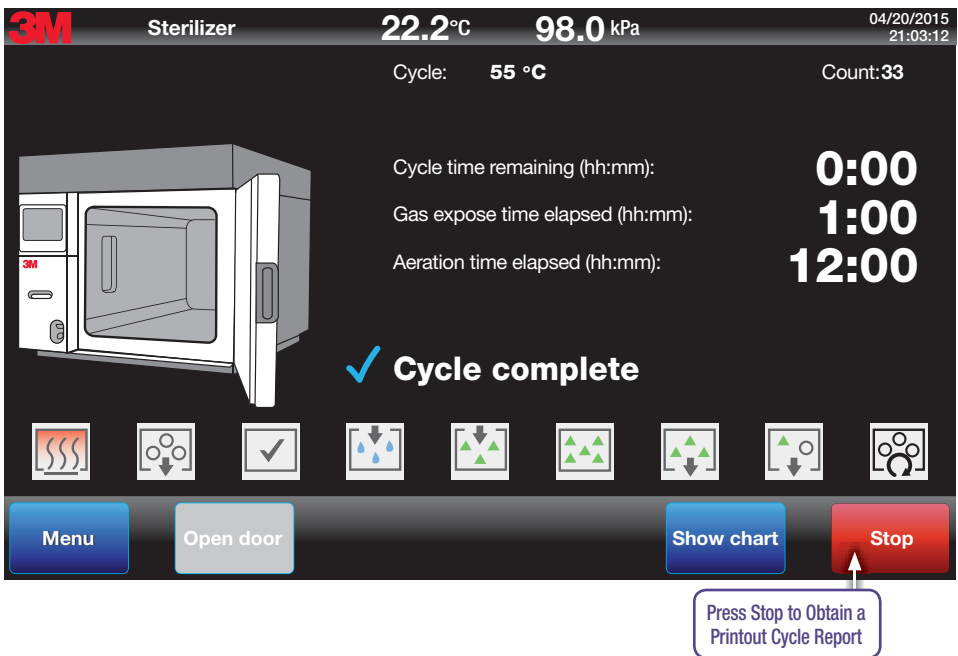


Figure 58.
Command to Obtain Cycle
Report Printout

12.9. Accessing the Chamber during the Aeration Stage

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

Always review the elapsed aeration time on the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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).

If it is necessary to access the chamber during the Aeration stage, for example to remove a BI PCD, routine BI Test Pack, or an instrument or item that requires minimal aeration, take all precautions to minimize exposure to EO and after opening the door, retrieve the item or items promptly, minimize handling and sorting, and close the door to limit off gassing of the load into the sterilizer room. When it is necessary to handle individually packaged items that are not fully aerated, butyl, neoprene, or nitrile gloves should be worn. The breathing zone of personnel should be monitored to verify the safety of the practices followed.

Do not remove the load until the total elapsed aeration time meets or exceeds the aeration time required by the device and packaging manufacturer's instructions for use. The U.S. Environmental Protection Agency (EPA) requires U.S. healthcare facilities to complete full aeration within the sterilizer chamber prior to transferring the load. This practice eliminates the potential for EO exposure that might occur if the load were transferred to a separate aeration chamber prior to full aeration.

During the Aeration stage, the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series door can only be opened with a Supervisor or Service PIN (Figures 59 and 60). Aeration timing will be interrupted if the door is opened. Once the door is closed and the aeration temperature returns to specification, aeration timing will continue.

1. To access the chamber during aeration, press the **Open Door** button on the touch screen. On double door units, press the **Open Unload Door** button. The Load Door cannot be opened during Aeration on double door units.
2. Enter a Supervisor or Service PIN (Figure 59).
3. Allow chamber pressure to equilibrate to room pressure; this typically requires 60-90 seconds.
4. Open the GS Series sterilizer door. The Aeration stage will be paused (Figure 60).
5. Close the GS Series sterilizer door to continue aeration.
6. If the total required aeration time has elapsed, press the **Stop** button. A printout of the cycle report will generate. The display will return to the main screen.

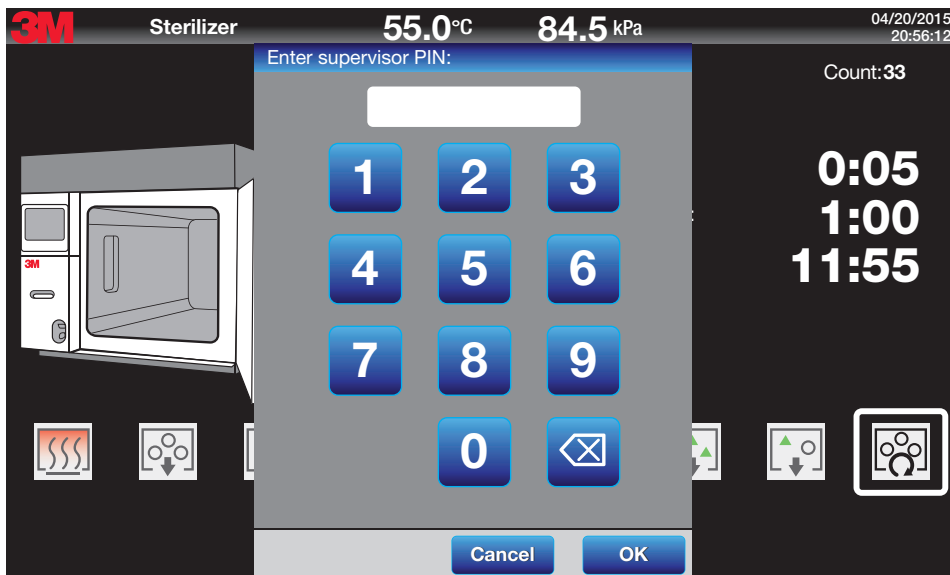


Figure 59.
Supervisor PIN Required to
Pause Aeration

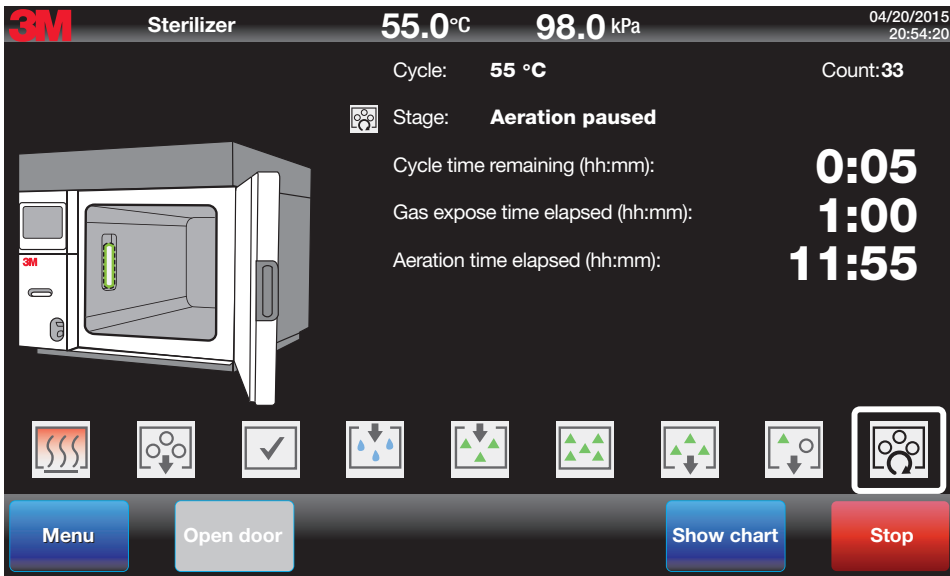


Figure 60.
Aeration Stage Paused

12.10. Empty 3M™ Steri-Gas™ EO Gas Cartridges

The 3M™ Steri-Gas™ 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 GS 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.

12.11. 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).

12.12. Sterilization Cycle Cancellations

12.12.1. 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 GS 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. On double door sterilizers, if a cycle is cancelled in any stage up to and including the Flushing stage, the Load Door is the only door that the sterilizer will allow to be opened as the cycle is not considered complete. When the Flushing stage is complete, the Unload Door is the only door that the system will allow to be opened to ensure that the load can only be accessed from the unload side of the sterilizer. Refer to Chapter 15: Cautions, Error Messages, and Troubleshooting for error codes and their respective corrective actions.

12.12.2. Automatic Cycle Cancellation

The 3M™ Steri-Vac™ Sterilizer/Aerator GS 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. On double door sterilizers the Unload Door cannot be opened after an automatic cycle cancellation as the cycle is not considered successfully complete. Refer to Chapter 15: Cautions, Error Messages, and Troubleshooting for error codes and their respective corrective actions.

12.13. Power Outages

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

When the power resumes, if critical cycle parameters monitored are still within acceptable limits for the specific stage of the cycle, 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 15: Cautions, Error Messages, and Troubleshooting for error codes and their respective corrective actions.

13. 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 GS 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).

13.1. 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.

The 3M™ Steri-Vac™ Sterilizer/Aerators GS Series is designed with embedded software that automatically controls and independently monitors the physical process parameters to ensure sterilization conditions are maintained throughout the sterilization cycle. The sterilizer embedded software regulates, independently monitors, and records all critical sterilization process parameters including pressure, temperature and percent relative humidity (%RH) in conditioning.

Documentation for physical parameters is provided on the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 48 – 52.

Each cycle report should be reviewed prior to load release per facility policies. Critical parameters for the 38 °C and 55 °C cycles are contained in Table 6. Verification of these parameters on the printed cycle report is illustrated in Figures 61 and 62. Verification of cycle performance should be conducted per facility policies. For all cycles confirm final status contains **Cycle Complete** on the printout footer (Figure 62). 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 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)	E0 Exposure Time (hr + min)	Aeration Temp (°C)	Aeration Time (min)
38°C	'Cycle Complete' + 'No Errors'	38 ± 3	40 - 80	4.5 hr ± 5.4 min	As Programmed per Manufacturers IFU	As Programmed per Manufacturers IFU
55°C	'Cycle Complete' + 'No Errors'	55 ± 3	40 - 80	1.0 hr ± 1.2 min		

Table 6. Preprogrammed GS Series Cycle Report Physical Parameter Requirements

3M	
Steri-Vac™ Sterilizer GS5-1D	
Serial number:	AA121212
Software version:	1.0.1
Facility:	City Hospital
Sterilizer ID:	Machine 2
Start time:	04/20/2015 05:27:42
Cycle count:	33
Cycle name:	55° C
Operator ID:	LMT
Load ID:	120413-1
EO cartridge lot:	2017-02AB

Figure 61.
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.

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

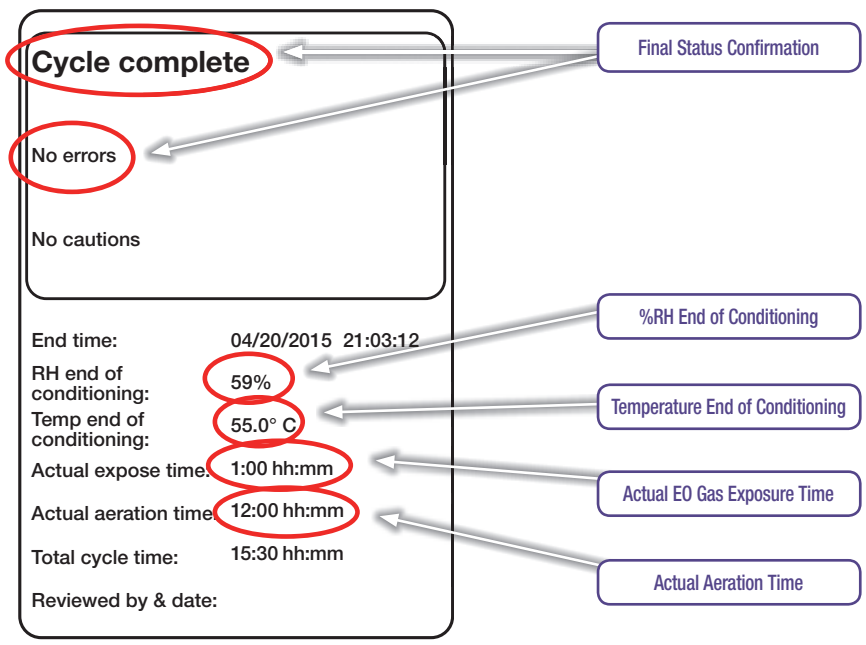


Figure 62.
Verifying Cycle Report -
Footer Information

13.2. 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).

BIs are intended to demonstrate whether conditions in the sterilizer chamber were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that all items were all exposed to adequate sterilization conditions. All BIs should be used in accordance with the biological indicator manufacturer's instructions.

For routine monitoring of the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series EO sterilization process, use biological indicators such as the 3M™ Attest™ Biological Indicators for EO.

3M™ Attest™ Biological indicators for EO:

- comply with applicable clauses of ANSI/AAMI/ISO 11138-1:2006 and ANSI/AAMI/ISO 11138-2:2006
- contain spores of *Bacillus atrophaeus*
- should be placed within an appropriate process challenge device (PCD)

A process challenge device (PCD) (also known as a Test Pack) is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item or set routinely processed.

A **routine** BI PCD (or Test Pack) per ANSI/AAMI ST41, or an equivalent commercially available BI PCD such as the 3M™ Attest™ Biological Indicator Test Pack for EO or 3M™ Attest™ Rapid Readout Biological Indicator Test Pack for EO, is used for routine biological monitoring of ethylene oxide (EO) sterilization cycles. A **routine** BI PCD is also used in sterilizer testing after process failures, malfunction, or major repair.

A **routine** BI PCD should be used in every load. The **routine** BI PCD should be placed in the center of the load.

Each load containing implantable devices should be monitored and quarantined until the results of the BI testing are available.

The BI **challenge** test pack per ANSI/AAMI ST41 should be used for sterilizer qualification testing after sterilizer installation, relocation, or major redesign.

BIs should also be used for periodic product quality assurance testing of representative samples of actual products being sterilized.

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.

13.3. Chemical Indicators

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 Operator's Manual. Always use chemical indicators and biological indicators per the device manufacturer's instructions for use (IFU).

13.3.1. External Chemical Indicator

The purpose of an external chemical indicator (CI), such as 3M™ Comply™ EO Indicator Tape, is to differentiate between processed and unprocessed items, not to establish whether the parameters for adequate sterilization were met.

Distinguish between processed and unprocessed items by affixing a process indicator, in the form of sterilizer indicator tape, an indicating label, or an indicating printed legend to each assembled package or rigid sterilization container system intended for sterilization.

An external indicator, such as 3M™ Comply™ EO Indicator Tape, should be used on all packages except for packages that allow visual inspection of an internal indicator, such as those with paper-plastic packaging. The external CI should visually denote that the package has been exposed to physical conditions present in the EO sterilizer. The indicator should be examined after aeration and also before use of the item to verify that the item has been exposed to a sterilization process.


13.3.2. Internal Chemical Indicators

An internal chemical indicator (CI), such as 3M™ Comply™ EO Chemical Indicator Strips, should be used within each package, tray, or containment device (rigid sterilization container system, instrument case, cassette, or organizing tray) to be sterilized. This internal CI may be a multivariable indicator or an integrating indicator.


The CI, such as the 3M™ Comply™ EO Chemical Indicator Strips, should be placed in that area of the package, tray, or containment device (rigid sterilization container system, instrument case, cassette, or organizing tray) considered least accessible to EO penetration; for a containment device, consult the manufacturer's instructions for placement of the CI. This location may or may not be the center of the package, tray, or containment device.

The CI is retrieved at the time of use and is interpreted by the user. The user should be trained and knowledgeable about the performance characteristics of the monitoring system and should be able to demonstrate competence.

14. 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 GS 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 GS 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.

14.1. Daily Cleaning

Using a soft cloth dampened with mild detergent and warm water, clean the following parts of the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 GS 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.

14.2. 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.

14.3. Preventive Maintenance



Performing preventive maintenance, at scheduled intervals, is a critical part of ensuring the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 63). There are no user-serviceable parts; use only 3M Health Care service personnel or authorized 3M service personnel for maintenance.

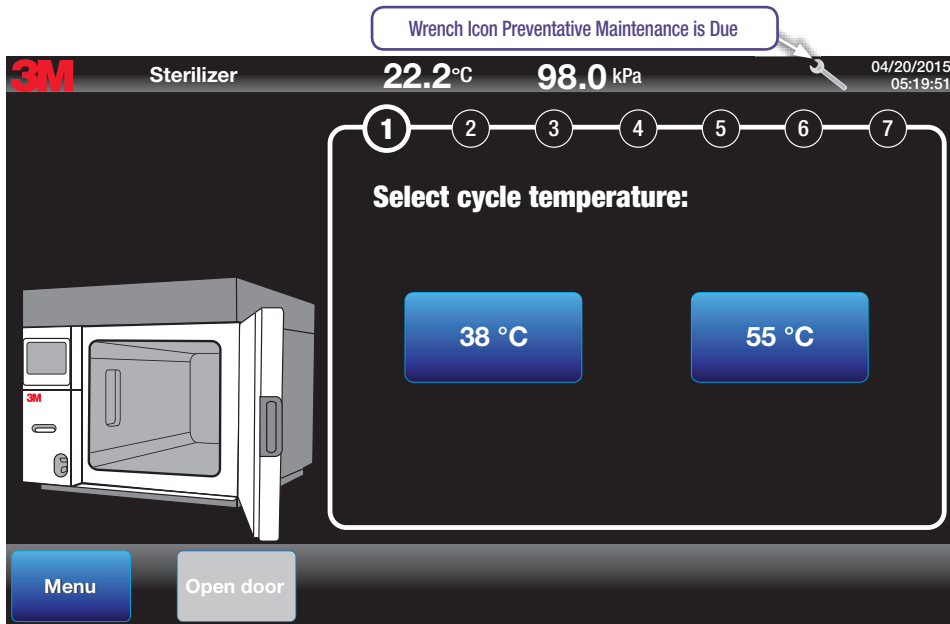


Figure 63.
Wrench Icon - Preventative
Maintenance is Due

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.

15. 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 GS Series is designed with embedded software that automatically controls, monitors and regulates the mechanical functions of the GS Series sterilizer and the sterilization process.

15.1. Caution Messages

If the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 64).

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

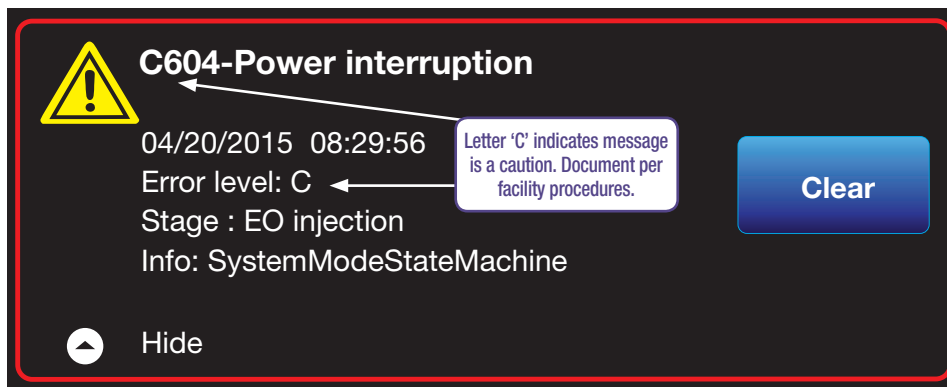


Figure 64.
Example of a Caution Message

15.2. Error Messages

If the 3M™ Steri-Vac™ Sterilizer/Aerator GS 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 GS 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 7. Some errors must be cleared by your 3M Health Care service personnel or authorized 3M service personnel with a Service PIN.

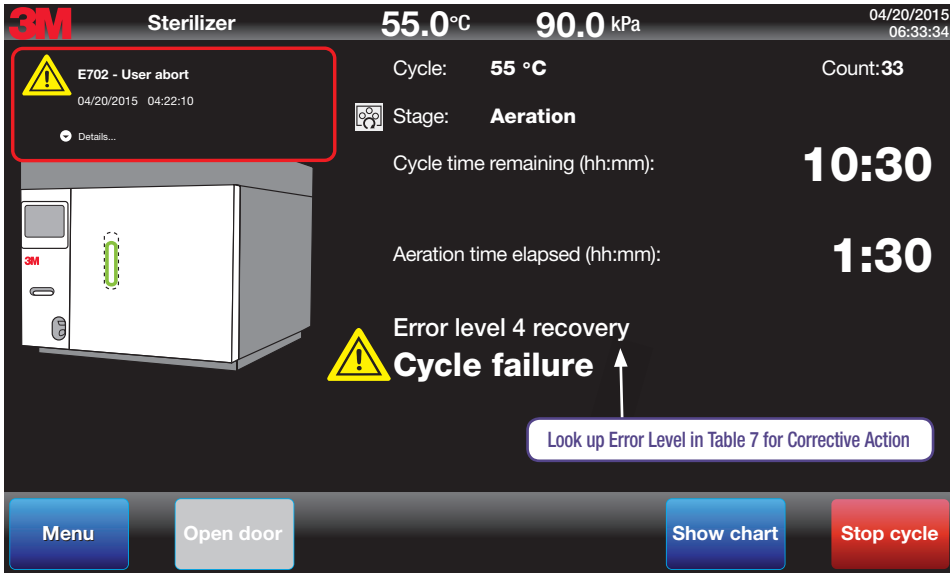


Figure 65.
Example of a Level 4 Error Message

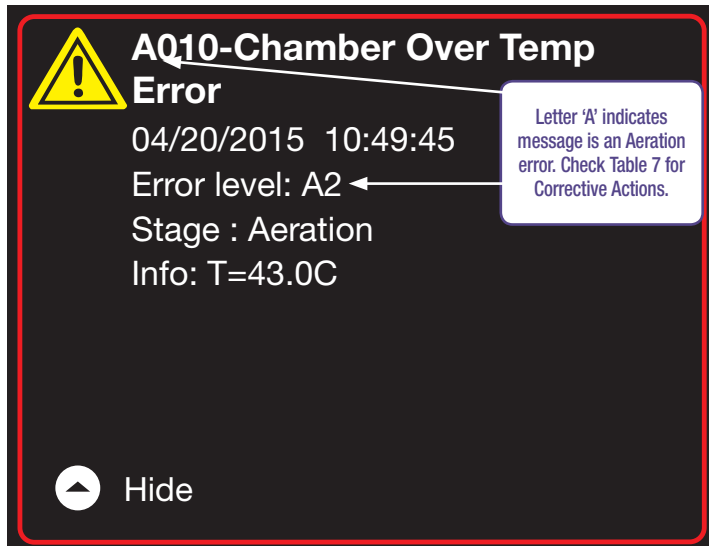


Figure 66.
Example of an Aeration Error Message

15.3. Error Levels and Corrective Actions

Look up error level in Table 7 for appropriate corrective actions.

Error Code 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.	<ul style="list-style-type: none"> – Chamber too hot to start a new cycle – Timeout attempting to reach target % RH set-point 	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.	<ul style="list-style-type: none"> – 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.	<ul style="list-style-type: none"> – 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.	<ul style="list-style-type: none"> – 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.	<ul style="list-style-type: none"> – 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.	<ul style="list-style-type: none"> – 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.	<ul style="list-style-type: none"> – Failure in controller pressure sensor after EO Injection – Exhaust line blockage detected 	Call Service. Service must access load and 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.	<ul style="list-style-type: none"> – 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.	<ul style="list-style-type: none"> – 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 7. 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 67 and 68.

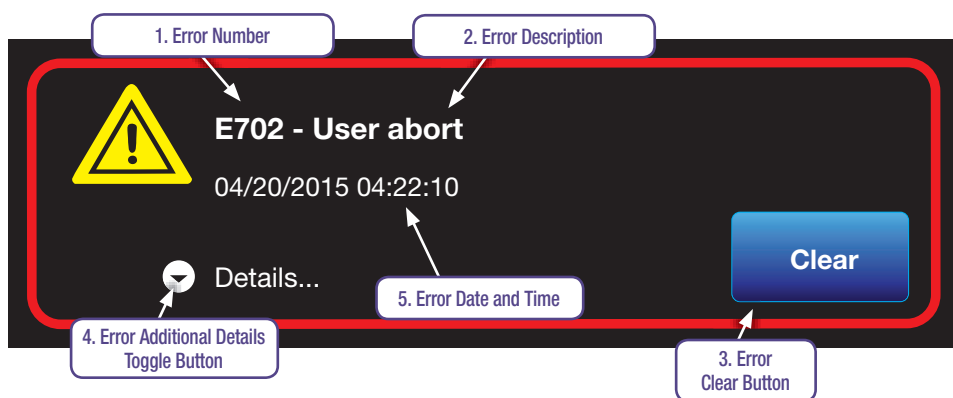


Figure 67.
Error Message –Details Hidden

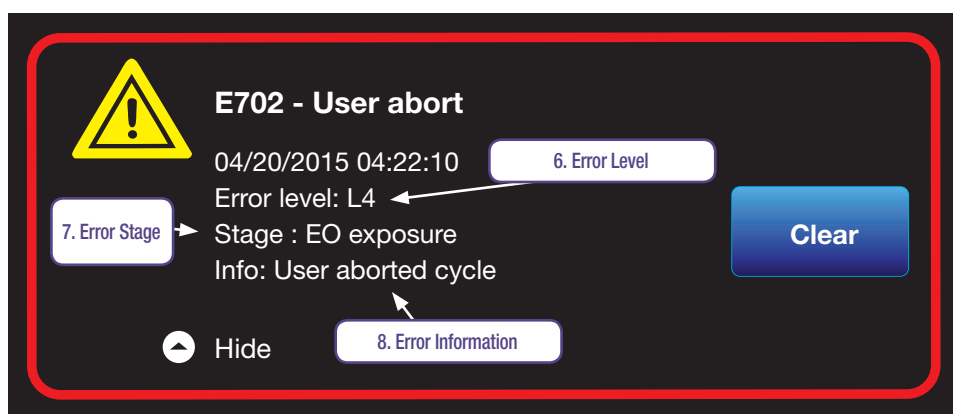


Figure 68.
Error Message – Details Revealed

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 7 – 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 7 - 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 8. Explanation of Error Messages

16. 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 trained 3M Health Care service personnel or 3M authorized service personnel.

Service Contact:

17. Preventive Maintenance

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

18. Ordering Accessories and Supplies

One set of upper and lower loading baskets are provided with each new 3M™ Steri-Vac™ Sterilizer/Aerator GS Series. Additional baskets are available for purchase. Table 9 provides order information for products used with the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series.

Accessories		
Name	Catalog Number	Packaging
Stainless Steel Stackable Basket for use in Model GS8 – 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 GS8 – 47 x 47 x 20cm (18.5 x 18.5 x 8 in.)	78-8078-5399-5	1 Basket
Stainless Steel Basket Cover GS8	78-8078-6251-7	1 Cover
Stainless Steel Lower Basket for use in Model GS5 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 GS5 Sterilizer – 39 x 80 x 18cm (15.5 x 31.5 x 7 in.)	78-8055-6039-4	1 Basket
Supplies		
Name	Catalog Number	Packaging
3M™ Steri-Gas™ 100% EO Gas Cartridges	4-100 EO net wt. 100 g. (3.52 oz.)	12 units/box
3M™ Steri-Gas™ 100% 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	50 units/box, 4 boxes/case
3M™ Attest™ Rapid Readout Biological Indicator for Ethylene Oxide	1294	50 units/box, 4 boxes/case
3M™ Attest™ Biological Indicator for EO Test Pack	1278 (25 control BIs)	25 units/box, 2 boxes/case
	1278F (5 control BIs)	
3M™ Attest™ Rapid Readout Biological Indicator for EO Test Pack	1298 (25 control BIs)	25 units/box, 2 boxes/case
	1298F (5 control BIs)	
3M™ Comply™ Chemical Indicator Strips	1251	500 units/box, 2 boxes/case
3M™ Comply™ Ethylene Oxide (EO) Indicator Tape 1224	1224-0 1.25 cm x 55 m (1/2 in. x 60 yd)	36 rolls/case
	1224-1 2.5 cm x 55 m (1 in. x 60 yds)	18 rolls/case
	1224-6 1.9 cm x 55 m (3/4 in. x 60 yds)	24 rolls/case
3M™ Breathable Peel Open Pouch for Ethylene Oxide	8502	250 each/box, 4 boxes/case
3M™ Breathable Peel Open Pouch for Ethylene Oxide	8504	250 each/box, 4 boxes/case
3M™ Breathable Peel Open Pouch for Ethylene Oxide	8505	250 each/box, 2 boxes/case
3M™ Breathable Peel Open Pouch for Ethylene Oxide	8506	250 each/box, 2 boxes/case
3M™ Breathable Peel Open Pouch for Ethylene Oxide	8507	250 each/box, 2 boxes/case
3M™ Breathable Peel Open Pouch for Ethylene Oxide	8508	250 each/box, 4 boxes/case

Table 9. Accessories and Supplies

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
3M.com/Medical



Made in the U.S.A. for
 **3M Health Care**
2510 Conway Ave
St. Paul, MN 55144



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Carl-Schurz-Str. 1
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Germany

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