



# Autoclave Impact Evaluation

Produced By My Green Lab With Funding Support From:





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## **My Green Lab**

### **Authors:**

Rachael Relph  
James Connelly  
Ryan Arnold  
Scott Grant

## **Industry Peer**

### **Reviewers:**

Scott Mechler  
Phil Pipitone  
Barbra Wells  
Allison Hunter  
Nick Ciancio



## Grant Description and Goals

Steam sterilizers, also known as Autoclaves, are a common type of equipment found in research laboratories, medical facilities, production facilities, and more. They use high temperatures and pressures in the presence of steam to sterilize their contents, and as a result, are intensive in their use of both water and energy.

Attempts to quantify the water and power that is used by these devices have been sporadic and not entirely successful; additionally, there does not currently exist a set standard for describing or categorizing the functions and designs of these machines. In partnership with the National Renewable Energy Labs (NREL), My Green Lab (MGL) is developing a standard testing method for steam sterilizers/autoclaves to enable the comparison of energy and water consumption across different manufacturers. The testing method will be used to engage manufacturers in ACT-labeling autoclaves. In recent years, MGL paved the way for testing and validation of the sustainability factors involved in producing and using equipment, consumables, chemicals, and more, through the ACT Label program. NREL and MGL see this project as an opportunity to drive efficiency from manufacturers and incentivize rebates from utilities for more energy and water-efficient autoclaves.



# General Function and Use

In addition to their use in medical and laboratory settings, autoclaves can be used in other industries as well to cure materials or as part of a manufacturing process.

In medical, dental, and other procedures involving human contact (i.e., tattoo parlors), autoclaves are used to sterilize the instruments used in these applications. Hazardous and biomedical waste is often autoclaved before final disposal, to ensure no pathogens are present in the waste; this can be done on the desktop, a centralized autoclave, or offsite using larger equipment such as a rotoclave that would not be seen in a laboratory or medical setting.

Regardless of the application, steam sterilizers/autoclaves are all designed to use pressurized steam to sterilize materials and operate with the same basic phases:

## 01

### Air Removal / Purge Phase

During this initial phase, steam is introduced into the sterilization vessel to completely replace the air inside. The steam can be produced in the vessel, wherein water in the bottom of the chamber heats, becomes steam, and displaces the air through a steam trap. This can be accomplished by using a connected steam generator, or by using an in-house steam line. Any of these three methods may be aided by vacuum pumps, which eliminate air from the vessel and replaces it with steam. This is especially effective with vessel media such as fabrics that may contain air pockets.

Cycle	Temperature	Sterilizing Time (Minutes)
Media	250°F (121°C)	15
Dry Goods /Glassware	273°F (134°C)	3.5
GM Soil Waste	258°F (126°C)	20
Bio-Hazard Waste	250°F (121°C)	15
CL3 Waste	273°F (134°C)	10

Figure 1. Sterilization cycle settings, per Consolidated

## 02

### Sterilization Phase

The objects to be sterilized are subjected to a program of varying temperature, pressure, and time. Sterilization cycles vary depending on the application, the composition of the items in the vessel, the level of sterility desired, and the time required to finish the cycle. Sterility is assumed using the Sterility Assurance Level (SAL), which is a confidence factor relating to the chances of viable microorganisms surviving the cycle. Recommendations of varying sterilization cycles by SAF<sup>1</sup> based on different objects to be sterilized can be seen to the right.

Temperature Setting	Liquid Quantity (ml)	Sterilizing Time (Minutes)
250°F (121°C)	75	25
250°F (121°C)	250	30
250°F (121°C)	500	40
250°F (121°C)	1000	45
250°F (121°C)	1500	50
250°F (121°C)	2000	55

Figure 2. SAF Recommended Sterilizing Times



# 03

## Exhaust Phase

Pressure and steam are released from the sterilization chamber, and the load is dried and cooled to a manageable temperature before the contents can be extracted. Steam is expelled from the chamber and/or jacket, with or without the aid of a vacuum pump/venturi valve. Additional cooling water is usually needed for the wastewater to temper to <140°F (melting point of PVC pipe) before entering the building's main wastewater lines.

The type of cycle that will be run on the autoclave is dependent on the items to be sterilized. For example, when sterilizing porous materials such as garments, users will often choose cycles that use a pulsing vacuum and pressure to fill the chamber with steam, rather than cycles that utilize gravity. Examples of factors considered in sterilization cycles for liquids are to the right (from Consolidated).<sup>2</sup> These settings can impact energy and water consumption and will be an important factor in developing a standard testing method.



# Categories of Autoclaves

The features and options available on autoclaves result in a wide range of autoclave types that make them best suited for specific applications.

There is variability in the size and shape of the sterilization vessel, the door configuration, the method of steam generation, the jacket coverage and more. Many of the features and design variations to be considered are addressed in Section IV, and each of these “impact areas” can impact energy and water consumption. Despite these variations, autoclaves can be grouped into the following four main categories, based on size and function.



Evaporation Expert, [CC BY-SA 4.0](https://commons.wikimedia.org/wiki/File:Evaporation_Expert_Tuttnauer.jpg), via Wikimedia Commons

## Benchtop Autoclaves

Benchtop autoclaves are small autoclave units that can comfortably fit onto a laboratory bench or other surface. Benchtop models are efficient in resource usage yet are often more time consuming due to the methods used to create and move steam.

<b>Typical volume:</b>	<b>15-50 L</b>
Used for:	Low-volume research use, medical/dental clinics. Not usually intended for sterilization of liquids.
Common manufacturers:	Ritter, Tuttnauer, Priorclave
	Often use simple water reservoirs, but can be designed with integrated steam generators or to utilize house DI water lines
Water requirements:	Typical manual fill and generate their own steam in the chamber using submerged heating elements but can be plumbed for autofill. Usually use softened tap water or distilled water but can be configured to use DI or RO water. Typical are not plumbed for wastewater.
Power requirements:	Smaller sizes use standard voltage/amperage connections.



Systec Autoclaves, [CC BY-SA 4.0](https://commons.wikimedia.org/wiki/File:Systec_Autoclaves), via Wikimedia Commons

## Top-Loading, Vertical Autoclaves

Top-Loading or Vertical Autoclaves are typically larger in size than the benchtop models yet are compact enough to fit under a bench. Loading of the chamber is done through a door on top of the unit, using a basket that holds the contents and can be removed after the cycle is complete and the load is cooled.

<b>Typical volume:</b>	<b>50-200 L</b>
Used for:	Research/laboratory facilities. Can be used for sterilizing liquids, media, glassware, fermenters, waste, and other items used in research and development labs.
Common manufacturers:	Amerex, Tuttnauer, Steris, Consolidated, Priorclave
Water requirements:	Typically generate their own steam in the chamber using submerged heating elements but can be plumbed for autofill. Usually use softened tap water or distilled water but can be configured to use DI or RO water. Typically, are not plumbed for wastewater.
Power requirements:	Smaller sizes use standard voltage/amperage connections.



Fernando A. Rivetti Suelotto, Public domain, via Wikimedia Commons

## Front-Loading, Steam-Jacketed Autoclaves

Front-loading, steam-jacketed autoclaves utilize a pressure vessel (also known as the chamber) which are surrounded by a secondary area referred to as a 'jacket'. The pressure vessel is typically reinforced with additional steel to maintain a rectangular shape suited to certain types of loads, such as trays of flat instruments. Steam is produced outside of the chamber and then piped into the jacket of the main vessel, to reduce the time to heat/pressurize the chamber and minimize condensation.

Jackets are often found on larger, high throughput autoclaves, and in highly populated medical or lab scenarios. They are also critical for terminal sterilization applications including pharmaceutical production.

<b>Typical volume:</b>	<b>80-500L +</b>
Used for:	High throughput, large volumes of wrapped instruments, laboratory and medical equipment, media, gowning, pharmaceutical production, GMP manufacturing, and biohazardous waste
Common manufacturers:	Amerex, Tuttnauer, Steris, Consolidated
Water requirements:	Most often must be plumbed into the building's source water and wastewater lines, due to the high volumes of water needed to fill the chamber/jacket with steam and to cool them properly when finished. RO water is commonly required. Depending on the country and market, the jacket and chamber can both be required to have steam running through them constantly.
Power requirements:	Often hardwired into the building; may use standard voltage/amperage or may require higher voltage, amperage or three-phase connection.



Foto Studio Wiegand, [CC BY-SA 4.0](https://commons.wikimedia.org/wiki/File:Autoclave.jpg), via Wikimedia Commons

## Front-Loading, Non-Steam Jacketed Autoclaves

In this design, the pressure vessel of an autoclave is not surrounded by a secondary 'jacket'. Chambers are typically round, minimizing design complexity and eliminating cold pockets that can occur in the corners of rectangular chambers. These are similar in size and function to jacketed models but use considerably less water and energy. They can be used for laboratory sterilization, product testing, and quality control but are not suitable for terminal sterilization, pharmaceutical production, or certain GMP applications.

<b>Typical volume:</b>	<b>80-500L +</b>
Used for:	Medium throughput, large volumes of media, liquids, biomedical waste, laboratory and industrial equipment, medical devices, soil, and sealed containers in research or quality assurance applications.
Common manufacturers:	Priorclave, Astell, Systec
Water requirements:	Often plumbed into the building's source water and wastewater lines but can be manually filled and drained to a container. Softened tap water is most often required.
Power requirements:	Often hardwired into the building; may use standard voltage/amperage or may require higher voltage, amperage or three-phase connection.



# Known Considerations and Data on Energy/Water Consumption

Due to the variation in design, function, and use of autoclaves, it has been historically difficult for manufacturers or users to obtain useful data comparing the energy and water use of one model to another.

When considering the energy and water that is used by a specific machine as compared to another, one must consider a variety of factors as outlined in the table below.

Impact Area	Impact Consideration
Water Purification	Many units require filtered, softened, or purified water to be used in steam generation to prevent equipment degradation. The amount of energy and water needed to create that water may depend on the building water quality.
Steam Generation	Steam may be generated by heating water inside the chamber, in a boiler attached to the unit, or the unit may use a house steam source. Energy and water consumption varies with each of these methods.
Jacketing	Steam is either initiated for sterilization based on use or constantly pumped through a jacket around the sterilization chamber to maintain a constant baseline temperature in the chamber to keep it ready for use. Both the extent of the jacket (full, partial or none), as well as the amount of time the jacket is kept at temperature will impact energy and water usage.
Effluent Management	In older, higher capacity autoclaves, the steam discharge that ejects into a building drain is often tempered by running a constant stream of cold water down the drain in order to prevent damage to PVC pipes that can melt at temperatures >140°F. Newer autoclaves may come with an effluent management device to eliminate the need for a constant flow of cold water and older models can be retrofitted with such devices. In some cases, the reject water from the water purification step can be used to quench the hot effluent as well.
Vessel Configuration	The shape of the sterilization chamber can impact energy and water use, with round chambers often requiring less energy and water, as they do not require jackets and can create steam “on-demand” directly in the chamber.
Vacuum Use	Gravity displacement during the purge cycle does not require the use of vacuum pumps and consumes no additional energy or water. Ring pumps and venturi valves both consume water to operate, and the amount of water used will depend on the sterilization cycle.
Cycle	The temperature, pressure and duration of a cycle, as well as the use of vacuums in the purge and exhaust cycles will impact energy and water use.
Idle or Standby Modes	Steam-jacketed autoclaves consume energy and water when in use during a cycle but also when not in use. The presence of energy saving idle modes or off cycles will impact daily energy and water consumption. Non-jacketed autoclaves consume energy and water only when in use.

The following section contains data and findings from existing studies and reports which attempt to quantify the resources of autoclaves. Due to the prevalence of steam-jacketed autoclaves in research labs and their high consumption of resources, all reports utilized in this section focus on the use of steam-jacketed autoclaves. Unfortunately, benchtop, top-loading, and non-jacketed models were not studied in any of the reports collected, highlighting some of the current gaps in knowledge regarding autoclaves and their impact across different model types.

Additionally, while these case studies give a glimpse into steam-jacketed autoclaves and their impacts, none of the studies below look at all the areas above to quantify energy and



water use for a standard set of conditions. In many cases, the case studies look at energy and water consumption related to only one or two of the impact areas listed above without indicating any variability between the other impact factors. It is therefore difficult to say whether all energy and water measurements are directly related to the impact area being examined or if they are cumulative from several different impact areas.

## Water Consumption

Cited below are studies quantifying the use of water in steam-jacketed autoclaves. It is important to understand that autoclaves use water 1) in the production of steam for the vessel and surrounding jacket, 2) in the cooling of effluent steam/condensate after sterilization is finished, and 3) in the process of vacuum creation if a venturi valve or ring pump are utilized.

### Impact Area: Effluent Management

#### Water Consumption Reduction Case Study — TDK Consulting<sup>3</sup>

In 2005, TDK consulting prepared a case study to evaluate the reduction in water use through the installation of a proprietary device, the Water Mizer, which monitors the effluent temperature and controls the addition of tempering water used to cool waste streams. If the wastewater line for the exiting steam is plumbed into the building's standard waste lines, a stream of 'tempering' water must often be introduced to the flow in order to ensure that the stream does not exceed 140F. When not addressed by included or 3rd party devices, the tempering water flows constantly into the waste lines, regardless if the unit is discharging hot water or if it is simply in standby mode. The study was performed on three jacketed AMSCO (Steris) autoclaves.

Summation of relevant findings:

<b>Average Cycles/day</b>	7.8
<b>Average gal/Sterilization Cycle</b>	244 gallons
<b>Average gal/year/unit, for Sterilization Cycles</b>	900,463 gallons
<b>Average gal/year/unit, for Standby Mode</b>	1,240,884 gallons
<b>Savings gal/year with Water Mizer</b>	992,707 (80% reduction in water use during standby)

The use of a water-saving device at the outlet can prevent hundreds of thousands of gallons of water per year from being needlessly wasted. These devices represent one of the simplest and most cost-effective methods to reduce water usage – however, notably, they are not dependent on the model or type of autoclave from which the waste steam is being produced. Therefore, while the data of this report does support the usage of Water Mizer style devices, it does not help determine which autoclaves are the most water-efficient.

### Impact Area: Jacketing

#### The University of California, Riverside Autoclave Study<sup>4</sup>

UCR assessed energy and water use for two models of Steris steam-jacketed autoclaves in 2016, while comparing it to the manufacture specifications of a Priorclave manufactured model designed without the use of a steam jacket.

Summation of relevant findings:

	<b>Steris Model 1*</b>	<b>Steris Model 2*</b>	<b>Priorclave**</b>
<b>Volume</b>	510 L	540 L	500 L
<b>Vessel Configuration</b>	Rectangle	Round	Round
<b>Steam Source</b>	Stand alone	Internal Generator	Internal Generator
<b>Average Cycles/day</b>	0.46	0.56	1
<b>Average Water Use (gal/day)</b>	648	654	43.8
<b>Range Water Use while Idle (gal/day)</b>	40 – 3,583	0 – 3,362	N/A

\* Report does not specify if Water Mizer was utilized in study.

\*\*Priorclave data taken from manufacturer specifications, not measured by UCR

While the water savings of a Priorclave model as compared to the two Steris models may seem straightforward, one must consider that the variables in this comparison are by no means standardized – variations exist in vessel shape, vessel size, steam source, and presence of/type of a vacuum.



## Energy Consumption

While water consumption is typically the greater cause for concern with autoclaves, it is important to quantify and compare the usage of energy as well.

### Impact Area: Vessel Configuration

#### Systec “Autoclaves Gone Green” article<sup>5</sup>

For two autoclaves with similar characteristics and design features, Systec measured the produced the following data with Microbiology International:<sup>5</sup>

	Systec HX430	Comparison Model
Volume	430 L	250 L
Vessel Configuration	Round	Rectangle
Steam Source	Steam Generator	Steam Generator
Run Hours/day	4	4
Average Energy (kWh/day)	72	260

Systec is attempting to highlight the energy savings in their model as compared to a competitor. However, their conclusion is that the round vessel shape of the Systec autoclave contributes to higher energy efficiency but there are too many varying parameters (vessel size, vessel configuration, and other unknowns) to fully make that conclusion.

## In Summary

Attempts to quantify the resource used by autoclaves is still too incomplete for purchasers, organizations, scientists, and engineers to truly understand the water and energy costs that will be associated with certain models or designs. Case studies, such as those above, are often well-intentioned but are unable to provide the necessary consistency required for comparative conclusions. For example, the number of hours an autoclave is run does not correlate to the number of cycles, making it challenging to consistently compare reports and their outcomes. To ultimately drive change in the autoclave market, there is a need for a standardized system of resource quantification to assist buyers in purchasing the most resource-efficient model that fits their specific needs.



# Known Autoclave Market Summary Data

While a comprehensive study of autoclaves in the field has not yet been conducted, estimations can be made based on available information on the overall autoclave market and its potential impact.

The following reports give insight into the overall size of the autoclave market, and its potential environmental impact.

## Center for Energy Efficient Laboratories (CEEL) 2015 Market Analysis<sup>6</sup>

In this report, various categories of common laboratory equipment are surveyed, and energy consumption is quantified. The study includes information on many types of equipment, both large and small, and unfortunately does not delineate between size, volume, manufacturer, or design of the autoclave. Based on the information collected (via voluntary survey participation, in California labs) the following conclusions are made in the 2015 report:

Density	Occurrence	Use
Avg 0.8 autoclaves/lab	54% of labs contain zero autoclaves 31% of labs contain 1 autoclave 15% of labs contain 2-9 autoclaves	80% of labs use the autoclave between 1-7 hours/day 50% of labs use the autoclave between 1-3 hours/day

A comparison of four markets in the United States (Hospitals, Life Science Research Facilities, Hospitals, and "Other") found a fairly even dispersion, of approximately 1 autoclave per defined laboratory space. Using the density information above, the CEEL report extrapolates to assume an estimated 16,000 autoclaves in use in California laboratories alone, and 160,000-320,000 in laboratories across the United States (see Fig 3 below).

Equipment	Average Number Per Lab Reported in CA	Estimated Total Number in CA	Equipment	Average Number Per Lab Reported in CA	Estimated Total Number in CA
-80° Freezer	2.9	58,000	PCR Machine	2.2	44,000
-20° Freezer	3.7	74,000	Magnetic Stirrer	3.0	60,000
Refrigerator	4.7	95,000	Vacuum Pump	2.1	42,000
Fume Hood	3.0	60,000	Shaker Table	1.2	24,000
Fluorescence Microscope	1.7	34,000	Autoclave	0.8	16,000
Heating Block	3.0	60,000	Incubator	3.0	60,000
Water Bath	2.6	52,000	Tissue Culture Hood	1.7	34,000
Centrifuge	3.8	76,000			

Figure 3.



The report mentions an anonymized university in California which had performed a large equipment inventory and reported having 167 autoclaves. The sizes, types, and capacities of the autoclaves were not mentioned, nor was the size or population of the university in question.

## Global Market Insights Article — Steam Autoclaves

According to this report,<sup>7</sup> the steam autoclaves market exceeded USD \$2.2 billion in 2020 and is expected to grow more than 9.7% between 2021 and 2027. Using an average price per autoclave of \$18,000 (source: Gambica Survey 2020), this would indicate that the global market is around 120,000 new autoclaves each year.

Extrapolating from the graphs in this article, where the US appears to have about 1/3 of the market, that would mean approximately 40,000 autoclaves are sold in the US each year. Taken together with the CEEL estimations it can be estimated that within the US there are between 160,000 and 320,000 autoclaves in use today with around 40,000 entering the market each year (some as replacements for existing units).

Regarding the size of autoclaves, data from Gambica estimates that autoclaves over 300L make up about 28% of the number of units sold, autoclaves between 60-300L make up about 31% of the units sold, while smaller autoclaves make up about 41% of units sold. Given that the larger front-loading autoclaves have a volume of 80-500L, this could mean that 59% of the autoclaves in the field are of this type. With this data, MGL concludes that between 94,000 and 188,000 front-loading autoclaves are currently in the field, with 23,600 entering the market each year (59% of the 40,000 sold).

Both the Global Market Insights Article and the CEEL Report estimates the density of autoclaves across the US, but with slightly different findings. The CEEL report found that autoclaves exist in the same density across academic, life science research, hospital, and other laboratories.

Meanwhile the Global Market Insight article concluded a higher number of autoclaves in hospitals and 'healthcare companies', but these may be in use outside of a laboratory setting. Overall, the real density of autoclaves across the market seems to remain unsettled.

Finally, several national lab sites were asked for data regarding autoclaves on their campuses. Only two were able to supply any information and in both cases, neither could say how many of their inventory were the larger, front-loading autoclaves.

### Known inventories for Federal Laboratory spaces:

Site	Number of Reported Autoclaves	Number of Assumed Front-Loading Autoclaves (59% of Total)
Sandia National Laboratories	8	5
Los Alamos National Laboratory	33	19
Average	20	12

If the same assumption is made that 59% of the autoclaves in the field at National labs are the front-loading varieties with an average of 20 autoclaves/facility, it can be extrapolated that there are a total of **340 autoclaves** housed in the 17 National Research Laboratories, with an estimated 204 being the front-loading type.

Overall, the Global Markets Insight Article helps paint a picture of the autoclave market, but its also worth noting the limits to the data. For example, large equipment such as front loading, plumbed autoclaves may present a challenge when recording the number or frequency of purchases, as they are often installed as part of a new build, a remodel, or large project. Therefore, autoclave purchases may not be easily tracked through the procurement process as smaller, more inherently mobile pieces of equipment.



# Impact Estimation

Overall, while it's obvious that a clear way to compare energy and water consumptions across autoclaves within a specific category is needed, some trends do emerge in the data that provide insight into the impact of autoclaves.

The limited data seems to support that front-loading, steam-jacketed autoclaves appear to consume the most energy and water, followed by the front-loading, non-steam-jacketed autoclaves.

If creating a common testing methodology to measure energy and water consumption is prioritized, the current resource intensity can not only be better understood, but also drive the market towards more efficient autoclaves. Using data taken from the University of California Riverside (UCR) and Center for Energy Efficiency Laboratories (CEEL) studies cited in this report, MGL can estimate an annualized energy and water consumption shown in the table below:

	Estimated Energy Consumption (kWh/day per unit)*	Estimated Water Consumption (gal/day per unit)*	Annualized Energy Consumption in the US (GWh)	Annualized Water Consumption in the US (billions of gallons)
<b>Front-Loading, Steam-jacketed</b>	84	650	2894-5788	22.4-44.8
<b>Front-Loading, Non-Steam-jacketed</b>	16	44	551-1102	1.5-3.0

\*Data taken/extrapolated from UCR case study results

Reductions in resource use by 5% could be attained through fairly simple upgrades or methodologies, such as powering down/idling the unit when not in use or discontinuing vacuum pump cycles when unnecessary. Other improvements, including the installation of a water conservation kit or replacing a steam-jacketed model with a non-steam jacketed model can result in savings of up to 90% compared to baseline measurements.<sup>8</sup>

	Energy Savings (GWh/year)	Water Savings (billions of gallons)	Energy Savings (GWh/year)	Water Savings (billions of gallons)	Energy Savings (GWh/year)	Water Savings (billions of gallons)
	With <b>5%</b> reduction		With <b>10%</b> reduction		With <b>15%</b> reduction	
<b>Front-Loading, Steam-jacketed</b>	162.4	1.3	324.8	2.5	487.1	2.5
<b>Front-Loading, Non-Steam-jacketed</b>	10.3	0.0	20.6	0.1	30.9	0.1
<b>Total</b>	172.7	1.3	345.4	2.6	518.0	2.6



If manufacturers and end-users can drive efficiencies in energy and water consumption in both front-loading unit types, it's clear there can be substantial positive impact on energy and water consumption in the US. These reductions in resource use could stem from any number of the previously addressed variables or design features. It is important that the scientists and

the organizational planners (facilities, EHS, architects) are aware of these factors when considering autoclave units, as their knowledge and input are key to realizing savings. The purpose of this National Renewable Energy Lab and My Green Lab grant aims to make this information clear, shared, and convenient as a step towards this awareness.



## Next Steps

**In the next phase of the grant partnership with NREL, MGL will work with manufacturers of the front-loading autoclaves to align on a common set of conditions to test autoclaves and evaluate energy and water consumption.**

These conditions will look to establish a common usage case where each autoclave is run for the same duration, temperature, and pressure settings, and for the same number of cycles per day. As there are many design factors that significantly impact energy and water usage, NREL and MGL will also clearly define and disclose the presence of each design feature that is deemed significant. Alignment on the testing parameters will be achieved during future workshops hosted by My Green Lab with key industry stakeholders.



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## Appendix:

# Energy and Water Consumption Testing Standard for Autoclaves

This document defines the inclusion criteria, testing protocols, and general expectations for measuring energy and water consumption of steam sterilizers/ autoclaves.

This process, completed with support from National Renewable Energy Laboratories (NREL), will result in a standard for quantifying resource use and other sustainability factors that are pertinent to the manufacture, use, and disposal of these units.

Produced By My Green Lab With  
Funding Support From:



### **My Green Lab Authors:**

Rachael Relph  
James Connelly  
Ryan Arnold  
Scott Grant

### **Industry Peer Reviewers:**

Scott Mechler  
Phil Pipitone  
Barbra Wells  
Allison Hunter  
Nick Ciancio



# Definitions

## Steam Sterilizer/Autoclave:

The two terms are used interchangeably, and these units will most often be referred to simply as 'autoclaves' in this document. The term "autoclave" refers to equipment that is designed to subject items in a sealed vessel to a set protocol to sterilize these contents by eliminating microbial contaminants. These units can range greatly in configuration, capacity, materials used, use cases, and more. Even so, there are 4 basic types:

- **Front Loading:** In this design, the door to access the sterilization chamber is hung vertically, and only one door or access point exists. The main inner vessel of an autoclave may be surrounded by a secondary area of steam referred to as a 'jacket' (see 1.2.3), but this is not required.
- **Benchtop:** Benchtop autoclaves are typically less than 100L in volume, do not utilize either a steam generator or house steam, and do not have the ability to vacuum the sterilization vessel.
- **Top Loading:** Top loading autoclaves may be similar in size and function to Front loading, however the door to access the chamber is located on the top of the unit. Items to be sterilized are loaded into the vessel (typically cylindrical) with a stainless-steel basket.
- **Walk-through/Pass-through:** Often seen in hospital settings or clean rooms, these autoclaves have access points on opposite sides of the unit to allow for high throughput use and efficient loading/unloading. Larger walk-through models may be the size of an entire room and require much more robust water and electric systems.

## Sterilization Chamber:

Containment area of the autoclave which holds the items to be sterilized. Also known as the pressure vessel and subject to the regulations specified in the ASME BPV Code, Section VIII Division 1. Typically constructed of stainless steel, they can also be constructed of other metals or with coatings. Typical shapes for front-loading autoclaves are round/cylindrical or square/rectangular. The vessel interior may be designed for one or multiple racks to hold contents for sterilization.

## Thermostatic Trap:

All autoclaves feature a thermostatic trap or steam valve, which is a device designed to allow air and water to escape from the chamber. Many varieties of traps exist, but they all perform the same basic function of removing condensate while preventing the escape of dry steam from the chamber.

## Steam Jacket:

A steam jacket refers to a secondary chamber that envelops the main sterilization chamber and is filled with steam during the cycles to ensure uniform heat distribution.

## Vacuum Pump:

Device is used to create a vacuum environment inside the sterilization chamber. The most common vacuum types found in autoclaves are liquid ring and venturi. The vacuum may be used at two points in the autoclave cycle:

- **Pre-Cycle:** Vacuum pump evacuates the sterilization chamber prior to filling the chamber with steam to minimize air pockets and condensation.
- **Post-Cycle:** Vacuum pump evacuates the steam from the sterilization chamber to decrease drying time for contents for waste and dry good cycles.

## Drain Tempering Valve Device:

Used in applications where a high-temperature discharge flow to a drain or sewer must be tempered with cold water. Many designs exist, but generally, a thermostatic valve automatically opens as hot wastewater is discharged to keep drain water within appropriate plumbing code temperature limits and to prevent damage to PVC pipes.

## Compressed Air:

Required to operate solenoid valves and to operate the chamber door seal (and/or steam-operated door seal). Media cycles need ballast cooling by the input of compressed air to prevent media from boiling off when water cooling in the jacket rapidly condenses the steam in the chamber.



# Scope

## Included Equipment/Models of Autoclave

- For specific criteria regarding the configuration and specifications of the units, see page 21 (Criteria).
- Autoclaves that are labeled as “research grade” (i.e., non-steam jacketed) or “medical grade” (i.e., steam jacketed) are both included in this evaluation, provided that they meet all other inclusion criteria.
- Autoclave models to be evaluated must be available for sale in North America, UK, and/or the EU.

## Measuring Resource Use

### Water

The protocol is designed to ensure that the following sources of water for the autoclave unit are measured and recorded in the analysis:

- Water type: a type of water required by autoclave manufacturers (RO, DI, Distilled, Softened) to measure the amount of water. required to purify water for steam generation, where applicable.
- Steam generation: water lines that enter the unit’s steam generator, or which feed into the vessel to produce steam directly.
- Cooling: water lines that are used to cool the chamber post-sterilization.
- Vacuum: water lines that feed into an either liquid ring or venturi-style vacuums.
- Tempering: water that is used to lower the temperature of effluent/wastewater.

### Energy

- Main circuits: power which is used to run the computer, screens, heating elements, general machinery.
- Accessories: any power used to operate accessory items such as steam generator, vacuum, air compressor, processed chilled water, etc. which are not powered by the main circuits.



# Criteria

## Required Variables for Inclusion

The following configurations and design features must be met or present for the model to qualify for testing. Some features may not be considered the 'standard' configuration for that model (e.g., steam source, voltage level), yet must be present and configured in this manner for testing to be standardized across all units and manufacturers.

**Table 1**

<b>Variable, Option or Design Feature</b>	<b>Acceptable Ranges, Types or Designs</b>
<b>Door Configuration</b>	Front loading only (Top loading and benchtop are not included)
<b>Vessel size</b>	200-1000L capacity (Total volume, per vessel dimensions)
<b>Voltage configuration</b>	As the voltage and amperage are often specified by the client, we will allow for any configuration which supports the accessories which are to be included by each manufacturer.
<b>Vacuum pump</b>	Options: liquid ring or venturi valve. Must be configured for post-cycle drying.
<b>Water Type</b>	RO, DI, distilled, and softened tap water configurations are permitted.
<b>Steam Source</b>	Steam can be produced inside the chamber or in a dedicated steam generator provided by the manufacturer. No house/ remote steam lines.
<b>Tempering Water</b>	All units to be tested must be outfitted with a water line indicated for cooling of the effluent water. The flow rate of the drain tempering water, when flowing, will not have minimum or maximum requirements, but it should cool the effective temperature of the effluent steam/water stream to 140°F (60°C) or lower. Manufacturers/testing personnel are at liberty to reuse, recycle, or otherwise capture the drain tempering water used while testing the unit. No requirements are set for purity/composition of this tempering water.
<b>Cooling</b>	Configured to use water or air for cooling post-sterilization (fan, jacket, coil, spray, or cyclone method).



## Optional Variables

The following configurations and design features may be present in the models to be tested **if the variable is considered 'standard' to the unit or model**. If the manufacturer reserves these options as purchasable features, they are not to be included in our baseline calculations. These options may affect the energy and water readings collected:

- "Smart" Drain-Tempering Valve device/Cooling Reservoir system.
- Steam Jacket (full or partial) for sterilization vessel.
- Automatic hibernation/off option.
- Vacuum pump or Venturi configured for pre-cycle air removal.
- Recirculation/heat exchange of venturi wastewater.
- Air compressor/ballast (for door and/or pneumatic valves).

Some resource conservation tools that manufacturers have developed or offer will not be able to be captured in this study and are currently not listed as optional to configure, including:

- » Use of Reverse Osmosis (RO) wastewater for cooling water (we cannot configure test units to use filtered water for testing purposes).
- » Use of house steam.



# Test Conditions

## Pre-testing Quality Control

All units to be tested under the following protocol should have passed the manufacturer's standard quality control specifications.

## Configuration

- The autoclaves to be tested will be configured and assembled in accordance with any specifications outlined in the existing manufacturer's guidelines. Any required features in Table 1 on page 21 should be present and assembled to the manufacturer's specifications.
- Accessories or options listed in Table 1 may be present at the time of testing. If the option, design, or feature causes the autoclave unit to require additional power or water input, refer to Data Collection and Validation on page 27 for instructions to ensure that the resource use is properly captured.

## Ambient Temperature/Surroundings

The testing protocol shall be run in an indoor space meeting the following conditions:

- Air temperature: 20-30°C.



# Data Collection Methodology

## Monitoring System and Equipment

Each Autoclave submitted for testing and validation will be equipped with a monitoring device, either the 'Green Apple' produced by Jellybean Monitoring (details here), or an equivalent system that has capabilities for monitoring the following variables in increments of 30 seconds or less. If the standard internal software and hardware of the autoclave can collect the following variables, this may be used to capture and log data, provided the calibration is current:

- Power (kW)
- Water (gallons or liters)
- Cycle count (each)

Optional logging variables include:

- Temperature of vessel (°C)
- Pressure of vessel (kPa)

## Specific Monitoring Requirements

### Power

Power must be measured for all features listed below. These may be connected on a single circuit, or individually powered by separate lines:

- Main computer board/screen
- Steam generator power supply
- Internal heating elements
- Vacuum pump power supply
- Air Compressor power supply (if applicable)

### Water

Water must be measured for all features listed below. These may be fed through a common source or through individual lines:

- Inlet line of steam generator or chamber reservoir (non-jacketed)
- Inlet to vacuum process water
- Inlet to cooling water (if applicable)
- Drain tempering water line (if applicable)



# Validation Protocol (Use Cases)

Once the autoclave unit(s) to be tested have been configured and set up to the specifications in the above sections, and monitoring devices have been installed and verified according to Data Collection Methodology on page 24, 'use case' scenarios will be run on the machine to quantify water and energy use. The goal is to run programs, cycles, and load types that can be standardized for all makes/models in the study, which capture standard resource-saving features or designs, and which accurately represent a typical level of use for the average consumer.

## Use Case Testing Requirements:

- Monitoring and logging of energy and water must begin a minimum of 5 minutes before the start of each program (starting via the main controller screen of the autoclave), and for 5 minutes after the end of the program.
- Cycles will be started when the machine is in idle mode. For these use case scenarios, the idle mode will be defined by the individual manufacturers; however, this must be a temperature/pressure setting that would allow for safe entry into the vessel:
  - » Temperature not to exceed 140°F (60°C), and
  - » No pressure detected in the chamber
- After the requisite sterilization, drying, or cooling time for each Use Case cycle (as defined in Use Cases on page 26) is completed, the sterilization vessel must spend time in 'standby' in order to mimic the time needed to unload and reload the chamber under normal use. The vessel must **reach a temperature of 140°F (60°C)** (or below) and **remain at this temperature for 15 minutes** before the next cycle is to be initiated.
- If the three cycles, with requisite standby time after each, are completed within the time frame of 24 hours, **the machine is allowed to enter hibernation or "off" state IF the manufacturer offers the feature as standard to customers purchasing the unit** (see OPTIONAL Variables on page 22).
  - » The unit must be programmed to enter a resource-savings mode based on pre-programmed factors such as time idle, time at a certain standby temperature, or time with no detected user interference.
  - » The unit may not be programmed to shut down at a certain set time point in the data collection cycle, e.g. shutting down at 4 pm or 12 hours into the testing cycle.
- The two different cycle types will be run 3 times total, each within a period of 24 total hours, for a total of 48 hours of collected data.
  - » Time and resources that the machine spends in standby, warm-up, and cooldown are all to be included in data collection.
  - » The data for the second 24-hour program must be collected separately.



- » The two 24-hour testing periods may be conducted back-to-back or with a period of time between them.
- There are no requirements for automated versus manual initiations of the use cases, provided that the requirements and protocols herein are adhered to.

## Use Cases

### Use Case 1: Vacuum + Cooling Cycle

This use case will be run 3 times during a 24-hour program.

- **Time in idle (low temperature/no pressure) state between the three cycles must be a minimum of 15 minutes. All three cycles must be completed within 24 hours.**

Load (Vessel Contents)	Sterilize Time (121°C)	Dry Time (Vacuum)	Idle Time (Loading Simulation)
EMPTY	20 minutes (not including time to reach sterilization temp)	10 minutes	15 minutes minimum

### Use Case 2: Gravity + Cooling Cycle

This use case will be run 3 times during the course of a 24-hour program.

- **Time in idle (low temperature/no pressure) state between the three cycles must be a minimum of 15 minutes. All three cycles must be completed within 24 hours.**

Load (Vessel Contents)	Sterilize Time (121°C)	Cooling Time**	Dry Time, min (No Vacuum)	Idle Time (Loading Simulation)
10X 1L flasks, filled to 1L with water	20 minutes (not including time to reach sterilization temp)	10 minutes	30 minutes	15 minutes

\*As the method used to cool the chamber is not standardized, there will be no expectation of final temperature after using the manufacturer's preferred method for the specified time.



# Data Collection and Validation

## Collection of Resource Use Data

Data can be collected and sent to MGL in the following ways:

- If the monitoring equipment is configured for internet connection (via ethernet), the data will automatically upload to a cloud server.
- If no internet connection is established, the manufacturer will be responsible for extracting the data files from the monitoring system and sending the files to MGL for analysis.

## Requirements for Data Submission

- Units are to be reported per the guidelines on page 24 under Monitoring System and Equipment.
- Data is to be reported in a file of type .csv, .xls(x), or .txt if necessary.
- Accompanying Documents:
  - » Photographs of the unit as configured for testing, meters and attachment points of external monitoring equipment are required. Other photographs may be submitted as desired.

## Data Reporting to ACT. Label

The data collected from the use cases and testing timeframes will be averaged to provide one metric for measured kWh/day and gal/day for power and water use.