Impact of the Drying Stage on Steam Sterilization Processes

Alien Arias Barreto, PhD
Head of Product Service, Terragene

Understanding the role of each phase in a steam sterilization process

Steam sterilization is a multi-stage process, where each phase contributes in a specific and non-interchangeable way to the overall effectiveness and reproducibility of sterilization. International standards such as ISO 17665 and EN 285 define steam sterilization as a validated sequence of conditioning, exposure, and post-treatment steps, rather than a single lethal event. Proper understanding of the function of each stage is essential to avoid compensating deficiencies in one phase by over-adjusting another, which can compromise load integrity and monitoring reliability.

Figure 1 shows a graphical example in which the effect of the main stages of the steam sterilization process on the pressure evolution over time at a point inside the chamber can be identified.

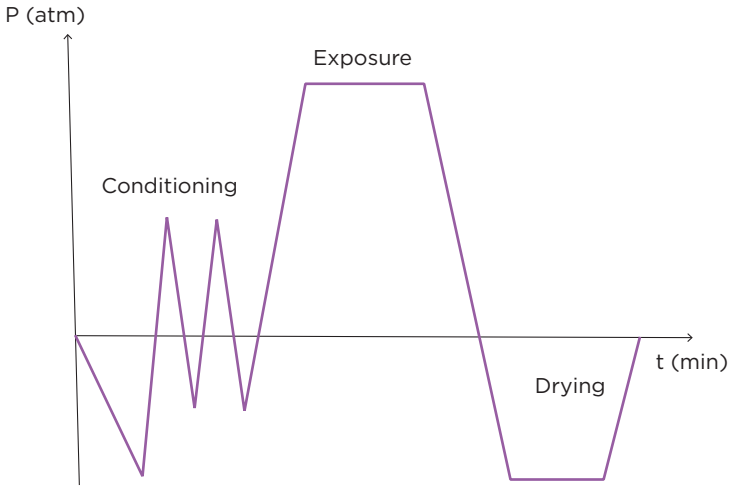

Figure 1. Schematic pressure curve in steam sterilization chamber

The conditioning (air removal) phase is critical for ensuring effective steam penetration, regardless of the air-removal mechanism employed. According to

AAMI ST79, residual air acts as an insulating barrier that prevents saturated steam from uniformly contacting all load surfaces. Air removal may be achieved through dynamic vacuum-assisted systems (prevacuum sterilizers), gravity displacement, or steam flush pressure pulse (SFPP) cycles, each relying on different physical principles to displace air from the chamber and the load. Regardless of the method, the objective is to establish homogeneous temperature and moisture conditions that allow efficient heat transfer. Inadequate conditioning (whether due to insufficient vacuum depth, ineffective steam flushing, or improper load configuration) cannot be compensated by extending the exposure phase, as entrapped air fundamentally alters heat transfer and compromises process efficacy.

The exposure (sterilization) phase is the main stage responsible for achieving microbial inactivation. During this phase, saturated steam transfers latent heat to the load, enabling protein denaturation and cell death. ISO 17665 clearly separates lethality assurance from drying performance, emphasizing that sterility is achieved during exposure under validated time–temperature conditions. Extending exposure parameters beyond validated limits does not improve sterility assurance and may increase condensate formation, negatively impacting subsequent stages.

The drying phase serves a functional purpose: removal of residual moisture to ensure package integrity and maintenance of the sterile barrier. Standards such as AAMI ST79 and EN 285 require the load to be dry at the end of the cycle but do not prescribe fixed drying times, instead mandating validation based on load type and packaging system. Excessive or prolonged vacuum drying does not enhance sterility and may induce adverse effects such as material stress, ink transfer in chemical indicators, or damage to packaging systems. Therefore, drying must be optimized as the minimum effective condition, completing the process without compromising the results achieved in earlier stages.

Comparative analysis of drying mechanisms in steam sterilization

Several drying mechanisms are used in steam sterilization, depending on sterilizer design and load characteristics. The most widely applied method is vacuum drying, where chamber pressure is reduced to lower the boiling point of water and promote evaporation of condensate. Vacuum drying is particularly effective for wrapped loads, rigid containers, and complex instrument sets, provided that vacuum depth and duration are appropriately controlled and validated.

Vacuum drying may be implemented as a sustained vacuum or as pulsed vacuum drying, in which vacuum is applied intermittently. Pulsed vacuum drying allows moisture to migrate progressively from within the load and packaging materials while reducing continuous mechanical stress. This approach is especially beneficial for dense or multilayer packaging systems, as it minimizes the risk of material deformation, moisture redistribution, or excessive stress on indicators and packaging components.

In contrast, gravity displacement sterilizers rely primarily on thermal convection and residual heat for drying, sometimes combined with limited air exchange. Because no deep vacuum is applied, this drying mechanism is inherently less efficient and generally suitable only for simple, lightly wrapped loads. Gravity-based drying is more sensitive to load configuration and environmental conditions, and it has a higher inherent risk of residual moisture when applied to complex or high-mass loads.

Many modern steam sterilizers also incorporate filtered air admission, typically through HEPA filtration, during the final stages of drying. The controlled admission

of sterile air serves to equalize chamber pressure, stabilize packaging materials, and support final moisture removal. This step plays an important role in preventing package collapse and maintaining the physical integrity of wraps, pouches, and container filters at the end of the cycle.

Guidance documents such as AAMI ST79 emphasize that drying parameters must be load-specific, validated, and optimized, rather than extended indiscriminately. Excessive or prolonged drying (particularly under sustained or deep vacuum) does not improve drying performance and may lead to adverse effects such as packaging damage, material fatigue, ink migration in chemical indicators, or anomalous behavior of biological indicators. Best practice therefore dictates applying the minimum effective drying conditions necessary to achieve a dry, intact load at cycle completion, ensuring process reliability without compromising materials or monitoring systems.

Table 1 summarizes the main drying systems implemented in current steam sterilization processes, along with their key advantages, limitations, and typical applications.

Table 1. Steam Sterilization Drying Mechanisms

Drying process	Operating principle	Typical application	Key advantages	Limitations / risks
Vacuum drying (sustained vacuum)	Chamber pressure is reduced to lower the boiling point of water, promoting evaporation of residual condensate	Prevacuum sterilizers; wrapped and complex loads	High drying efficiency; effective for dense instrument sets	Risk of flash boiling, packaging stress, ink migration, and indicator anomalies if vacuum is deep or prolonged
Pulsed vacuum drying	Alternating vacuum and pressure equalization to allow gradual moisture migration	Complex loads, rigid containers, multilayer wraps	Reduced mechanical stress; improved moisture release control	Longer cycle complexity; requires proper validation
Gravity / thermal convection drying	Evaporation driven by residual heat and natural air/steam circulation	Gravity displacement sterilizers; simple loads	Simple design; no vacuum system required	Limited efficiency; higher risk of wet packs with complex loads
Vacuum drying with filtered air admission	Vacuum drying followed by sterile (HEPA-filtered) air admission to stabilize the load	Modern prevacuum sterilizers; wrapped loads	Improves package integrity; reduces collapse and stress	Ineffective if preceding vacuum phase is improperly configured
Extended drying	Increased drying time beyond standard cycle parameters	Heavy loads; rigid containers; long lumens	Can address residual moisture in validated cases	Should not be used to compensate for poor conditioning or loading practices

Recommended Drying Parameters in Steam Sterilization Processes

From the regulatory point of view, U.S. CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities (2008) lists recommended drying times for gravity displacement and prevacuum steam sterilizers (Table 2). Standards such as AAMI ST79 and ISO 17665 do not list explicit vacuum pressure values as fixed requirements. Rather, they emphasize that drying parameters (vacuum, time) must be validated for specific loads and equipment as part of the sterilization process control.

Table 2. Sterilizer type, example item, and exposure time according to the Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

Type of Sterilizer	Item	Exposure time at 250°F (121°C)	Exposure time at 270°F (132°C)	Drying time
Gravity displacement	Wrapped instruments	30 min	15 min	15-30 min
Gravity displacement	Textile packs	30 min	25 min	15 min
Gravity displacement	Wrapped utensils	30 min	15 min	15-30 min
Dynamic-air-removal (e.g., prevacuum)	Wrapped instruments	Not Applicable	4 min	20-30 min
Dynamic-air -removal (e.g., prevacuum)	Textile packs	Not Applicable	4 min	5-20 min
Dynamic-air -removal (e.g., prevacuum)	Wrapped utensils	Not Applicable	4 min	20 min

From a parametric perspective, moderate vacuum levels are generally sufficient. For example, a typical hospital prevacuum cycle may apply a drying vacuum of 50 mbar absolute (≈ 0.05 bar abs) for 20 minutes. At this pressure, the boiling point of water is approximately 33 °C, which allows residual condensate on instruments and packaging materials to evaporate using the stored thermal energy of the load (often still above 80–90 °C at the start of drying). Under these conditions, most wrapped

instrument sets exit the cycle dry and intact.

For heavier or more complex loads, such as rigid containers or large instrument trays, drying time may be extended to 25 minutes while maintaining a similar vacuum level (e.g., 40–60 mbar abs). This extension allows additional time for moisture migration from internal surfaces and porous materials without increasing mechanical stress. Importantly, the vacuum depth is not significantly increased; the adjustment is primarily temporal and must be validated for that specific load.

Problems arise when drying is performed using sustained and prolonged deep vacuum. Under these conditions, any residual moisture can undergo intermittent flash boiling, producing localized vapor expansion. Instead of improving dryness, this can cause moisture redistribution within packaging materials, stress on wraps and pouches, and instability of chemical indicator inks. From a numerical standpoint, once the residual water mass has been reduced below a critical threshold (often within the first 10–20 minutes), additional vacuum time does not further reduce moisture content.

Risks Associated with Sustained Vacuum Drying in Steam Sterilization

Avoiding sustained vacuum drying in steam sterilization longer than 30–35 minutes is considered good engineering and process practice because, beyond this threshold, the process enters a zone of diminishing returns. Prolonged vacuum exposure does not produce additional meaningful drying, but instead increases the likelihood of adverse effects on the load, packaging systems, process monitoring devices, and the sterilizer itself.

Condensate thermodynamics and flash boiling play a central role. Under sustained moderate to deep vacuum conditions (approximately 30–50 mbar absolute), the boiling point of water drops below 30–35 °C. Residual condensate remaining within the load may therefore undergo intermittent flash boiling, generating micro-aerosols rather than being steadily removed. This phenomenon promotes internal moisture redistribution within the packaging system, resulting in apparent dryness on external surfaces without true moisture removal from internal layers.

A second critical factor is progressive mechanical fatigue of packaging materials. Maintaining a continuous pressure differential for extended periods weakens cellulosic fibers in sterilization wraps, promotes pouch collapse, and accelerates fatigue of filters and valves in rigid container systems. Even when the load appears dry at the end of the cycle, these mechanical stresses can compromise sterile barrier integrity, increasing the risk of post-sterilization contamination during handling and storage.

Prolonged sustained vacuum is also associated with anomalous responses of chemical and biological indicators. Chemical indicators may exhibit ink migration, non-homogeneous color development, or false results due to repeated phase changes and mechanical stress. Biological indicators may be affected through ampoule breakage or microleaks. Importantly, these effects are time-dependent, with probability increasing as vacuum duration extends beyond validated limits.

Finally, from an equipment and process efficiency perspective, extended sustained vacuum imposes unnecessary stress on the sterilizer without improving process outcomes. Vacuum pumps, valves, and seals experience increased operating time and thermal cycling, leading to accelerated wear and higher energy consumption.

At the same time, neither microbial lethality nor drying stability is improved once the effective drying threshold has been reached.

Final considerations

Steam sterilization must be understood and managed as an integrated, multi-phase process in which each stage (conditioning, exposure, and drying) fulfills a distinct and non-substitutable function. Effective sterilization cannot be achieved by compensating deficiencies in one phase through excessive adjustment of another, particularly during the drying stage. Proper air removal ensures uniform steam penetration, validated exposure parameters provide microbial lethality, and optimized drying conditions preserve package integrity and sterile barrier performance. The analysis of drying mechanisms and parameters demonstrates that moderate, load-specific, and validated drying conditions are sufficient to achieve reliable outcomes, while sustained or prolonged vacuum drying offers no additional benefit and introduces avoidable risks to packaging materials, indicators, and equipment. A balanced, evidence-based approach, aligned with international standards and focused on the minimum effective conditions, remains essential to ensure both process efficacy and long-term system reliability in steam sterilization practice.

Resources:

- ANSI/AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* 2017.
- ISO 17665 *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices.* 2024.
- EN 285:2015+A1:2021. *Sterilization — Steam sterilizers — Large sterilizers.* Brussels: European Committee for Standardization.
- CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities.* 2008