DISCOVERY OF *EXTRA PLATEAU PERIOD* IN HOSPITAL PRESSURE STEAM STERILIZATION AND ITS IMPACT ON STERILIZATION QUALITY

by

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This study identifies and investigates the extra plateau period (EPP), a previously unreported phenomenon in hospital pressure steam sterilization, where temperature and pressure stabilize at elevated levels before entering the sterilization stage. Utilizing digital temperature-pressure detectors and standard test packs, a comprehensive analysis of 58 sterilizers across 31 hospitals was conducted under small-load (Bowie-Dick test) and full-load (sterilization program) conditions, in accordance with the Chinese standard Technical Requirements for Large Steam Sterilizers (GB 8599) or the European standard Sterilization – Steam Sterilizers – Large Sterilizers (EN 285). The findings revealed that 39.66% of the sterilizers (23 out of 58), all of which were older cross-atmospheric pulsating models, exhibited EPP. The Bowie-Dick test program revealed that all affected sterilizers exhibited EPP, with plateau times averaging 462.5 seconds – a 118.88% increase over the established values. A similar trend was observed in 73.91% of sterilization programs, which exhibited EPP, resulting in a 39.91% increase in plateau times (749.9 seconds vs. 536 seconds). The consequences of EPP manifested in substantial delays in temperature penetration within test packs, leading to Bowie-Dick test false negatives and rendering physical monitoring ineffective despite apparent compliance with traditional quality checks. These findings underscore critical risks to sterilization quality, including undetected equipment malfunctions and compromised infection control. The study underscores the necessity for enhanced parameter monitoring in older sterilizers and advocates for precision quality control strategies to ensure patient safety.

Keywords: *pressure steam sterilization, extra plateau period, digital monitoring, sterilization quality control, hospital infection prevention, Bowie-Dick test failure*

Introduction

In the hospital Central Sterile Supply Department, pre-vacuum pressure steam sterilizers [1] play a pivotal role in ensuring the sterility of heat-resistant surgical instruments. These sterilizers are dependent on precise temperature, pressure, and duration parameters to

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achieve effective microbial inactivation. Prior to the commencement of daily operations, the Bowie-Dick (B-D) test is mandated to verify the air removal efficiency under no-load conditions, followed by sterilization cycles with loaded instruments. Conventional quality control methodologies encompass physical, chemical, and biological monitoring techniques, which are designed to ensure adherence to standards such as WS 310.3-2016 and EN 285. However, emerging challenges in sterilization monitoring, particularly with aging equipment, highlight gaps in detecting subtle operational anomalies [2, 3].

Recent advancements in digital monitoring have enabled detailed tracking of sterilization parameters. However, a curious phenomenon was observed during routine quality assessments of 58 sterilizers across 31 hospitals. Prior to the sterilization phase, certain sterilizers exhibited prolonged stabilization of temperature and pressure at elevated levels, termed the EPP. This phenomenon, which has not been previously documented in the extant literature, gives rise to critical inquiries. Of particular concern is the potential impact of EPP on sterilization efficacy. Furthermore, can traditional monitoring methods reliably detect it? Does it mask equipment malfunctions, leading to false assurances of sterility?

It is noteworthy that EPP occurred exclusively in older cross-atmospheric pulsating sterilizers (Group A), which are characterized by intermittent vacuum pulses using ambient air. This is in contrast to newer positive-negative pressure pulsating models (Group B), which utilize controlled vacuum cycles. The prolonged plateau times associated with EPP – exceeding set values by up to 118.88% in B-D tests – suggest potential risks, including delayed steam penetration and false negative results in B-D tests. These risks compromise the quality of sterilization procedures and jeopardize patient safety.

The objective of this study is threefold: first, to quantify the incidence and characteristics of EPP. Second, to evaluate its impact on sterilization quality control methods; and third, to propose strategies to mitigate associated risks. By addressing this knowledge gap, we aim to enhance the precision of sterilization monitoring and inform equipment maintenance protocols for aging healthcare infrastructure.

Methods

A total of 31 hospitals and 58 large pressure steam sterilizers in ten regions of Zhengzhou City, Henan Province were selected for the study. The pressure steam sterilizers of different brands were divided into two groups, Group A and Group B, based on their vacuum pumping methods. Group A contains 35 pressure steam sterilizers, which are classified as cross-atmospheric pulsating vacuum sterilizers. These older models have a maximum service life of 12 years. Group B consists of 23 sterilizers that employ positive and negative pressure pulsating vacuum, and these models have a maximum service life of seven years.

According to the method for detecting sterilizer parameters stipulated in the Chinese national standard GB 8599, formulated with reference to the European standard EN285, a 7 kg standard test pack is to be combined with a temperature and pressure detector. In accordance with the standard requirements, the probe is placed in the test pack for distribution points. Subsequently, small-load tests are conducted on the B-D test program of all investigated sterilizers, and full-load tests are carried out by running the sterilization program. Concurrently, the results of daily B-D tests, physical monitoring, chemical monitoring, and biological monitoring of the sterilizer are observed, and the qualification status of key sterilization parameters is recorded.

The temperature and pressure detector, manufactured by BIG DIPPER, has undergone calibration procedures. The data analysis software is in accordance with the requirements of GB8599 for the physical parameter detection of pressure steam sterilizers.

The standard test pack for sterilization monitoring is fabricated in accordance with the established standard. The standard test pack, which has a length, width, and height of 220 mm × 300 mm × 250 mm, is folded after the textile sheet has been cleaned. The total weight of the test pack is recorded with an accuracy of ±0.14 kg, yielding a total weight of 7 kg.

The testers have undergone professional training and are required to place points on the test standard pack as stipulated by GB 8599. Subsequent to the execution of the test, the collected data is entered into a computer database. Thereafter, an analysis is conducted to assess the qualification status of critical parameters, including sterilization temperature, sterilization pressure, and sterilization time. The sterilization operation curve chart is observed, and analysis is conducted according to the data list results to comprehensively judge the sterilization performance of the pressure steam sterilizer.

Results

Discovery of the extra plateau period in the pressure steam sterilization program

A comparison of the normal pressure steam sterilization program, fig. 1, revealed that, under specific conditions, some sterilizers in Group A exhibited a deviation from the standard behavior. During the heating stage of the sterilization program, these sterilizers maintained a relatively high pressure and temperature for a duration that extended beyond the typical sterilization plateau period. This phenomenon, characterized by the presence of an additional plateau period, was observed to occur outside the conventional sterilization stage. This phenomenon, occurring outside the standard sterilization plateau period and persisting at elevated pressures and temperatures, is designated as the EPP, fig. 2. Subsequent findings

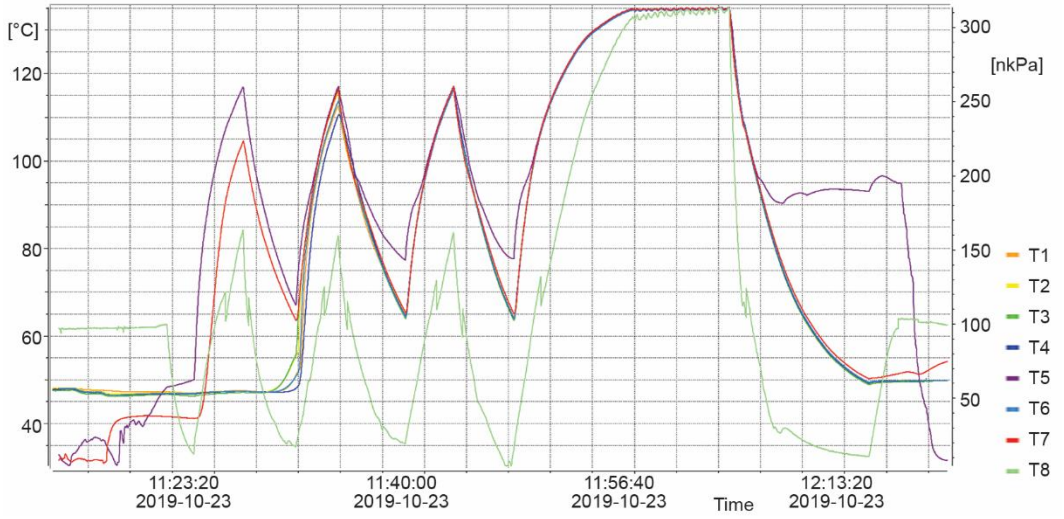

Figure 1. In a normal sterilization cycle, after the temperature and pressure rise and reach the set values, it enters the sterilization stage

from ongoing monitoring efforts. During the extra plateau period and sterilization stage, a significant delay in temperature rise is observed in the standard test pack, and the temperature rise does not reach the set sterilization temperature, fig. 3. Notwithstanding, under these circumstances, the results of daily B-D tests, physical monitoring, chemical monitoring, and biological monitoring of the pressure steam sterilizer are all satisfactory.

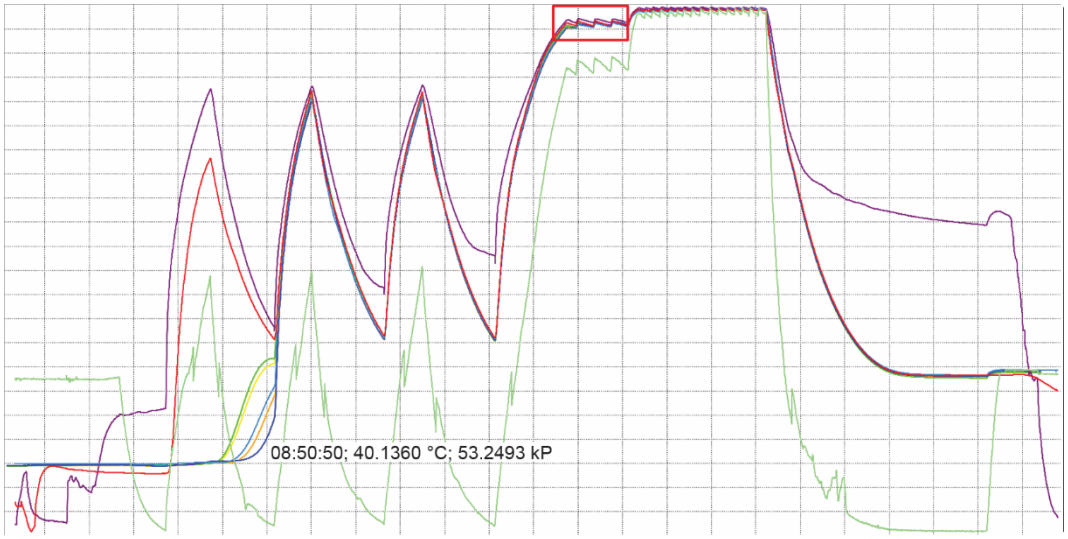

Figure 2. Before entering the sterilization stage, the temperature and pressure are stably maintained at a relatively high level, presenting an additional plateau period

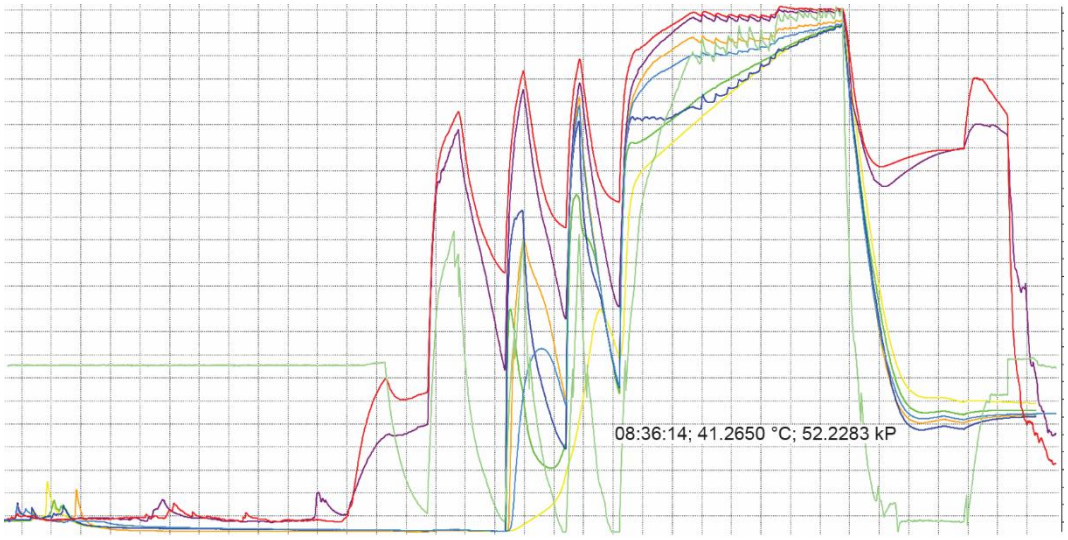

Figure 3. In the additional plateau period and sterilization stage, a delay in temperature rise occurs inside the standard test pack. Sterilization parameters

A meticulous selection process was implemented for the subjects involved in the investigation. Hospitals were selected from ten different regions in Zhengzhou City, Henan Province, to ensure a diverse representation. The pressure steam sterilizers, which play a pivotal role in hospital sterilization procedures, were meticulously categorized into two groups based on their vacuum pumping methodologies. Group A consists of 35 cross-atmospheric pulsating vacuum sterilizers with older models, indicating that they have been in service for a relatively long time. The maximum service life of these sterilizers, which is 12 years, suggests the potential for issues related to wear and tear and outdated technology. In contrast, Group B comprises 23 sterilizers that utilize positive and negative pressure pulsating vacuum and are of more recent models with a maximum service life of seven years, suggesting the incorporation of advanced technology and potentially superior performance.

The methods section places particular emphasis on strict adherence to national and international standards. The integration of the temperature and pressure detector with the 7 kg standard test pack constitutes a pivotal step in the precise measurement of sterilization parameters. The probe placement within the test pack, as delineated by the standard, is of paramount importance, ensuring the consistency and reliability of the results. Conducting small-load tests on the B-D test program and full-load tests on the sterilization program provides a comprehensive assessment of the sterilizer's performance under different conditions. The observation of daily B-D tests, physical monitoring, chemical monitoring, and biological monitoring results facilitates comprehension of the sterilizer's overall effectiveness. Furthermore, the calibration of the temperature and pressure detector by BIG DIPPER, in conjunction with the utilization of data analysis software that adheres to the GB8599 requirements, serves to augment the accuracy and reliability of the measurements. The production of the standard test pack in accordance with established protocols ensures the comparability and validity of test results. The professional training of testers and their adherence to GB 8599 for test pack placement points ensure that the testing process is carried out correctly. The subsequent analysis of key parameters, including sterilization temperature, pressure, and duration, in conjunction with the observation of the sterilization operation curve chart and the meticulous examination of the data list results, furnishes a comprehensive evaluation of the sterilizer performance.

The discovery of the EPP in the pressure steam sterilization program is a significant finding. A comparison with the standard sterilization program reveals the aberrant behavior of specific sterilizers in Group A. The designation of this phenomenon as the EPP stems from its occurrence beyond the conventional sterilization plateau period and the maintenance of elevated pressure and temperature. The observation of temperature rise delays and potential failure to reach the set sterilization temperature in the standard test pack during this period is concerning. However, the fact that the daily B-D tests, physical monitoring, chemical monitoring, and biological monitoring results are all qualified despite this abnormal phenomenon raises questions about the effectiveness of these monitoring methods and the potential risks to sterilization quality.

Occurrence frequency of extra plateau period

A total of 58 pressure steam sterilizers were monitored, of which 23 (39.66%) exhibited an additional plateau period during the temperature rise stage. It is noteworthy that all of these sterilizers are classified into Group A. In contrast, no such additional plateau period has been observed in the sterilizers of Group B. Furthermore, it has been observed that the pulsating vacuum method can influence the frequency of occurrence of the additional plateau period. Among the 23 sterilizers employing positive and negative pressure pulsating vacuum, no

additional plateau periods were observed. However, a notable occurrence was identified among the 35 sterilizers employing cross-atmospheric pulsating vacuum: 23 of these exhibited an additional plateau period during the sterilization cycle, exhibiting an incidence rate of 65.71%. Of the 23 sterilizers exhibiting this phenomenon, only three have been found to possess the capability to monitor sterilization parameters, yielding a pass rate of 13.04%.

Proportion of extra plateau period in Bowie-Dick test program and sterilization program

A total of 23 pressure steam sterilizers with an EPP were examined, and it was found that all sterilizers exhibited an EPP in the B-D test program. The frequency of the sterilization program that incorporates an additional plateau period is 17 times, while the proportion of the sterilization program that includes this feature is 73.91%.

Relationship between the incidence of extra plateau period and the set sterilization temperature

In the context of the sterilization program, the set sterilization temperature of 133.7 °C has been observed to result in the highest incidence rate of 100%, as illustrated in tab. 1.

Table 1. Relationship between the incidence of EPP in the sterilization program and the set sterilization temperature

Set sterilization temperature [°C]	Batches (times)	Batches with extra plateau (times)	Proportion [%]
134	33	8	24.24
134.2	3	0	0
133.7	2	2	100.00
132	20	7	35.00

Comparison of sterilization time with extra plateau period

In the context of the B-D test program, which incorporates an additional plateau period, the mean set sterilization duration is 211.3 seconds. The mean measured plateau time is 462.5 seconds, which exceeds the mean set time by 118.88%. The median value is 454 seconds, and the longest recorded plateau period is 1414 seconds, which exceeds the average set sterilization time. In the sterilization program with an additional plateau period, the average set sterilization time is 536 seconds, and the average measured plateau time is 749.9 seconds, which exceeds the average set time by 39.91%. The median plateau time for the B-D test program is 723 seconds, with a maximum plateau period of 1260 seconds. For the B-D test program and the sterilization program under normal sterilization operation, the average measured plateau time exceeds the average set time by 30.74% and 10.38%, respectively, tab. 2.

Daily monitoring status of sterilizers with extra plateau period

For sterilizers exhibiting an additional plateau period in the pressure steam sterilization cycle, the results of the daily B-D test, chemical monitoring, and biological monitoring are all satisfactory. However, physical monitoring has been found to be ineffective in detect-

ing the presence of an additional plateau period. The study revealed that among the 23 pressure steam sterilizers exhibiting an additional plateau period, only one sterilizer's physical monitoring recorded an exceptionally prolonged sterilization duration. However, no determination of an unqualified sterilization process was made.

Table 2. Comparison of plateau time of sterilization program with EPP and normal sterilization program

Sterilizer	Program	Average set sterilization time [seconds]	Average measured plateau time [seconds]	Variance	Median [seconds]	Maximum value [seconds]	Minimum value [seconds]	Range
With EPP	B-D test	211.3	462.5	51747	454	1414	239	1175
	Sterilization program	536.5	749.9	53795	723	1260	443	817
Under normal sterilization operation	B-D test	203.3	265.8	48867.7	256	475	91	384
	Sterilization program	447.8	494.3	47701.9	522	670	301	369

Note: For the program with an EPP, the plateau time is the sum of the EPP and the sterilization plateau period; for the normal program, it is the sterilization plateau period time.

Discussion

The discovery of the EPP in hospital pressure steam sterilization challenges conventional quality control paradigms and necessitates a global reevaluation of sterilization monitoring practices. While the present study focuses on sterilizers within China's healthcare system, the implications of EPP extend to international contexts, particularly in regions reliant on aging medical infrastructure or adhering to similar sterilization standards.

International standards and extra plateau period detection gaps

Current international standards for steam sterilization, such as EN 285 (Europe) and ANSI/AAMI ST8 (U.S.), emphasize compliance with temperature, pressure, and time parameters during the sterilization plateau period. However, these standards do not explicitly address the detection of pre-sterilization anomalies like EPP. Our findings reveal that EPP-induced delays in temperature penetration, fig. 3, may evade detection under existing protocols, even in systems compliant with GB 8599/EN 285. This finding underscores a universal limitation inherent in traditional monitoring methods, which prioritize endpoint validation over dynamic process analysis. For instance, the widely adopted B-D test, as outlined in both ISO 11140 and WS 310.3-2016 frameworks, relies on predetermined time thresholds (*e.g.*, 3.5-4 minutes) that do not consider prolonged stabilization phases. These limitations are especially pronounced in low-resource settings, where older sterilizers (analogous to Group A) remain prevalent.

Global disparities in sterilizer aging and technology adoption

The EPP predominantly affects aging cross-atmospheric sterilizers (Group A), which remain prevalent in developing nations due to limited budgets, whereas high-income countries increasingly adopt advanced models (Group B) free from EPP. Conversely, high-income countries are progressively adopting advanced positive-negative pressure pulsating models (Group B), which demonstrate an absence of EPP. For instance, a 2023 WHO report indicated that over 40% of sterilizers in Sub-Saharan Africa have been in service for more than 10 years, a condition analogous to that of Group A devices in the present study. This technological disparity amplifies infection risks in resource-limited regions, where delayed equipment upgrades and insufficient staff training compound the challenges posed by EPP.

Implications for global infection control

Hospital-acquired infections (HAI) persist as a global public health concern, with sterile processing failures accounting for 15%-25% of cases. The EPP introduces a latent risk by allowing incomplete microbial inactivation in seemingly compliant cycles due to delayed temperature penetration. This risk is further compounded in settings without digital monitoring tools. For instance, a 2022 multicenter study across Southeast Asia revealed that 32% of sterilizers exhibited unexplained sterilization failures, which may be linked to undetected EPP-like anomalies. These findings underscore the necessity for incorporating real-time digital monitoring mechanisms, such as temperature-pressure detectors, into global sterilization protocols, particularly in regions characterized by aged infrastructure.

Toward international collaboration and standard revisions

In order to address the risks associated with EPP, the global community is advised to implement three actionable steps. The first step is to revise existing standards. International bodies (*e.g.*, ISO, WHO) should mandate dynamic parameter tracking (*e.g.*, sub-minute data logging) in sterilization guidelines to detect EPP. The second step is the technology transfer. High-income nations and organizations could subsidize digital monitoring tools for low-resource settings, aligning with the WHO Medical Device Donation Guidelines. The third step is the cross-regional research. Multinational studies are needed to validate the prevalence and impacts of EPP across diverse sterilizer models and operational environments.

Limitations and future directions

Although this study provides novel insights into the EPP phenomenon, several limitations must be acknowledged. First, the data were collected exclusively from sterilizers in Zhengzhou, China, which may limit the generalizability of the findings to other regions with different sterilization practices or maintenance protocols. For example, European hospitals predominantly use pre-vacuum cycles, while Japan enforces stricter autoclave regulations – contexts in which EPP dynamics may be different. Second, the causes of EPP (*e.g.*, vacuum pump degradation, control system errors) remain speculative because the study focused on phenomenological observations rather than mechanistic analyses. Third, the sample size of Group B sterilizers (n = 23) was relatively small and may underrepresent the performance variability of newer models.

To address these gaps, we suggest the following priorities for future directions.

- Collaborative studies in diverse healthcare systems (*e.g.*, sub-Saharan Africa, Europe, Southeast Asia) are essential to assess EPP prevalence and operational impact in different infrastructural and regulatory environments.
- Rigorous engineering analyses should investigate the etiology of EPP, including vacuum system wear, steam quality variations, and control software limitations.
- Partnerships with biomedical engineers could advance innovations such as AI-driven predictive maintenance systems to prevent EPP in aging sterilizers, or embedded sensors for real-time parameter tracking.
- International bodies (*e.g.* WHO, ISO) should initiate working groups to revise sterilization standards to include EPP detection requirements and promote equitable access to digital monitoring tools.

These efforts will not only highlight the global relevance of EPP, but also bridge the gap between localized observations and universally applicable solutions.

Conclusions

The discovery of the EPP in hospital pressure steam sterilization exposes a critical but under-recognized vulnerability in global healthcare safety. This phenomenon, characterized by prolonged temperature and pressure stabilization prior to sterilization, results in delayed steam penetration in test packs, rendering traditional monitoring methods (*e.g.*, B-D testing, physical logs) ineffective. Crucially, EPP only affects aging cross-atmospheric pulsed sterilizers (Group A), which remain prevalent in resource-limited settings, while advanced positive-negative pressure models (Group B) show no such anomalies. These findings call into question the adequacy of current international standards (*e.g.*, EN 285, ANSI/AAMI ST8) that prioritize endpoint validation over dynamic process analysis, thereby masking equipment malfunction and increasing the risk of HAI.

The impact of EPP extends beyond regional borders. In low- and middle-income countries, where aging sterilizers dominate the healthcare infrastructure, undetected EPP threatens to exacerbate HAI due to incomplete microbial inactivation. Conversely, high-income countries that rely on advanced technologies may overlook global disparities in sterilization quality. Urgent action is needed to address these challenges: revising international standards to mandate real-time parameter tracking, prioritizing technology transfer to equip low-resource regions with digital monitoring tools, and launching multinational studies to validate the prevalence of EPP in different healthcare systems.

In the pursuit of enhanced efficiency and reliability within industrial processes, future endeavors must be unwaveringly concentrated on closing the persisting gaps between technology and knowledge. These gaps, which have long hindered seamless operations, are particularly evident in the domain of sterilization procedures. The EPP, or equipment performance problems, such as the often overlooked issue of vacuum system degradation, can significantly compromise the effectiveness of sterilization. Thus, in-depth mechanistic studies that meticulously delve into the fundamental causes of EPP are of utmost importance. By comprehensively understanding the root factors contributing to vacuum system degradation, such as component wear-and-tear over time, exposure to corrosive substances, or issues with the sealing mechanisms, targeted solutions can be developed.

Simultaneously, innovative initiatives like AI-powered predictive maintenance systems hold the key to a revolutionary transformation in the field of sterilization quality control. These advanced systems can continuously monitor the performance of sterilization equipment

through a network of sensors. Leveraging machine learning algorithms, they analyze vast amounts of real-time data, including temperature, pressure, and equipment vibration levels. By detecting even the slightest anomalies in the data patterns, these systems can accurately predict potential equipment failures or performance issues well in advance. This enables maintenance teams to schedule proactive maintenance, replacing parts before they fail and preventing costly downtime and sub-standard sterilization outcomes.

Future efforts must focus on bridging technology and knowledge gaps. Mechanistic investigations into the root causes of EPP (*e.g.*, vacuum system degradation) and innovations such as AI-driven predictive maintenance systems could revolutionize sterilization quality control. AI-driven control mechanisms [3] can precisely regulate the various parameters involved in the sterilization process, such as temperature, humidity, and exposure time. On the other hand, artificial intelligence-driven thermal management strategies [4] play a crucial role in maintaining the stability of sterilization equipment. Sterilization processes often generate a significant amount of heat, and improper thermal management can lead to equipment malfunction and inconsistent sterilization results. AI-driven thermal management systems can dynamically adjust cooling mechanisms, such as fans or liquid-cooling systems, based on the real-time temperature distribution within the equipment [5].

By fostering global collaboration and aligning policies with an equity-driven framework, the healthcare community can mitigate latent risks, ensure patient safety, and ensure that sterilization practices evolve to meet the demands of modern medicine.

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