

Monitoring of each sterilization load: an essential element.



Why do I have to monitor every load?

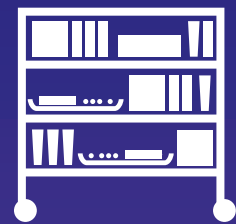
Steam quality is essential

The steam used for sterilization processes must be of high quality (saturated steam). The steam can carry non-condensable gases inside it which can be responsible for incomplete sterilization. For this reason, effective monitoring systems must be able to detect when the steam is of poor quality and can threaten the sterility of the load.



Each load is a unique event.

As shown in clinical studies^{1,2} it is not usually possible to standardise sterilizer loads by size, weight, orientation and type of packaging and so each load should be considered as a unique event.



International standards require every load to be monitored.

Due to process variability, international standards (EN 285:2015 and EN ISO 17665 (1-3):2006) require that every load be monitored to ensure sterility assurance is guaranteed.



What are the risks if I don't monitor every load?

Failure to monitor each load means that you do not know the effectiveness of each sterilization process and the actual lethality of the cycle, exposing the patient to the increased risk of surgical site infections (SSI) due to non-sterile surgical instruments.



How can I deliver greater patient safety?

A complete sterility assurance programme should be implemented.

Safe surgery starts with safe instruments. A safe sterilisation process can only be provided by monitoring every step. Developing a complete sterility assurance programme will ensure successful device reprocessing. A modern biological indicator is highly effective in providing regular evidence of microbial lethality.



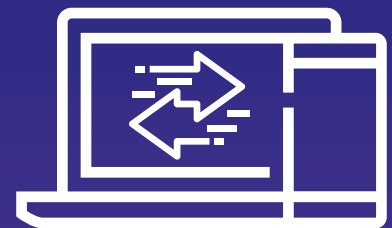
Modern biological indicators.

When biological indicators (BI's) were first developed decades ago, the results were read visually, usually after 24 hours or more and recorded manually in paper systems. Modern BIs still use a technique to determine the survival or killing of a microbial organism but use a rapid and objective approach that produces results in minutes instead of days. These quick results allow high-risk loads to be released in real time making a proactive programme possible rather than a retrospective one.



Digital information and analysis.

Modern BIs allow extremely fast results that do not require any interpretation, and provide digital results that can be recorded, retrieved and stored electronically. This is aligned with today's requirements for data management and traceability.



1 Kirk, B. 2018, (in preparation) Evaluation of the variability of production processes used to sterilize reusable medical devices in a hospital sterile service department.

2 Lapanaitis, N, et al 2018 (in press). Evaluation of the variability of production autoclave cycles.