

Sterisonic™ GxP Cell Culture CO₂ Incubator

Application Guide / MCO-19AIC(UVH)



Ideal for Highly Regulated/GMP or Sensitive Applications

The combination of MCO-19AIC incubator performance functions permit use with confidence in high-value cell protocols among hard-to-grow cell lines, cells highly sensitive to contamination, ultra-sensitive media and reagents, or protocols that require a strict isolation and decontamination between processes.

These include but are not limited to:

- Stem cell research
- Autologous tissue regeneration & regenerative medicine
- In vitro fertilization (FDA 510(k) clearance applied for)
- Genomic and proteomic expression
- Esoteric plant and amphibian cell culture
- Hypersensitive and transgenic cell culture
- Low media volume microplate work

Advantages in GMP and GLP Applications

Systems and design of the Sterisonic™ GxP incubator support both clinical and non-clinical applications, starting with research and leading into development, manufacturing and quality control. As laboratories work to maintain contemporary tools and technologies in advance of new demands for both commercial and clinical success, selection of the laboratory incubator must include consideration for scalability and compliance. When retrofitting or building a new laboratory, lab planners must anticipate reporting and data logging performance of laboratory incubators heretofore classified as commodity equipment, but now recognized a critical link in the chain of custody for quality management and validation.

The Sterisonic™ GxP incubator offers significant advantages in complying with GMP and GLP criteria imposed by outside and internal regulatory agencies or process manuals.

- With respect to GMP, the incubator includes relational operating systems and safeguards designed to protect the cell culture or cell expressed product, particularly when associated with direct human application such as IVF, stem cells, regenerative tissue processes or autologous cell culture.
- GLP criteria promoting continuity in technique and preserving the acquisition and integrity of performance data associated with the typical incubator performance as well as the sterilization cycle is accommodated through the integral control and monitoring system, complete with data point logging and archiving, and optional communications for remote or offsite monitoring.

In developing the Sterisonic™ contamination control model, SANYO engineers based their H₂O₂ design on well-documented efficacy of the increasingly popular hydrogen peroxide vapor sterilization technique often used in decontamination of biological safety cabinets, environmental chambers and other enclosures. When H₂O₂ vapor is deployed in association with the narrow bandwidth ultraviolet light decontamination system already designed into the SANYO incubator, the complete sterilization process is safe, effective and significantly faster than conventional high-heat decontamination solutions.

Typical Applications for Sterisonic™ GxP			
Protocol		Requirements	Sterisonic™ GxP Advantages
Stem cell culture		<ul style="list-style-type: none"> • Highly stable temperature and CO₂ control with elevated relative humidity to minimize small sample media desiccation. 	<ul style="list-style-type: none"> • Precise temperature control at all shelf levels established through microprocessor controlled Direct Heat and Air™ air-jacket heating system¹⁰. • Precise CO₂ control, impervious to short-term humidity shifts following door openings. • Safe, hydrogen peroxide vapor 3-hour sterilization <i>in situ</i> without heat. • Constant scrubbing of chamber air to reduce potential for mycoplasma and other contaminants. • Scalable for use in routine research or for cell cultures highly sensitive to environmental stability and contamination.
IVF		<ul style="list-style-type: none"> • Complete sterilization between batch processes. • Continuous mitigation of airborne contaminants following door openings. 	
Regenerative tissue culture		<ul style="list-style-type: none"> • Elimination of cross-contamination. • Flexibility for a broad range of cell culture applications. 	
Conventional cell culture			