Manual abstract:

@@@@SterisonicTM GxP Selection Feature H2O2 Vapor Decontamination SafeCell UV Decontamination TM CO2 Incubators MCO19AIC(UVH) Standard Standard Standard N/A MCO19AIC(UV) Optional Standard Standard N/A MCO19AIC Optional Optional Standard N/A MCO19M(UVH) Standard Standard Standard Standard CO2 /O2 Incubators MCO19M(UV) Optional Standard Standard Standard MCO19M Optional Optional Standard Standard Single Beam, Dual Detector IR CO2 Sensor Oxygen Concentration Control, Zirconia Control Product Applications The combination of SterisonicTM GxP 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 and regenerative medicine · In vitro fertilization1 · Genomic and proteomic expression · Esoteric plant and amphibian cell culture · Hypersensitive and transgenic cell culture · Low media volume microplate work 1 MCO-19AIC(UVH) Designed for use with a variety of standard cell culture vessels and protocols. · Interior components and adjustable shelves are configured for easy access, in situ decontamination and flexible arrangement for a variety of applications. · Four adjustable shelves are included, standard; maximum shelf capacity is 15 shelves. MCO-19M Multi-Gas Incubator, Oxygen and CO2 Control · Ideal for in vitro fertilization (IVF), genetic research, regenerative medicine and other protocols that require CO2 and sub-ambient (hypoxic) or above-ambient oxygen control. @@multi-point, air-jacketed temperature control system, elevated relative humidity with integral water-level sensor. 501(k) clearance applied for. Contact SANYO for status. MCO-19AIC and MCO-20AIC CO2 incubators have received U.S. Food and Drug Administration 510(k) clearance for in vitro fertilization applications in accordance with the FDA Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992. Reference: Number K013703. Regulation Number: 21 CFR 884-6120, Assisted Reproduction Accessories, Regulatory Class II, Product Code 85MOG, October 30, 2001 2 SterisonicTM GxP Series Cell Culture Incubators SterisoncTM GxP Features and Benefits The SANYO SterisonicTM GxP is designed for a wide array of demanding and highly regulated applications in the biomedical, pharmaceutical, medical research and clinical laboratory. Representing years of research, development and component testing, the SterisonicTM GxP incorporates a collective of mutually functional systems and design attributes to offer a holistic solution to cell culture protocols, from the most sophisticated to more familiar and conventional processes. Decontamination System · The unique SterisonicTM GxP H2O2 decontamination system limits downtime to less than three hours when total chamber decontamination with verification is desired.

@@· Active Background Contamination ControlTM fights contamination while cell culture protocols are in process. The patented SafeCellTM UV system scrubs interior airflow to destroy airborne and humidity pan contaminants. Exclusive inCu saFeTM copperenriched stainless steel interior surfaces assure constant germicidal protection. Control and Monitoring · The SterisonicTM GxP control and information center includes an intuitive pop-up menu, high resolution LCD for inputs, outputs and performance at-a-glance. · Multi-point data logging offers push-button graphical display.

An optional PC interface permits remote transmission for GMP/GLP protocols as required. · Precise PID logic controls and adjusts to all temperature, CO2 setpoints and alarm parameters. Zirconia O2 Control System, MCO-19M Series A zirconia oxygen sensor maintains sub-ambient O2 levels from 1% to 18%. Additionally, enriched O2 levels from 22% to 80% are enabled with proper safety precautions. @@@@· An electronic P .I.D. @@@@· Cabinet based on MCO-19 platform with inCu saFeTM copper-enriched stainless steel chamber, continuous contamination control, patented D.H.A.

multi-point, air-jacketed temperature control system, elevated relative humidity with integral water-level sensor. CO2 Control SANYO proprietary single-beam, dual detector infrared (IR2) CO2 sensor delivers precise CO2 control, quick recovery following door openings, and auto sampling with no moving parts. · Continuous zero calibration is standard. · An optional semi-automatic, one-point calibration system is available. Catalog No. MCO-SG; see Accessories. Shelf brackets are formed with an exaggerated angle to minimize surface contact with flat shelves. MCO-19M MCO-19M shown with four separate inner doors with gaskets. 3 SterisoncTM GxP Features and Benefits Temperature and Humidity Control · The patented Direct Heat and AirTM conditioning system manages setpoint temperature through multiple, variable warming points under microprocessor control. · The humidity pan is easy to fill, easy to clean; the automatic optical sensor advises of low water level.*

14937 may be used as a validation guideline. For references online visit www.sanyobiomedical.com/sterisonic. Unlike conventional incubators, unique features of the SANYO SterisonicTM GxP incubator permit use of the H2O2 process in situ with complete safety, zero impact on adjacent equipment or the environment, and speed to return the incubator to service.

· The H2O2 decontamination process functions with the patented SANYO SafeCellTM UV system. Following a seven-minute H2O2 vaporization, circulation and dwell cycle, vaporization is stopped and the SafeCellTM UV lamp turned ON for up to ninety minutes. · When exposed to UV light, the H2O2 vapor breaks down into water and oxygen, leaving only traces of water droplets. These droplets automatically condense onto a naturally cooler section of the interior floor for easy wipe-up. · Throughout the entire cycle the SterisonicTM GxP airflow system continues to gently circulate interior air assuring 100% vapor contact with all interior surfaces, ultimately creating a serial dilution of H2O2 as it passes over the UV lamp.

· Orientation of interior sample ports of the single beam, dual detector IR CO2 sensor creates a slight Venturi flow through the sample chamber, permitting total decontamination of the CO2 system at the same time. · Shape and location of interior components such as shelves, shelf brackets, plenum covers and the humidity pan permit the components to remain in the chamber during the decontamination process, conveniently bypassing the need for a separate autoclave cycle. @@H2O2 has long been widely used in the pharmaceutical industry. In aerospace research, H2O2 is used to sterilize satellites.

@@@@@@@@@@@@@@@@@@Brackets slip easily into vertical supports that attach to interior chamber walls with clearance sufficient to permit proper air circulation. control as a function of the patented Direct Heat and Air JacketTM, automatically warms the inner door glass in proportion to total heat demand and condensation control. Field Reversible Door The field-reversible door allows universal installation using the left-hand hinge (standard) or a right-hand hinge modification · The outer door includes a universal finger grip at each side. · Mounting holes for hinge hardware are pre-drilled and capped with easily removable trim plugs. · The door heater cable plugs into the alternate connection to complete the change. Inner Door and Gasket The inner design is critical to successful contamination control technique.

· The inner gasket body forms an effective thermal transition between the ambient air and warm, humidified incubator atmosphere, minimizing condensation and eliminating moisture traps which can harbor contaminants. · The inner door gasket is a dual durometer extrusion (two levels of softness) from closed-cell silicone to inhibit contamination. · The gasket feather-edge allows the inner glass door to close gently against the chamber opening for a tight peripheral seal. · The entire inner door gasket is removable for cleaning and/or replacement if required. · Radiant heat from the outer door, apportioned by the microprocessor MCO-38AIC(UVH) Stacking Doubles Capacity in Same Footprint. · The SterisonicTM GxP cabinet is designed for stacking, allowing one unit to be positioned on top of another, doubling interior volume without additional floor space. · The combination of stacking and reversible doors offers the most installation options possible. · An optional roller base is recommended for stacked installations to permit mobility if required; see Accessories. Shelves and Inventory Management Convenient space efficient inventory management is simplified through a system of adjustable, extendable shelves. · Inventory shelves and brackets are formed from polished copper-enharmless water droplets.
Finish. Shelves, humidity pan and plenum are returned to operating position. SterisonicTM GxP H202 Decontamination Cycle (3 Hours, total) Elapsed Time: 15 min. 30 min. 45 min.
1 2 3 4 5 6 Conventional High Heat Decontamination (24 Hours, total) PREP: 15 min. Remove interior components sensitive to high heat. Start Cycle: 90 min. Interior chamber elevates to high heat. Sterilize: 14 hours Interior chamber remains at high heat.
6 SterisonicTM GxP Series Cell Culture Incubators www.sanyobiomedical.com SterisonicTM GxP Control System · Digital alphanumeric LCD display. · Message display · Pop-up menu 1 · Visual alarm indicator · H2O2 decontamination sequence start key 2 · Menu call button · Display contrast adjustment · Positive feedback tactile input buttons · Positive feedback tactile entry and function keys 4 3 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 Finish. Incubator must trolTM process eliminates contamination without downtime. At the base of the plenum an isolated beam of high intensity, ozone-free ultraviolet light destroys contaminants in the air and in the humidity water reservoir, away from active cell cultures. SafeCellTM UV Lamp Program Cycles Mode After H2O2 Vaporization After Door Opening OFF 24 Hour Continuous ON Function The UV lamp automatically cycles ON for up to 90 minutes following the seven-minute H2O2 vapor cycle, reducing the H2O2 to water droplets. These droplets automatically condense onto a naturally cooler section of the interior floor for easy wipe-up. UV lamp automatically ON for five minutes after door is closed decontaminates incoming room air. If UV protection is not desired.

Useful for overnight decontamination prior to first use, clinical decontamination protocols between patients, or following total chamber wipe-out after maintenance or service. · Contaminants trapped within the distilled water pan are destroyed by ultraviolet light. · Sterile, humidified air is released from the lower plenum for vertical convection through and around the perforated shelves. Interior air motion is suspended when the door is opened, minimizing movement of room air contaminants into the chamber. · UV light is isolated by the plenum cover to protect cell cultures · Airborne contaminants are eliminated by an automatic UV cycle that automatically turns ON for a specified period after each door opening.
@@@@@@@@@@@@@@@@@@contrast, with continuous auto-zero calibration. @@Gentle vertical airflow, continuous with inner door closed. @@Data Acquisition Automatic log function of temperature and CO2. Remote alarm contacts standard. Optional 4-20mA connection.
Optional PC interface, Catalog No. MTR-480 with RS232/RS485 data ports available Cabinet Design and Construction Interior, Shelves Inner Door Insulation Outer Door Access Port Leveling Feet 4, Copper-enriched stainless steel. Tempered glass. Rigid foam polyurethane. Reversible, heated. @@4, adjustable. 12 SterisonicTM GxP Series Cell Culture Incubators www.sanyobiomedical.com SterisonicTM GxP CO2/O2 Series Specifications SterisonicTM GxP CO2/O2 Incubators Description Single Chamber Model Number Dual Chamber Model Number Major Operating Systems H2O2 Decontamination System SafeCell UV System TM MCO-19M(UVH) MCO-38M(UVH) MCO-19M(UV) MCO-38M(UV) MCO-19M MCO-38M Standard Standard Standard Standard Standard Standard Optional Standard Standard Standard Standard Standard Optional Optional Standard Standard Standard Standard Single Beam, Dual Detector IR CO2 Sensor inCu saFeTM Copper Enriched Stainless Steel Interior LCD Graphical Controller/Display, Door Mounted Direct Heat, AirTM (DHA) Air Jacket Decontamination H2O2 Decontamination System Interior UV Lamp, Programmable, Ozone Free Copper Enriched Stainless Steel Interior with Germicidal Protection Environmental Performance Temperature Control Range Temperature Control Uniformity Deviation CO2 Control Range and Deviation CO2 Sensor Platform CO2 Calibration O2 Control Range and Deviation O2 Sensor Platform Airflow Interior Humidity Control, Monitoring, Alarm Temperature and CO2 Control Display Data Acquisition Communications Vaporization in situ Standard Standard Optional Standard Standard Optional Optional Standard +5ºC above ambient to 50°C (in a 5ºC to 35ºC ambient) ±0.25ºC (in 25ºC ambient, setting 37ºC, 5% CO2, no load) 0% to 20%, ±0.
15% in 25ºC ambient, setting 37ºC, 5% CO2, no load Ceramic based, single beam, dual wavelength measurement of actual vs. contrast, with continuous auto-zero calibration.

Single point zero automatic; semi-automatic one point span at reference (optional). 1-18%, 22-80%, ±0.2% in 25ºC ambient, setting 37ºC, no load Zirconia sensor, microprocessor P.I.D. control Gentle vertical airflow, continuous with inner door closed. @@Data Acquisition Automatic log function of temperature and CO2. Remote alarm contacts standard.

Optional 4-20mA connection. Optional PC interface, Catalog No. @@@@Reversible, heated. @@@@For accessories or options not listed herein, contact SANYO or your authorized SANYO sales representative. SterisonicTM GxP CO2 Series Incubators Single Chamber Model Number Dual Chamber Model Number MCO-19AIC(UVH) MCO-38AIC(UVH) Catalog No. H2O2 Decontamination Kit H2O2 Vapor Atomizer H2O2 Reagent (Formulated for SANYO Sterisonic GxP) TM MCO-19AIC(UV) MCO-38AIC(UV) Catalog No. MCO-HL N/A N/A MCO-21GC MCO-SG MCO-100L MCO-18RB MCO-47ST MCO-25ST MCO-CL MTR-480 MCO-420MA Built-In MCO-19AIC MCO-38AIC Catalog No. N/A N/A N/A MCO-21GC MCO-SG MCO-100L MCO-18RB MCO-47ST MCO-25ST MCO-CL MTR-480 MCO-420MA MCO-19UVS Built-in MCO-HP MCO-H2O2 MCO-21GC MCO-SG MCO-100L MCO-18RB MCO-47ST MCO-25ST MCO-CL MTR-480 MCO-420MA Built-In Automatic CO2 Cylinder Switchover System Gas Calibration System, semi-automatic one point calibration function. CO2 Cylinder Regulator, CGA fitting 320 Roller Base. For use in single or stacked installations.
inCu saFe Shelf and Brackets. Includes two shelf brackets. Full shelf TM inCu saFeTM Half Tray System Integrated Cooling Option Communications Port. Located at rear of chamber. Connector, cable and software not supplied.
Communications Port. Located at rear of chamber, analog 4-20mA. SafeCell UV System Kit Narrow-bandwidth 253.7nm lamp and assembly. TM H2O2 Reagent (MCO-H2O2) SANYO H2O2 solution is specially formulated for optimal use with the MCO-HP atomizer.
Each pre-measured bottle is sufficient for a complete H2O2 decontamination sequence. @@Water bath/ circulator not included. Permits stable operation at ambient or below ambient temperatures. @@@@@@N/A N/A MCO-H2O2 MCO-21GC MCO-SG MCO-100L MCO-100N MCO-100M MCO-18RB MCO-47ST MCO-25ST MCO-CL MTR-480 MCO-420MA Built-In MCO-19M MCO-38M Catalog No. N/A N/A N/A MCO-21GC MCO-SG MCO-100L MCO-100N MCO-100M MCO-18RB MCO-47ST MCO-25ST MCO-CL MTR-480 MCO-420MA MCO-19UVS Built-in MCO-HP MCO-H2O2 MCO-21GC MCO-SG MCO-100L MCO-100N MCO-100M MCO-18RB MCO-47ST MCO-25ST MCO-CL MTR-480 MCO-420MA Built-In Automatic CO2 Cylinder Switchover System Gas Calibration System, semi-automatic one point calibration function. CO2 Cylinder Regulator, CGA fitting 320 N2 Cylinder Regulator, CGA fitting 580 (for low oxygen applications) O2 Cylinder Regulator, CGA fitting 540 (for high oxygen applications) Roller Base. For use in single or stacked installations. inCu saFe Shelf and Brackets. Includes two shelf brackets. Full shelf TM inCu saFeTM Half Tray System Integrated Cooling Option Communications Port.

Located at rear of chamber. Connector, cable and software not supplied. Communications Port. Located at rear of chamber, analog 4-20mA. SafeCell UV System Kit Narrow-bandwidth 253.7nm lamp and assembly. TM Integrated Cooling Option Feature Temperature Range Relative Humidity Components +18ºC to +50ºC, distribution +/-0.25ºC, variation +/-0.1ºC 5ºC to +50ºC, 95% +/- 5%RH; 20ºC to 25ºC > 80%RH; 18ºC > 70%RH Includes temperature mapping results for individual unit per serial number Stainless Steel Cooling Coil, Interconnection Lines, 6 L, Refrigerated Water Bath & Circulator (Optional/Not Provided) 15 Service and Technical Support Unique SANYO Services · On-site consultation · Specialized documentation for each individual unit · Customized testing procedures based on personalized customer requirements SANYO Connect SANYO's customer-driven biomedical service program guarantees local attention from qualified SANYO service representatives, whenever and wherever you need it. · New Unit Installation and Training · Preventative Maintenance · Warranty and Non-Warranty Repairs · Calibration/Validation Services · Refurbishment and Reconditioning · Customized Service and Warranty Programs · In-Stock Parts for Immediate Delivery Predelivery and On-Site Services Predelivery services include factory acceptance testing, calibration, and temperature mapping.
On-site services include installation qualification, operational qualification, performance qualification, calibration and temperature mapping. Product conforms to RoHS (European Restriction of Hazardous Substance directives) SANYO Electric Co.,Ltd., Biomedical Division, Gumma is certified for quality management system:ISO9001/medical devices quality management system:ISO13485/environmental management system:ISO14001 SafeCellTM UV U.S. Patent 6255103; Direct Heat and Air JacketTM U.S. Patent 5519188; SafeCellTM UV, inCu saFeTM, Direct Heat and Air JacketTM, P .I.D. /RTM and Active Background Contamination ControlTM, are trademarks of SANYO Electric Biomedical Co., Ltd. © 2010 Specifications subject to change without notice. SANYO North America Corporation Biomedical Solutions Division 1300 Michael Drive, Suite A, Wood Dale, IL 60191 Toll free USA (800) 858-8442, Fax (630) 238-0074 www.sanyobiomedical.com 101910V6 .