Forma Steri-Cycle CR cleanroom-compatible CO_2 incubators – CTS Series

Proven solutions for commercial cell
and gene therapy manufacturing

ThermoFisher
SCIENTIFIC

Thoughtfully designed for your cell therapy needs now

Our integrated solutions support your GMP and cleanroom needs for cell and gene therapy—from CO_2 incubators and centrifuges to cold storage, biological safety cabinets, and beyond. Our high-quality products, factory acceptance testing documentation, and on-site compliance services help you get up and running faster, stay compliant, pass regulatory audits, and stay on schedule as you translate your cell therapy from discovery to clinical research and commercial manufacturing.

Cell therapy system

CTS lab equipment

Factory acceptance test documentation

Quality services

Forma Steri-Cycle CR CO$_2$ incubators – CTS Series

Thermo Scientific™ Forma™ Steri-Cycle™ CR CO$_2$ incubators – CTS Series are designed to meet the needs of today's labs generating rapid-fire discoveries. Known for optimal cell growth conditions and minimal contamination risk, they keep your projects moving. Manufactured with the same quality you've come to depend on from Thermo Scientific™ laboratory equipment, Forma Steri-Cycle CR incubators are the next wave of industry-leading innovation for your cleanroom.

- First of its kind: third party–certified, cleanroom-compatible CO$_2$ incubator, suitable for use in ISO Class 5 and GMP Grade A/B environments

- Ultimate contamination control: proven 180°C high-heat sterilization

- Unique Thermo Scientific™ THRIVE™ active airflow technology delivers homogeneous growth conditions quickly, avoiding unwanted variation for propagation of high-value cultures

- In-chamber HEPA filtration enables ISO Class 5 chamber conditions for your samples

- Cleanability inside and out with electropolished 304-1.4301 stainless steel inner chamber and brushed 304L-1.4307 stainless steel exterior casing with IP54 compliance

- Compatible with common cGMP facility protocols and cleanroom procedures including STERIS™ vaporized hydrogen peroxide (VHP) biodecontamination technology

- IR sensor

- 4–20 mA data output

Support tomorrow's breakthroughs today

Ensuring the superior performance you've come to expect, Forma Steri-Cycle CR CO_2 incubators offer the ultimate conditions for high-value cultures with every element of their design. Homogeneous culturing conditions are provided by THRIVE active airflow technology, with all parameters recovering fast from any door opening. All sensors and probes are situated in the culturing chamber so that they measure and react to the conditions experienced by the cultured cells. Enhanced simplicity means intuitive controls, reduced handling time, and easy cleanability.

Microbial contamination is a constant risk for cultured cells. Forma Steri-Cycle CR CO_2 incubators represent the ultimate contamination control design. From the in-chamber ISO Class 5 HEPA filtration system; the covered, protected humidity reservoir; and the electropolished interior to the automated on-demand 180°C sterilization cycle with efficacy proven according to international pharmacopeias, your precious cultures are protected from every direction.

Dependability you can rely on

Designed from the very beginning to bring together effective technologies and outstanding performance, Forma Steri-Cycle CR CO_2 incubators provide the foundation for your innovation. With years in service and installations around the globe, Forma Steri-Cycle CO_2 incubators have a record of design leadership and culturing excellence. As you've come to expect, Forma Steri-Cycle CR incubators provides optimal cell growth conditions, complete contamination control, and operational simplicity.

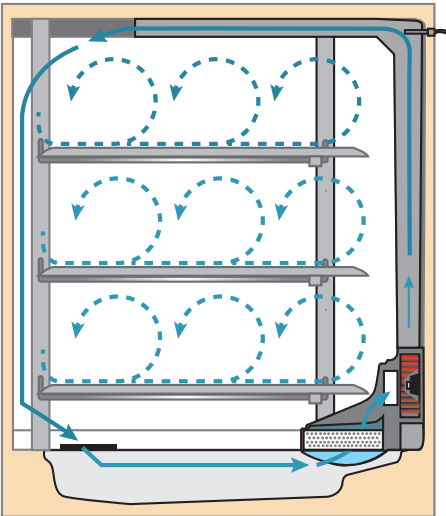# Better solutions for optimal cell growth

Advanced design for sensitive cultures with complete contamination control

Designed to achieve your next breakthrough, our latest incubator series provides everything necessary for your most demanding and highly critical applications.

This series combines our latest technology advancements in contamination control and uniform growth conditions with existing reliable features.

- Choice of 165 L (5.8 cu. ft.) and 255 L (9.0 cu. ft.) in a compact footprint, readily stackable

- Choice of electropolished stainless steel or 100% copper interior

- THRIVE active airflow provides fast recovery for stable culturing conditions

- Proven protection from every direction including ISO Class 5 HEPA filtration, on-demand sterilization, and naturally easy-to-maintain copper

- Unique covered humidity reservoir is designed to maximize humidity without condensation

- Thermo Scientific™ iCAN™ touchscreen interface provides complete data visibility with data logging, error and usage logs, performance trend graphing, and multiple language options

- Optional O$_2$ control with choice of 1–21% or 5–90% ranges

THRIVE active airflow

An in-chamber fan gently and evenly distributes clean, humidified air throughout the chamber ensuring all cells experience the same conditions without the threat of desiccation

Better solutions for optimal cell growth

Revolutionary THRIVE airflow technology is designed to provide fast recovery of all parameters in 10 minutes or less following a routine door opening. In-chamber fan gently distributes clean, humidified air throughout the chamber ensuring homogeneous conditions to avoid unwanted variations in your culture environment.

- In-chamber probes and sensors respond quickly to correct changes in conditions and remain in place during sterilization

- Dual temperature probes provide over-temperature protection

- Temperature-resistant IR180Si infrared (IR) CO$_2$ sensor replaces the traditional incandescent infrared (IR) light source with silicon microelectromechanical systems (MEMS) technology that improves stability and extends service life

Exclusive condensation-free humidification system
Our unique integrated, covered, 3-liter capacity humidity reservoir maximizes relative humidity without condensation to help ensure a dry inner chamber, preventing a breeding ground for contaminants. Water level is continuously monitored and displayed on the iCAN touchscreen and the reservoir can be filled without disturbing cultures and easily emptied through a built-in copper drain.

When clean is critical—both inside and out

Exclusive Thermo Scientific™ Steri-Run™ Cycle

High-temperature sterilization cycle reaches 180°C on all chamber surfaces and is independently proven to achieve total sterilization and a 12-log sterility assurance level (SAL). Intuitive electronic door lock automatically engages during the cycle ensuring safety during runs. The Steri-Run cycle sterilization function can be utilized in the cleanroom without disrupting exterior air cleanliness.

HEPA air filtration designed for air purity

An in-chamber HEPA system continuously filters the entire chamber air volume every 60 seconds to achieve cleanroom-quality ISO Class 5 air within 5 minutes of routine door opening.

Electropolished inner chamber

The high-quality electropolished stainless steel inner chamber starts with 304 grade stainless steel. Then the electropolishing process assures a surface roughness (Ra) of less than 0.4 μm, more refined than the commonly accepted Ra of ≤0.8 μm. To help prevent the risk of unwanted microbial growth, this precision reduces microscopic structures where microorganisms could adhere to ensure thorough cleaning.

Easy-to-maintain 100% copper interiors are available

Optional corrosion-resistant copper interior components provide a naturally durable surface, easy to clean with no special handling.

VHP compatibility

Proven compatibility with STERIS dry process systems using vaporized hydrogen peroxide, a dry, noncondensing vapor commonly used for biodecontamination of airborne and surface contaminants in cleanrooms and production environments.

What's new with Forma Steri-Cycle CR incubators?

Particle control exhaust system

A cleanroom is not like a typical lab. An ISO Class 5 cleanroom is ten thousand times cleaner than normal indoor room air, which is ISO Class 9. Airborne particles can be detrimental to cells and dangerous to patients. Beyond the dangers posed by microbial contaminants, particles from laboratory equipment could cause damage to blood vessels and tissues if included in a sterile injectable drug. Particulates represented the second leading cause of injectable drug recalls by the US FDA from 2009 to 2019 (Eglovitch JS. *Informa Pharma Intelligence* April 25, 2019.)

We've met the rising demand for proven cleanroom compatibility with the first particle control system designed for a CO$_2$ incubator. This innovative technology controls and captures particulates released from all sides of the incubator into the cleanroom environment. Air throughout the casing is directed through a HEPA filter to assure no disruption to the environment.

Third party–validated and certified for ISO Class 5 and GMP Grade A/B environments

This new cleanroom-compatible design has been fully and independently evaluated according to DIN EN ISO 14644-1 and VDI 2083 Part 9.1.

Through rigorous testing, the Forma Steri-Cycle CR incubator has successfully achieved ISO Class 5 compatibility in both standard operating and sterilization modes. The measurement results show that in the cleanroom for the considered particle sizes 0.5 µm and 5.0 µm, the air cleanliness class ISO 5 is achieved according to DIN EN ISO 14644-1. According to the EU-GMP guideline, ISO Class 5 corresponds to GMP Grade A/B regarding the particle sizes 0.5 µm and 5.0 µm.

Brushed 304L-grade stainless steel exterior

In cleanroom environments, CO$_2$ incubators need to be robust enough to withstand the demanding cleaning procedures required. Our brushed 304L-1.4307 stainless steel exterior is easy to clean and maintain even with some of the more robust cleaning procedures typical of cleanroom and GMP settings, while continuing to operate with precision to keep precious contents healthy and safe.

IP54-rated

Important for controlled environments that need thorough and frequent cleaning, the incubator, including its electronics, is designed to be protected from dust and resist liquids from any direction.
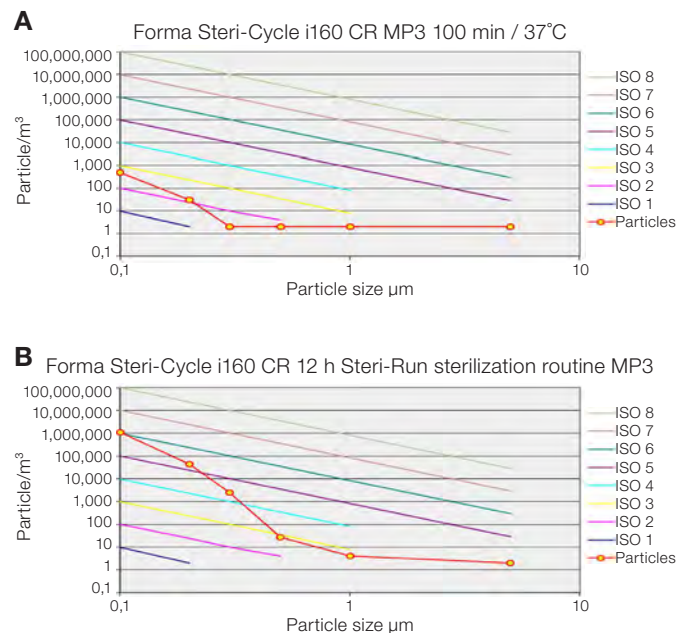
A Forma Steri-Cycle i160 CR MP3 100 min / 37°C

B Forma Steri-Cycle i160 CR 12 h Steri-Run sterilization routine MP3

Figure 1. Results of TÜV SÜD Industrie Service GmbH Report. Compatibility testing with required cleanliness and surface cleanliness according to DIN EN ISO 14644-1 and VDI 2083 Part 9.1 for the Forma Steri-Cycle i160 CR incubator, December 2020.

Accurate and durable CO$_2$ sensor technology

Temperature-resistant, bulb-free IR CO$_2$ sensor with MEMS-emitter technology

We use advanced temperature-resistant IR180Si infrared CO$_2$ sensors with silicon MEMS-emitter technology that improves stability and reliable service life. This sensor is ideal for labs looking for the best of both technologies for advanced, high-volume, or value culturing.

• Internal auto-calibration eliminates drift due to changes in ambient conditions that can affect traditional IR sensors

• IR180Si CO$_2$ measurement not affected by changes in temperature, humidity, oxygen, or barometric pressure*

• Highly responsive with recovery under 5 minutes from door openings
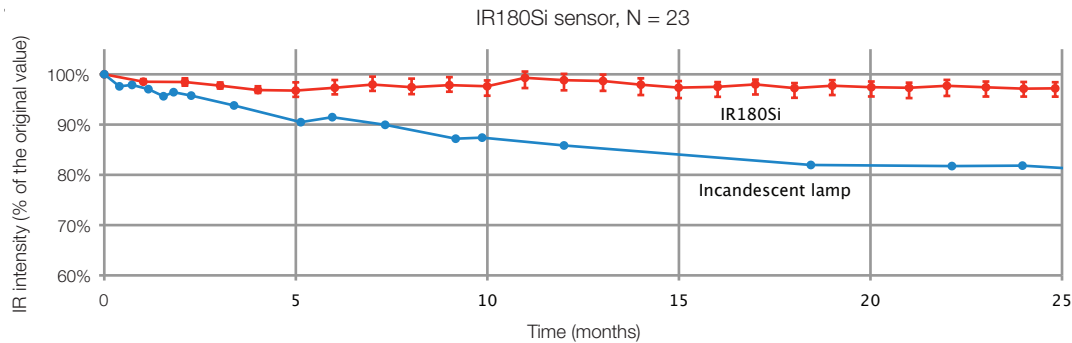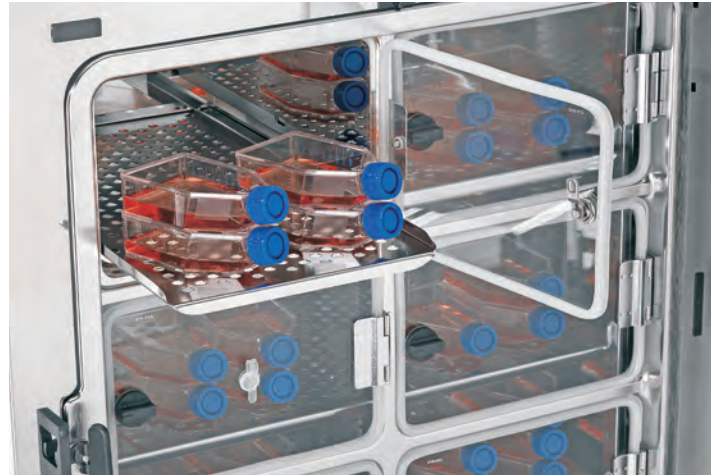

Figure 2. A traditional IR sensor contains an incandescent bulb that puts out less light as it ages, resulting in sensor drift. The IR180Si sensor eliminates this problem. Our silicon MEMS emitter is designed to retain intensity over time, lasting up to 50% longer than ordinary IR sensors.

* Information cited based on sensor manufacturer's data.

Culturing flexibility with variable oxygen control

Many cell types thrive best in CO_2 incubators with reduced oxygen. Culturing cells at lower oxygen concentration will better simulate physiological conditions, resulting in cell behaviors that are more predictive of the *in vivo* environment.

Our variable oxygen control (or "tri-gas") incubators can generate conditions to help your cells grow faster and healthier. With the Forma Steri-Cycle CR CO_2 incubator, you can choose between two optional O_2 control ranges: simulate hypoxic (1–21%) environments for primary cell, stem cell, and embryo research applications, or hyperoxic (5–90%) conditions for work in lung, retina, and other sensitive tissues.
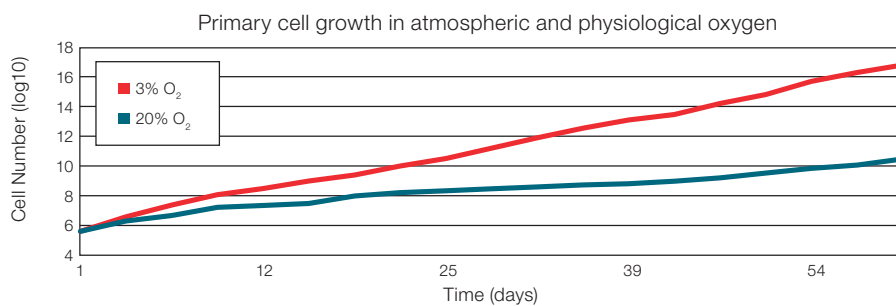

Figure 3. **Cells cultured in low oxygen (hypoxia) will generally grow faster, live longer, and show lower stress.** Adapted from Parinello et al. *Nature Cell Biology* 2003.

"Our lab mandates this [5% oxygen in the tri-gas incubator] in order to mimic conditions in the body, so that cells are as close to those conditions as possible and nothing is different. All of the signals for proper epigenetics are there."

–Stem cell researcher at biomedical research institute
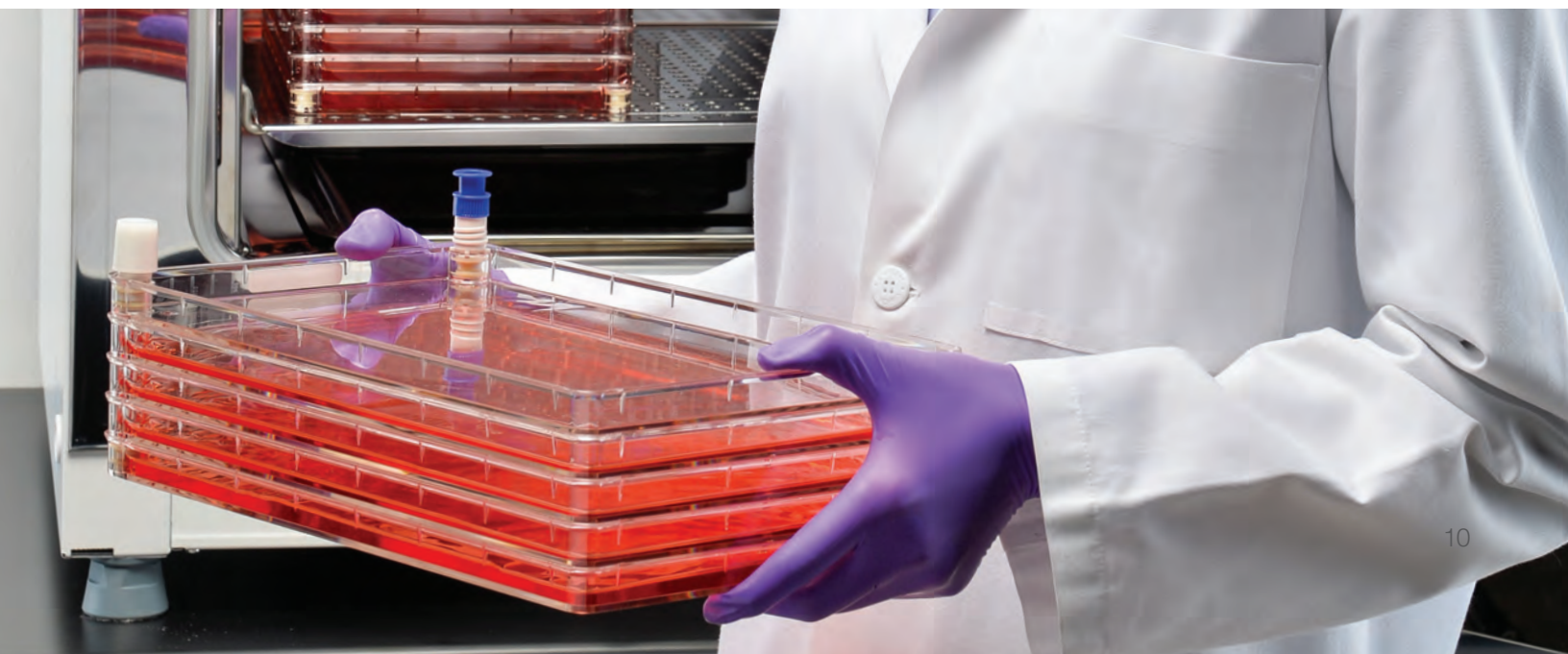
High-temperature sterilization with push-button simplicity

With the push of a button, the simple overnight routine of the Steri-Run cycle provides fast, easy elimination of microbial contaminants and eliminates the need for separate autoclaving of parts.

- Fully automatic 180°C cycle assures total, uniform sterilization of all chamber surfaces (12-log SAL)

- Independent third-party tests prove elimination of biological contaminants including fungal mold, vegetative and spore forms of bacteria, including mycoplasma

- Avoids the physical constraints and variation associated with UV germicidal lamps and the ongoing costs, handling and storage of potentially toxic germicides

The US and EU Pharmacopeias no longer recommend a given temperature and time for sterilization. Instead, they require proof of performance. To meet requirements of a 12-log SAL, a 6-log reduction of biological indicator endospores must be demonstrated in half the time.
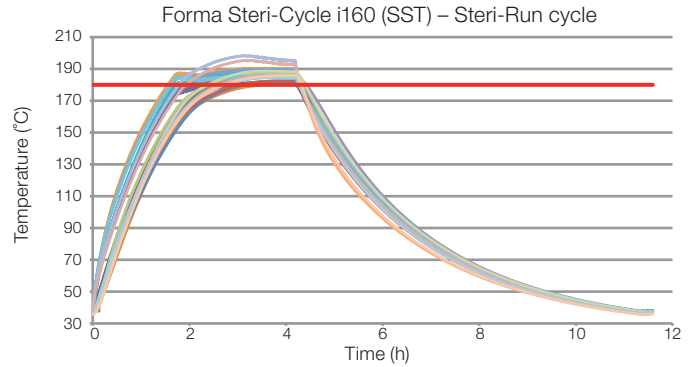

Forma Steri-Cycle i160 (SST) – Steri-Run cycle

Figure 3. Validation that all surfaces reach 180°C with a 48-point test on all chamber areas including the glass door and shelves.

Independent third-party testing proved the Steri-Run cycle, when heated to 180°C for 45 minutes, eliminated all microorganisms validating that the full cycle of 90 minutes at 180°C meets requirements for a >12-log sterility assurance level (SAL).

Microorganisms eliminated during the Steri-Run cycle*				
Microorganism	**ATCC #**	**Average positive control***	**Number recovered***	**Log reduction***
Aspergillus brasiliensis	16404	2.98×10^4	NG**	−4.5
Escherichia coli	25922	2.22×10^4	NG	−4.3
Mycoplasma pneumoniae	15531	1.25×10^6	NG	−6.1
Bacillus atrophaeus spores	51189	2.16×10^7	NG	−7.3
Geobacillus stearothermophilus spores	12980	4.81×10^6	NG	−6.7

* Average based on 3 independent tests performed on different days.

** NG=no growth.

		Forma Steri-Cycle i160 CR CO_2 Incubator	Forma Steri-Cycle i250 CR CO_2 Incubator
Construction	Chamber volume	165 L (5.8 cu. ft.)	255 L (9.0 cu. ft.)
	Interior chamber	Electropolished stainless steel or 100% solid copper	
	Exterior casing	304L-1.4307 brushed stainless steel	
	Access port	42 mm diameter	
	Data outputs	Remote alarm contacts, USB, and 4-20 mA	
Dimensions	Internal dimensions (w x h x d)	470 x 607 x 576 mm	607 x 670 x 629 mm
		18.5 x 23.9 x 22.7 in.	23.9 x 26.4 x 24.8 in.
	External dimensions (w x h x d)	637 x 901 x 881 mm	774 x 964 x 934 mm
		25.1 x 35.4 x 34.6 in.	30.5 x 38.1 x 36.8 in.
	Operating weight	95 kg (209 lb)	119 kg (262 lb)
Shelves	Dimensions (w x d)	423 x 465 mm (16.7 x 18.3 in.)	560 x 500 mm (22.05 x 19.68 in.)
	Number standard/maximum	3/11	3/12
	Max. load per shelf/total load	10/30 kg (22/66 lbs)	10/30 kg (CU models), 14/42 kg (SST models)
	Construction	Perforated, adjustable	
Electrical	Rated voltage	1/N/PE AC (±10%), 230, 220V, 120V, 100V	
	Nominal kW consumption (Steri-Run cycle)	0.56 (1.06)–230 V, 0.51 (0.97)–220 V	0.76 (1.26)–230 V, 0.69 (1.16)–220 V,)
		0.55 (1.01)–120 V, 0.39 (0.72)–100 V	0.75 (1.25)-120 V, 0.53 (0.89)–100 V
	Rated frequency	50/60 Hz	
	Heat emission to environment at 37°C	0.06 kWh/h	0.07 kWh/h
	During Steri-Run cycle:	0.26 kWh/h (average), 0.78 kWh/h (heating time), 0.59 kWh/h (hold time)	

Temperature	Control	±0.1°C	
	Range	Range 3°C above ambient to 55°C	
	Uniformity	< ±0.3°C	
	Ambient range	18–28°C	
	Tracking alarm	±1°C	
Sterilization cycle	Cycle temperature	180°C on all internal surfaces	
	Cycle duration	Under 12 hours	Under 14 hours
Humidity	Relative humidity (RH)	≥93% at 37°C	
	Humidity reservoir	max. 3 L/min 0.5 L	
CO_2	Control	±0.1%	
	Range	0–20%	
	Tracking alarm	±1%	
	Inlet pressure	12–15 PSI (0.8–1.0 bar)	
	Gas purity	min. 99.5% or medical quality	
	CO_2 inlet	1/8 in. hose (barbed)	
O_2	Control	±0.1%	
	Range	1-21% or 5-90%	
	Tracking alarm	±1%	
	Inlet pressure	12–15 PSI (0.8-1.0 bar)	
	Gas purity	min. 99.5% or med. quality	
	O_2 inlet	1/8 in. hose (barbed)	

Factory acceptance test (FAT) documentation binder

Comprehensive documentation package that supports a timely and rapid validation process

Regulatory certificates
- Declaration of conformity (CE) with EU law, CSA, and QMS Certificates

Recommended protocols
- User-replaceable parts and consumables lists

- Suggested customer maintenance schedule

- Recommended solutions and procedures

Product-specific factory documentation and specification
- Certificates of conformance, calibration, sensor calibration, and technical specifications

- Third-party certificate of compatibility with ISO Class 5 and GMP Grade A/B cleanroom environments

Remote monitoring
4–20 mA signal output is included for interfacing with external data collection solutions, such as Thermo Scientific™ remote monitoring systems, which are ideal for GMP environments because of their external sensors and CFR 21–compliant software packages.

Ordering information
CTS Series products come with IR CO_2 sensor, 4-20 mA data output, and documentation package

Product	Cat. No.		
	120 V 50/60Hz	230 V 50Hz	100 V (Japan only)
Forma Steri-Cycle i160 CR CO_2 Incubator with electropolished stainless steel interior	51033777	51033778	51033776
Forma Steri-Cycle i160 CR CO_2 Incubator with 100% copper	51033780	51033781	51033779
Forma Steri-Cycle i250 CR CO_2 Incubator with electropolished stainless steel interior	51033789	51033790	51033788
Forma Steri-Cycle i250 CR CO_2 Incubator with 100% copper	51033792	51033793	51033791

Options and accessories to customize your Forma Steri-Cycle CR CO_2 incubators

Gas-tight 6-segment inner door

Thermo Scientific™ Cell Locker™ chamber

CO_2 resistant shaker

2-stage gas regulator

Ordering information

Factory installed	Forma Steri-Cycle i160 CR CO_2 Incubator	Forma Steri-Cycle i250 CR CO_2 Incubator
Country versions*		
Electrical configuration for Switzerland	51900300	
Electrical configuration for Great Britain	51900303	
Electrical configuration for Italy	51900306	
Electrical configuration for Australia	51900449	
Electrical configuration for Denmark	51900481	
Electrical configuration for China	51900900	
Chamber configuration		
Cell Locker–equipped inner chamber (replaces glass door and shelving system - does not include Cell Lockers)	51901222	
Package of 6 Cell Lockers with stainless steel sliding tray and transport cover	50151650X6	
Package of 6 Cell Lockers with copper sliding tray and transport cover	50154739X6	
Gas-tight 3-segment inner door (replaces single inner door configuration)	51901144	
Gas-tight 6-segment inner door (replaces single inner door configuration)	51901221	51901127
6 each of split shelf, copper (for use with gas-tight 6-segment inner door configuration)		51901122
6 each of split shelf, stainless steel (for use with gas-tight 6-segment inner door configuration)		51901123
GMP-compatible reinforced clip bar shelves, stainless steel	51901375	51901377
O_2 control		
1–21% O_2 control	51901137	
5–90% O_2 control	51901138	
1–21% O_2 control with gas-tight screen 6 inner glass doors and 1/2 width shelves		51901133
5–90% O_2 control with gas-tight screen 6 inner glass doors and 1/2 width shelves		51901134

* Available for 230 V models only.

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Cleanroom accessories

Roller base, stacking adapter, and stands were all included in the third-party evaluation to ensure material compatibility with the GMP and ISO cleanroom conditions.
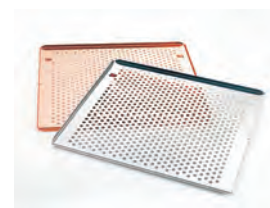

Stacking adapter

Support frame for single chamber without casters

Caster frame, 76 mm

Exhaust HEPA filter

Stainless steel and copper shelves

Ordering information

Customer installed	Forma Steri-Cycle i160 CR CO$_2$ Incubator	Forma Steri-Cycle i250 CR CO$_2$ Incubator
Support frames, stacking adapters, and shelving		
Cleanroom-compatible low-profile roller base for double chamber, 76 mm high (with casters)	50161859	50162731
Cleanroom-compatible support frame for single chamber, 780 mm high (without casters)	50162104	50162771
Cleanroom-compatible adapter required for stacking i160 CR models	50162145	
Cleanroom-compatible adapter required for stacking i250 CR models		50162632
Additional stainless steel shelf, full-width, 2 support rails	50051909	50065793
Additional shelf, solid copper, full-width, with 2 support rails	50051910	50065794
Reinforced clip bar shelf, copper	50160247	50160245
Reinforced clip bar shelf, stainless steel	50160246	50160234
Set of 4 HERAtrays, 1/4 width, in stainless steel		50065807
Set of 4 HERAtrays, 1/4 width, in copper		50065808
Set of 3 HERAtrays, 1/3 width, in stainless steel	50051913	50065805
Set of 3 HERAtrays, 1/3 width, in solid copper	50051914	50065806
Set of 2 HERAtrays, 1/2 width, in stainless steel	50058672	
Set of 2 HERAtrays, 1/2 width, in copper	50061050	
Set of 2 HERAtrays, 1/2 width for half width shelves, in stainless steel		50065809
Set of 2 HERAtrays, 1/2 width for half width shelves, in copper		50065810
CO$_2$/O$_2$ accessories and monitoring		
Replacement in-chamber HEPA filter	50141920	
Replacement in-chamber prefilter	50144774	
Door lock retrofit kit, key entry, to prevent unauthorized access	50145438	
CO$_2$ gas regulator, 2-stage, for gas tank	3429937	
N$_2$ gas regulator, 2-stage for gas tank	3429942	
O$_2$ gas regulator, 2-stage for gas tank	3429943	
External gas guard automatic change-over to reserve tank, 120 V, 50/60 Hz	50059043	
External gas guard automatic change-over to reserve tank, 230 V, 50/60 Hz	50046033	
IR gas tester with travel case (for advanced calibration and testing purposes for CO$_2$ model)	50121515	
IR Tester for CO$_2$/O$_2$	50145789	
IR gas tester interface kit	50122015	
5 inlet port filters for IR testers	50060287	
Shakers for CO$_2$ incubators		
CO$_2$ resistant shaker, 120 V	88881101	
CO$_2$ resistant shaker, 230 V	88881102	
CO$_2$ resistant shaker with universal platform, 120 V, with universal platform and flask clamp starter kit	88881103	
CO$_2$ resistant shaker with universal platform, 230 V, with universal platform and flask clamp starter kit	88881104	

Qualification services

Gain confidence with our qualification services that can help reduce your risk of noncompliant instruments

Remain compliant with our industry-exclusive, no-charge requalification guarantee*
With Unity Lab Services qualification services, you'll be confident that your instruments maintain compliance. Unlike other OEM service providers who charge for requalification services, we are the only provider to guarantee that we will requalify instruments and equipment at no charge if a key component fails while under the original factory warranty or a qualifying service instrument plan.

Pass audits the first time with our robust and easy-to-understand OEM qualification protocols and harmonized documentation
Our factory-developed qualification protocols are written to support industry standards and regulatory requirements. Our qualification services provide consistent, audit-ready documentation that meets predetermined and/or user specifications. In addition, our harmonized qualification protocols and documentation across all instruments save you administrative work, review time, and complicated approval processes, helping to ensure the best audit outcome.

Stay on schedule with our full-range, single-source support from experienced engineers
Unity Lab Services provides a full-service solution for installing, repairing, qualifying, and mitigating risks so your instruments (including other manufacturers' units) get up and running faster and your research stays on schedule. Our factory-certified validation engineers are product experts with experience in regulated environments, ensuring your qualifications are delivered efficiently and effectively to industry standards.

* Unity Lab Services is the only OEM service provider to offer a guarantee and promise to requalify instruments and equipment at no charge if a key component fails while under the original factory warranty or a qualifying instrument service plan.

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Service solutions*

Qualification/service	Description
Installation qualification (IQ)	• Verifies that the equipment, manuals, supplies, and any other accessories arrived undamaged as specified in the sales order. Verifies equipment and any other accessories are assembled and installed. Any abnormal event(s) observed during the IQ is documented in the IQ protocol. • Verifies that the installation site and equipment environment meet manufacturer-specified environmental requirements.
Operation qualification (OQ)	• System component information: records detailed configuration information for each system component. • OQ limits: records a list of manufacturer-recommended limits for ensuring that the system is operating as expected. • Equipment operational tests and results: tests important equipment functions to verify that the equipment operates as intended by the manufacturer and required by the user. Includes a group of important equipment parameters selected for testing depending on the intended use of the equipment. Key tests: min/max speed, brief/extended time, temperature for refrigerated models
Temperature mapping	• Equipment capabilities tests: monitors important equipment capabilities to ensure that the equipment is performing in accordance with the intended use of the system. • Multipoint temperature mapping: monitors temperature for a 24-hour period with 1-minute data collection intervals.

* Physical installation of equipment is not included in the bundle. Installation can be provided for a separate fee.

Go to **unitylabservices.com/complianceservices** to learn more or request a quote for service.

Tips to stay compliant
Our annual calibration and preventative maintenance services are designed to help you stay compliant. For more information, call Customer Care or contact your local sales representative.

Find out more at **thermofisher.com/cleanroomco2**

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