



Cell and gene therapy

Forma Steri-Cult CO₂ Incubator CTS Series

Excellent performance
for high-value cultures

For cell and gene therapy research and manufacturing

Thermo Scientific™ Forma™ Steri-Cult CO₂ Incubator Cell Therapy Systems (CTS™) Series consists of our popular Steri-Cult models with enhanced features, extensive documentation, and certifications. Our compliance services support your Good Manufacturing Practice (GMP) needs.

The CTS Series helps you get up and running faster, stay compliant, navigate regulatory audits, and stay on schedule as you take your cell therapy from discovery to clinical research and commercial manufacturing.



Product



**Documentation
package**



**Compliance
services**



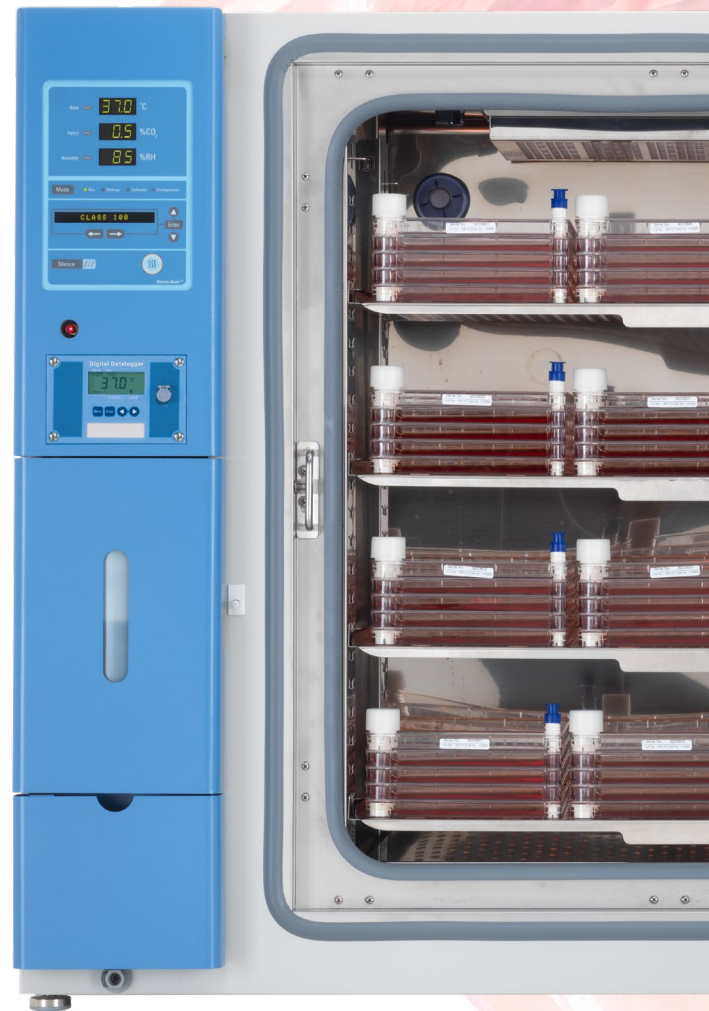
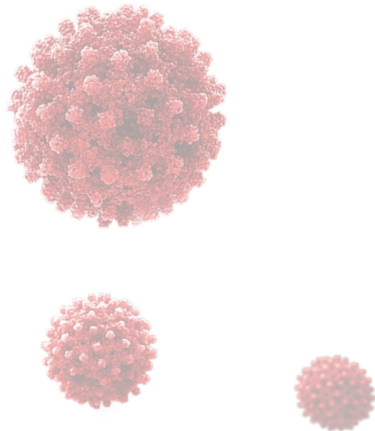
Forma Steri-Cult CO₂ Incubator CTS Series

Excellent protection for high-value cultures

Thermo Scientific™ Forma™ Steri-Cult CO₂ Incubators are designed to meet the needs of today's rapid-fire discoveries. Starting with the quality you've come to depend on from Thermo Fisher Scientific products, Steri-Cult CO₂ incubators have added features that can help take your work to the next level. Known for unique features ideally suited for manufacturing, Steri-Cult CO₂ incubators offer proven contamination control features, fast recovery and excellent uniformity that help reduce downtime and improve quality.

Features

- Ultimate contamination control: proven 12-log 140°C sterilization for high-value cultures, in-chamber HEPA filtration enabling ISO Class 5 conditions, and an external active humidification system
- Largest stackable culturing capacity available ideal for high-volume culturing
- Active humidification system and IR CO₂ sensor with in-chamber fan for fast recovery and outstanding uniformity to support optimum cell viability
- Designed for easy cleaning with electropolished stainless steel inner chamber to reduce microscopic structures where microorganisms could hide
- Proven compatible with common cGMP facility protocols and clean room procedures such as STERIS vaporized hydrogen peroxide (VHP) biodecontamination technology
- 4-20 mA data output





Support tomorrow's breakthroughs today

Contamination control and cleanability

Ultimate contamination control

The risk of contamination is ever-present. Grice EA et al. 2008 showed that humans carry 10,000 microbes/cm² on skin, and Armstrong SE et al. 2010 showed that even biopharma cultures were contaminated at a rate of 8.45%.

Steri-Cult CO₂ incubators offer the ultimate protection for high-value cultures with every element of their design, from the in-chamber ISO Class 5 HEPA filtration system to the easily cleaned electropolished chamber and proven automated sterilization cycles.

When cleanability is critical

Electropolished inner chamber

The high-quality electropolished 100% stainless steel inner chamber assures a surface roughness (Ra) of less than 0.4 µm, more refined than the commonly accepted Ra ≤ 0.8 µm. To minimize the risk of unwanted microbial growth, this degree of precision reduces microscopic structures where microorganisms could adhere.

VHP compatibility test results

Proven compatibility with STERIS™ “dry process” vaporized hydrogen peroxide (VHP), commonly used for biodecontamination of airborne and surface contaminants in clean rooms and production environments.

Remote monitoring

4-20mA signal output is included for interfacing with external data collection systems, such as the Thermo Scientific™ Smart-Vue™ Pro Remote Monitoring System provides external sensors and CFR-21 compliant software packages ideal for GMP environments. The Smart-Vue Pro system offers a customizable and scalable architecture that is compatible across multiple brands and equipment types, offering self-installation and long range capabilities.



Learn more at thermofisher.com/smart-vuepro





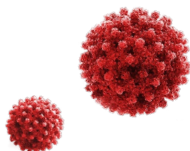
Product documentation package

Certifications and protocols to help with validation

| Binder element | Description |
|--|---|
| Product support documents | |
| Design qualification (technical data sheet, drawings) ¹ | Basic specification descriptions of the product and may include some summary drawings |
| Recommended maintenance schedule | User-based recommended maintenance and schedule |
| Consumables and customer-replaceable parts | Replaceable parts based upon usage or wear |
| Recommended cleaning procedures | Effective and typical procedures |
| Regulatory and compliance certifications | |
| Declaration of conformity with EU laws (CE) | CE certificate proof |
| CSA certificate | CSA certificate proof |
| Certificate of environmental status | Regulatory certificates for various sustainability items |
| Quality Management System (QMS) certificate | Factory/site-based quality system description |
| Traceability/ validation documents | |
| Certificate of conformance | Production certificate |
| FAT report ² | End-of-line test summary with checklist of performance |
| Key material of construction specifications | Technical specifications |
| STERIS™ VHP compatibility certificate | Test certificate for vaporized hydrogen peroxide cleaning |
| HEPA filter certificate ² | Certificate of filter performance |
| Temperature sensor calibration document ² | Certificate from supplier on calibration |
| RH sensor calibration document ² | Certificate from supplier on calibration |
| CO ₂ sensor calibration document ² | Certificate from supplier on calibration |
| CO ₂ valve certificate of compliance ² | Certificate from supplier on compliance |
| Certificate of electropolishing ² | Material certificate of surface finish |

1) These documents are available from the factory prior to purchase upon request (in addition to CAD format drawings).

2) These are serialized documents.





Compliance services¹

On-site qualification

Unity™ Lab Services, as part of Thermo Fisher Scientific, offers on-site qualification services that help ensure your laboratory equipment meets global standards and mitigates the risk of regulatory non-compliance. Our full-range compliance portfolio offers improved productivity, single-vendor convenience, a no-charge requalification guarantee,² and comprehensive documentation reports that give you peace of mind by supporting your quality management system, traceability, and audit readiness. Our standardized field qualifications for CO₂ incubators include IQ, OQ and temperature mapping services. Semi-customized protocols are available. Contact your local sales or service team for services in your location.

Qualification services

| Installation qualification (IQ) ³ |
|--|
| Component verification |
| Assembly verification |
| Installation verification |
| Site verification |

| Operational qualification (OQ) |
|-----------------------------------|
| System configuration |
| Set points |
| Alarms and safety |
| System functionality |
| All functional attributes |
| Reference measurements for |
| CO ₂ |
| Temperature |
| Humidity |



Mapping services⁴

| | Description |
|------------------------|--|
| Temperature mapping | Manufacturing performance specifications verified via a multi-point temperature mapping with recommended test profile and probe configuration. |
| Door open recovery | Temperature map during door open recovery. |
| Power failure recovery | Temperature map during power failure. |

Selecting the right compliance services solution is a significant part of your quality system. Our factory-trained, highly skilled field service engineers will support your project from the time of order until regulatory sign-off to help you pass qualifications. Our best practices ultimately help you reduce costs and maintain operational uptime.

1. Compliance services are only available in select locations including the United States, Germany, France, the United Kingdom, Ireland, Spain, Portugal, Italy, Austria, Switzerland, Norway, Sweden, Denmark, Belgium and the Netherlands. For more information, contact your local sales or service representative.
2. Our no-charge requalification guarantee for laboratory equipment applies only to equipment under a qualifying Unity Lab Services equipment service plan or warranty and includes requalification on covered corrective maintenance repair at no additional charge. [Terms and conditions apply: https://www.unitylabservices.com/content/dam/uls/support/terms-conditions/BN20201026-1220-TsCs-Requalification%20Guarantee-FINAL.pdf](https://www.unitylabservices.com/content/dam/uls/support/terms-conditions/BN20201026-1220-TsCs-Requalification%20Guarantee-FINAL.pdf)
3. Installation of equipment is not included within our IQ services. Additional fees apply for inside delivery shipping method or for full installation and setup of equipment.
4. Key offerings may vary by region.

Order details

Product and documentation package

| Product description | Voltage | Cat. No. |
|--|---------|----------|
| Forma Steri-Cult CO ₂ incubator, electropolished stainless steel 8.2 cu. ft. (232.2 L), Factory Acceptance Testing Documentation | 115 V | 3307E |
| Forma Steri-Cult CO ₂ incubator, electropolished Stainless Steel 8.2 cu. ft. (232.2 L), Factory Acceptance Testing Documentation | 230 V | 3308E |
| Forma Steri-Cult CO ₂ incubator, electropolished Stainless Steel 11.4 cu. ft. (322.8 L), Factory Acceptance Testing Documentation | 115 V | 3310E |
| Forma Steri-Cult CO ₂ incubator, electropolished Stainless Steel 1.4 cu. ft. (322.8 L), Factory Acceptance Testing Documentation | 230 V | 3311E |

All models in the CTS Series come complete with IR CO₂ sensor, 4-20mA data output, and electropolished stainless steel interior.

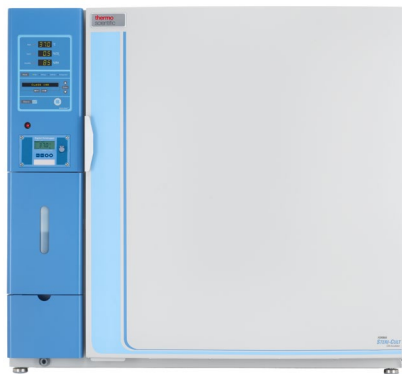
Accessories

| Product description | Cat. No. |
|---|----------|
| Electropolished stainless steel reinforced shelf 11.4 cu. ft. (322.8 L) | 192104 |
| Roller dolly for one or two (stacked) model 3307E (3308E) | 1900162 |
| Roller dolly for one or two (stacked) model 3310E (3311E) | 1900163 |

Compliance services*

| Qualification service | Cat. No. |
|---|------------------|
| On-site IQ/OQ + temperature mapping service | IOPQPCKE89003500 |
| On-site IQ/OQ service | IOQPCKE89003500 |
| On-site temperature mapping service | TEMPMAP |

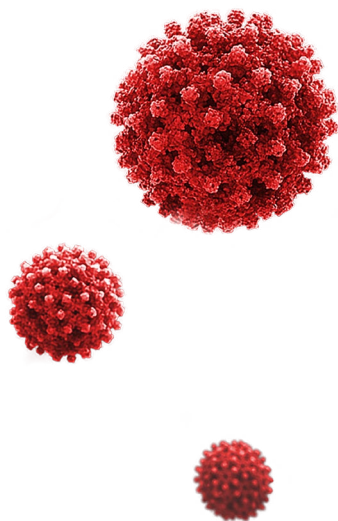
* See page 6 for details and availability.



Remote monitoring*

| | Product description | Region | Cat. No. |
|--|--|-------------|--------------|
| Module (Duo) | Smart-View Pro Duo 915MHz only. Delivered with two 3.6 V lithium batteries, one sensor mounting kit, one mounting holder, one antenna and one 1.5 m/5 ft. flat cable. | USA, Canada | SVPHWRMOD012 |
| | Smart-View Pro Duo 868MHz only. Delivered with two 3.6 V lithium batteries, one sensor mounting kit, one mounting holder, one antenna and one 1.5 m/5 ft. flat cable. | Europe | SVPHWRMOD022 |
| Module (Quatro) | Smart-View Pro Quatro 915MHz only. Delivered with two 3.6 V lithium batteries, two sensor mounting kit, one mounting holder, one antenna and two 1.5 m/5 ft. flat cables. | USA, Canada | SVPHWRMOD014 |
| | Smart-View Pro Quatro 868MHz only. Delivered with two 3.6 V lithium batteries, two sensor mounting kit, one mounting holder, one antenna and two 1.5 m/5 ft. flat cables. | Europe | SVPHWRMOD024 |
| Gateway | Smart-View Pro LoRaWAN 915 MHz platform-enabled Ethernet/Wi-Fi connectivity receiver with universal power supply | USA, Canada | SVPHWRLGW001 |
| | Smart-View Pro LoRaWAN 865-868* MHz platform-enabled Ethernet/Wi-Fi connectivity receiver with universal power supply | Europe | SVPHWRLGW002 |
| Sensor (CO₂/temp/rh) | OCEASOFT Smart Triple Point Sensor for CO ₂ , temperature, and relative humidity, CO ₂ : 0.5/9.9%. Temp: 0/+50°C, RH: 0/99%, calibrated at 5% CO ₂ /37°C/80% RH | All regions | SVPSENCCS001 |

* Not available in all countries or regions. Frequencies that are approved for use are country-specific. 865–868 MHz is approved for use in most European markets, and 915 MHz is approved for use in North American markets. Please consult your local representative for more details.



Learn more at thermofisher.com/ctslabequipment

thermo scientific