

CTS Compleo Fill and Finish System

Closed cell therapy fill and finish system

Streamline formulation and filling with a flexible, automated system for cell therapy manufacturing.

Key features of the Gibco™ CTS™ Compleo™ Fill and Finish System

- **Functionally closed, automated system**—reduces variability to help better control formulation and filling as compared to manual processing
- **High accuracy at low fill volume**—at 0.5 mL fill, volumetric accuracy of $\pm 10\%$
- **Flexible input configuration**—up to 4 inputs, depending on in-process sample allocation
- **Flexible output configuration**—adjustable dosing capability per line for up to 10 outputs, compatible with sterile-weldable cryobags, vials, and luer lock connections
- **Supports 21 CFR Part 11 compliance**—open platform communications unified architecture (OPC-UA) interface enables connection to a 21 CFR Part 11-compliant system



| Specifications | |
|------------------------------------|---|
| Instrument | |
| CTS Compleo Fill and Finish System | <ul style="list-style-type: none"> • Cat. No. A57164 • System includes: instrument, mixer, and computer system validated by Thermo Fisher Scientific for use with the CTS Compleo system* |
| Input capacity | Up to 4 inputs depending on in-process sample allocation |
| Flow rate | 5–50 mL/min |
| Number of outputs | 1–10 depending on number of input bags and orientation |
| Output volume range | 0.5 mL to 750 mL per individual dose |
| Output volume accuracy | $\pm 10\%$ at volumes as low as 0.5 mL |
| Volume verification | Independent volume checking mechanism, bubble sensors measure the volume transferred based on the volume of fluid pumped |
| Output container compatibility | Compatible with most cryobags and vials; can be connected via luer lock fittings or sterile welding |
| In-process sampling | Can dispense multiple samples with as little as 0.2 mL per sample |
| Air removal (burping) | Automatic (pre- and/or post-fill) or manual |
| Operating noise level | 65 dBA (typical) to 70 dBA (maximum) |
| Dimensions (H x W x D) | <ul style="list-style-type: none"> • Instrument: 31.5 x 11.4 x 18.0 in. (80 x 29 x 46 cm) • Instrument width if poles fully extended: 17.3 in. (44 cm) max |
| Weight | 55.0 lb (25.0 kg) |
| Connectivity | OPC-UA interface |
| Protocol Builder software | <ul style="list-style-type: none"> • Standard on all instruments, software guides users through the protocol development process • Create, modify, optimize, simulate, and save protocols |

| Mixer | |
|--|--|
| On/off | <ul style="list-style-type: none"> Controlled by instrument, activated as required during protocol Mechanical push button also enables user to turn the module on and off |
| Speed | 0 to 80 cycles/min, defined within the protocol being performed |
| Single-use kit | |
| Gibco™ CTS™ Compleo™ Single-Use Kit | <ul style="list-style-type: none"> Cat. No. A58165 (5 pack) Includes a 1 L mixing bag with a formulation capacity of up to 750 mL |
| Input capacity | Up to 4 inputs depending on in-process sample allocation |
| Output lines | <ul style="list-style-type: none"> Maximum of 10 output lines, depending on the number of input bags and orientation Line G can dispense multiple in-process samples into connected vessels for user testing |
| Mixing bag material | FP-FLEX™ bag, made from a single-layer, 12 mil polyolefin film |
| Kit tubing material | DEHP-free PVC |
| Tube dimensions | OD: 0.160 in. (4.0 mm); ID: 0.094 in. (2.4 mm) |
| Single-use kit sterilization | Gamma irradiation |
| Pump tube material | PharmaPure™ TPE (thermoplastic elastomer) tubing |
| Air inlet filter | 0.2 µm sterile filter, allows sterile air to be drawn into the kit via line A |
| Luer lock material | MABS (methyl methacrylate acrylonitrile butadiene styrene) |
| Kit identifier | Each kit is individually barcoded, read by the system at the start of the protocol |
| 21 CFR Part 11 compliance | |
| Optional software | Gibco™ CTS™ Compleo™ SAE (security, audit, and e-signature) Software supporting GMP compliance |
| Services | |
| Service plan | Maximize instrument uptime with superior services and support; recommend purchasing with the instrument |
| SmartStart training | Provides an introduction to system operation; included with instrument purchase |
| Qualification services | Instrument hardware qualification options include IQ/OQ (installation qualification and operational qualification) |
| Additional products to support manufacturing | |
| Gibco™ CTS™ media and reagents | These products are GMP-manufactured, safety-tested, and backed by regulatory documentation to support clinical and commercial manufacturing. Available in bottle (and some in bioprocess container) formats. |
| Gibco™ PeproGMP™ cytokines | Designed and manufactured for end-to-end cell therapy and biotherapeutic manufacturing, Gibco™ PeproTech™ GMP proteins are supported by extensive testing, documentation, and regulatory resources to reduce risk and quality system burden. |

* Computer system not shown.

The Regulatory Support File for the CTS Compleo system is available upon request at thermofisher.com/regulatory.

 Learn more at thermofisher.com/compleo

