



AT A GLANCE

LimONE

COMPLIANCE & QUALITY

GMP compatibility	Designed for use in GMP environments and to support GMP operations.
Regulatory standards	The commercial LimONE will be manufactured under an ISO 13485 quality management system; software designed to support FDA 21 CFR Part 11 requirements (e.g., access control, audit trails, e-records/signatures).
Consumables sterility & single-use	LimONE consumables are single-use, gamma-sterilized, and include: <ul style="list-style-type: none"> – Welding-compatible tubing kit (PVC) – Transparent, biocompatible culture chamber
DMSO compatibility	Consumables are designed to be compatible with DMSO-containing solutions.
Cleaning & maintenance	Compatible with standard cleaning reagents; cleaning approach aligned with incubator cleaning procedures.
Consumables shelf life	2 years (to be confirmed through stability studies).

CORE FUNCTIONALITY

Main functionality	Automated cell incubation (horizontal mode) + automated cell processing (vertical mode).
Cell processing capability	Automated wash, concentration, and media exchange within the culture chamber; the commercial LimONE will reach 700 × g.
Cell selection	Compatible with non-magnetic cell selection approaches (see application note) with development project ongoing. LimONE does not support magnetic cell selection (interoperable with third party systems).
Genetic modification	Compatible with viral vectors and non-viral reagents (e.g. LNPs), protocol dependent. LimONE does not support electroporation (interoperable with third party systems).

Feeding strategy	Automated bolus feed to max working volume (horizontal); media exchange at any time (alternative to continuous perfusion), configurable exchange volumes/percentages.
Analytics	LimONE provides visualization of basic sensor readings (temperature, CO ₂ and pressure), logs and alarms across devices. We are actively working on integrating advanced sensors into LimONE.
Interoperability	Designed to connect to other devices via consumable fluid path and software interfaces.

VOLUMES & LIQUID HANDLING

Volume range	2–400 mL (horizontal mode) and 5–800 mL (vertical mode).
Liquid handling	Large volumes automated pumping to/from welded bags (5 mL–2000 mL); small volumes manually handled via sterile connectors (0.1 mL–50 mL).
Flow rate range	25–150 mL/min.
Dead volumes	~10 mL (bag↔ culture chamber) ~3 mL (syringe↔ culture chamber) ~1 mL (culture chamber).
Low-volume pelleting	Can keep cells pelleted down to 5 mL in the culture chamber post-centrifugation (from 400/800 mL).

ENVIRONMENT CONTROL & UTILITIES

Utilities	Pure CO ₂ and compressed air gas lines (OD 10 mm, 1–1.5 bar).
Sensors	LimONE includes: <ul style="list-style-type: none"> – Closed-loop CO₂ control within the culture chamber. – Automated temperature control. Additional sensors are currently under development

REAGENT & CELLS

Reagent compatibility	LimONE is reagent-agnostic. We have demonstrated compatibility with commonly used suspension cell culture media.
Cell compatibility	LimONE is optimized for suspension cells and has demonstrated compatibility with T cells, HSCs, TILs, and NK cells. While these represent the most mature use cases, the platform architecture is cell agnostic.
Cell density	Wide range supported (process dependent); example T-cell workflows may start around 0.5×10^6 cells/mL and reach multi-billion cells at max volume in ~7 days (protocol dependent).

PERFORMANCE

Cell processing	Benchmarked against established gold-standard systems with comparable performance across key metrics.
Cell expansion	Benchmarked against established gold-standard systems with comparable performance across key metrics.

SOFTWARE ARCHITECTURE

Connectivity	Wi-Fi, Ethernet, USB.
Remote access	OPC-UA architecture enabling live remote monitoring of logs, process data, and alarms (subject to customer IT policies).

PRACTICALITIES

System footprint	Designed to fit on a standard lab bench.
Dimensions & weight	Current version of LimONE is ~50 kg; 685 × 1025 × 625 mm (W × D × H).
Power requirements	~650 W (EU) / ~1000 W (US via provided converter).
Operating conditions	+15°C to +30°C; 10–75% RH, non-condensing.
External equipment needs	Tube welder and tube sealer.
Parallelization	Core technology designed to be parallelizable.
Servicing	Preventive maintenance expected annually.
Pricing	Available for early adopters contact sales@limula.ch for access and further details.

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This document reflects the current stage of LimONE, which continues to evolve as we progress toward the commercial version