



NEW LiCellGrow

**Cell state visualization through continuous changes in glucose and lactate concentrations
Optimal culture conditions maintained through automatic culture control,
contributing to enhanced cell quality**

Ensuring cell quality and stability is vitally important in the manufacture of cell and gene therapy products such as cells for CAR-T therapy. However, manufacturing with cells as raw materials can be affected by factors such as variations in the manufacturing process and in the characteristics of the cells, which makes product quality unstable. Understanding the state of cells throughout the manufacturing process is thus an essential factor for enhancing the quality of cell and gene therapy products.

PHCbi offers an innovative solution—the LiCellGrow Cell Expansion System. Our unique In-Line Sensor monitors cell culture in real time, allowing automatic control of the culture to match the metabolic state of the cells while maintaining sterile conditions. This enables the state of the cells to be quantified, greatly improving the efficiency and stability of the manufacturing process.

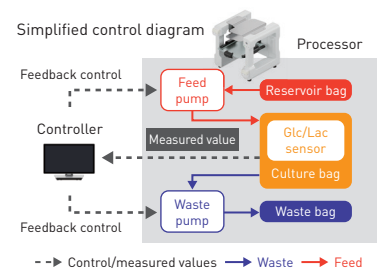
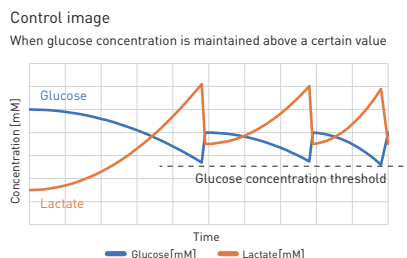
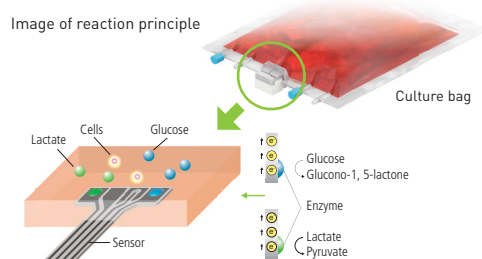
For Research Purpose Only

Product under development

Continuous measurement by the In-Line Sensor allows visualization of changes in glucose and lactate concentrations Automatic culture medium replacement ensures an optimal culture environment at all times

Glycolysis is one of the major energy metabolism pathways in cells. Since this process takes in glucose and produces lactate, changes in these substances are considered to be a useful indicator of the cellular state. The LiCellGrow Cell Expansion System not only conventionally detects pH/DO in the medium, but also measures the concentrations of glucose and lactate in real time. It is also capable of automatically replacing the culture medium based on the measured glucose and lactate values.

The dedicated Culture Bag is fitted with the PHCbi In-Line Sensor, which provides real-time measurements of glucose and lactate as continuous line data. The measured values are converted to concentrations to visualize cell status, and this information is used for automatically replenishing the medium and draining waste. This ensures that glucose and lactate concentrations in the medium are controlled and that cells are always cultured in their most suitable environment.



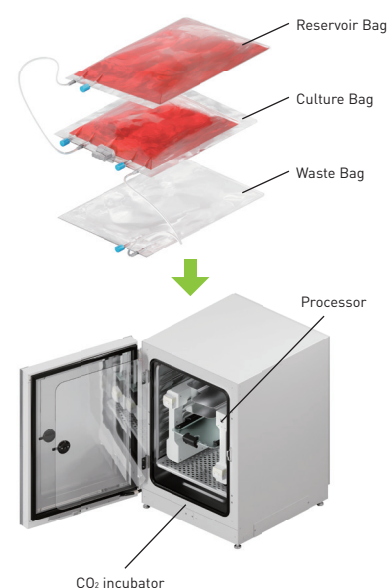
Closed system culture with single-use Culture Bags Highly reproducible culture with guaranteed sterility

The gas-permeable dedicated Culture Bags and the In-Line Sensor are for single use only, and they are gamma-irradiated before supply. The system simply needs to be fitted to rapidly start culture and maintain a sterile environment. The processor is installed inside the customer's CO₂ incubator, which controls temperature and CO₂ to allow culture in a highly reliable and reproducible environment. With measurement automated by In-Line monitoring, this system eliminates the need for sampling, greatly reducing the risk of contamination.

Monitoring of the cell culture process for cell management with a high level of quality control

Contributing to process development based on the QbD concept

Quality by Design (QbD) emphasizes consideration of product quality right from the design stage. Visualizing the concentrations of glucose and lactate in cell culture is essential for ensuring cell product quality. It enables the condition of cells in culture to be directly determined metabolically, which is difficult with conventional pH/DO monitoring, leading to optimization of the cell culture process. Using this functionality to create the desired culture environment helps in the development of processes based on the QbD philosophy.



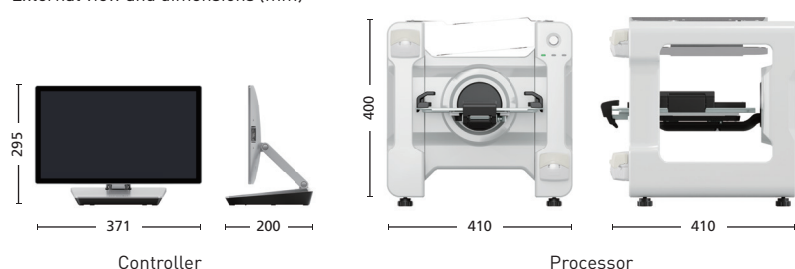
Main product specifications

Product overview	Name	Cell Expansion System (with glucose/lactate In-Line monitoring/control function)	Product overview	Culture Bag capacity	<ul style="list-style-type: none"> • 500 mL (minimum culture volume 100 mL) • 1000 mL (minimum culture volume 300 mL)
	Monitoring parameters	<ul style="list-style-type: none"> • Glucose, lactate (simultaneous measurement of both parameters) • pH/DO (simultaneous measurement of both parameters) *pH/DO measurement is available as an option 		Reservoir waste bag capacity	3000 mL
	Main device components	Controller, Processor		Monitoring time	Maximum 10 days
	Main consumables (single use)	Culture bag, Sensor holder, Reservoir waste bag		Measurement ranges	Glucose: 1-27 mM Lactate: 1.5-15 mM pH: 6.0 ~ 8.0 DO: 0 ~ 250% a.s. (a.s. = air saturation)

Controller	External dimensions	Width 371 mm × Depth 200 mm × Height 295 mm	Processor	External dimensions	Width 410 mm × Depth 410 mm × Height 400 mm
	Screen	15.6-inch-wide touch panel display		Installation	Inside CO ₂ incubator
	Weight	2.5 kg (excluding accessories)		Weight	14 kg *1

*1 Please use the dedicated reinforced tray when installing the processor in a PHCbi CO₂ incubator

External view and dimensions (mm)



- Specifications may change at the time of marketing because the product is under development.
- Actual colors may vary slightly from the printed images.
- Product specifications, ratings, and design may be subject to change without notice due to improvements, etc.