

CelCradle X®-Standalone Bioreactor

CelCradle X[®]

The Closed Automated Benchtop
Cradle Bioreactor

CelCradle X[®]

The CelCradle X (CCX) is a closed, automated single-use benchtop bioreactor that comes with its own fully automated harvesting system. Its design features an external Siemens HMI PLC control tower, automated parameter controls for pH and DO, and separation of the matrix (where packed-bed resides) and mixing vessel making it ideal for adherent cultures especially for autologous cell therapy applications.

The matrix vessel can accommodate packed-bed volumes from 0.1 – 0.3 L to achieve higher cell density yields. Choose from different Tide Motion macroporous carriers or your own for your next adherent cell expansion.

**cell yield may vary based on cell type, media used, process efficiency, and more.*



CelCradle X – Standalone Bioreactor (CCX-SB)

Features:

- Touchscreen Siemens HMI PLC Control Tower
- Single use optical pH and DO sensor dots for parameter control and monitoring
- Culture in batch, fed-batch, perfusion, and 100% media exchange
- Culture in normal or hypoxic conditions
- Partnered with CelCradle X Harvesting System (CCX-HS) for closed system live whole cell harvest

**design and specifications subject to change*

CelCradle X – Isolator Integration (CCX-ISIN)

Features:

- Dockable CelCradle X unit with integrated Siemens HMI controller
- Work in an ISO Class 5 environment
- Integrated with independent H₂O₂ biodecontamination system
- Fully enclosed cell processing via third party or Esco bioprocessing equipment integration



What's In It?

Main Chamber

Acts as a large CO₂ incubator that houses the matrix vessel, mixing vessel, feed/harvest-, glucose/alkali bags.

Glucose/Alkali Bags

Contains glucose/alkali solution for pH control

Feed/Harvest Bags

Contains culture medium for the feed process as well as harvest bag for harvesting waste/conditioned media.

Run in:

- » batch
- » fed-batch
- » perfusion mode

Matrix Vessel

Used to house the macroporous carrier/client's own carrier where cells reside

Control Tower

Runs in 21 CFR Part 11 Compliant software via intuitive HMI. It controls the parameters need to run the CCX unit.

Integrated with:

- Emergency Stop Button
- On/Off Switch
- Four (4) Peristaltic Pumps (feed, harvest)

Mixing Vessel

Equipped with magnetic impeller for mixing. This is where the pH and DO optical sensors are located for pH and DO level monitoring and where tubings are connected for running a specific process mode.

Load Cell

1. **Matrix Vessel** - Responsible for detecting the weight of the matrix vessel for the Tide Motion control.
2. **Mixing Vessel** – Responsible for detecting the weight of the mixing vessel for perfusion process

Applications

- Autologous Adherent Cell Therapy
- cGMP Stem Cell Manufacturing
- Intracellular, Secreted Viral Vector or Virus Production
- Monoclonal Antibody/Secreted Proteins
- Exosome Production
- Adherent Cell Master Cell bank (MCB) or Working Cell Bank (WCB) Generation

CelCradle X[®] Harvesting System

The CelCradle X[®] Harvesting System (CCXHS) is used to automatically harvest live whole cells in a closed horizontal manner, from the CelCradle X matrix vessel through setting up culture harvest parameters. It can also be used for small scale process development for TideXcell Harvesting System (TXLHS).

The automated harvesting run involves set up from washing to harvesting live whole cells, with an efficiency of more than 90%. All major harvesting processes are standardized for increased cell harvest and viability, enabling the production of GMP-compliant cell products.

**harvesting efficiency may vary based on cell line, media, enzyme used, and etc.*



Applications

- Closed, automated process from rinsing to harvesting
- Mammalian cell harvest
- Biomass harvest for seed train, bioprinting, or cellular agriculture
- Intracellular virus harvest

Features:

- Single-use harvest assembly kit for closed, automated harvesting
- Harvest viable cells within 1-3 hours
- Heating incubator for harvest procedures that requires 37 °C
- Achieve >90-120% harvesting efficiency

Note: Harvesting efficiency will be dependent on the cell line used, media or enzyme used, process, etc.

How Does It Work?

CCXHS - Shaking Incubator Chamber

CCX Matrix Vessel

Placed within the incubator in a horizontal manner for efficient shaking during cell detachment step

Pinch Valve



**design and specifications subject to change*

Pinch Light Valve Indicator

Peristaltic Pump

Responsible for pumping media into and out of the bags as tubes are connected into a manifold to the CCX matrix.

CCXHS Assembly Kit

Includes the bag that will hold the rinse solution, enzyme, media, inhibitor, harvest, and waste, inhibitor bags into place.

**the size of the bags will vary based on packed-bed volume used.*

Bag Hanger Rod

Emergency Stop Button

Stops operation at once when pressed

CCXHS Controller

Controls parameters for the CCXHS harvest run

Auxiliary Peristaltic Pump

(additional pump for back-up)

Harvesting Procedure

- 1. Install.** Connect the tubing manifold to the CCX matrix vessel and input your parameters in the CCXHS controller.
- 2. Removal of culture medium/waste.** Existing media or waste is pumped out of the vessel to start the harvest process.
- 3. Rinse: Cells are washed via PBS/EDTA addition.** The system's rotary arms will rotate the bottle from left to right to distribute the PBS equally and slowly rinse the surface. The wash solution will be pumped out afterwards.
- 4. Enzyme:** Trypsin/EDTA (or other dissociating solution) is pumped into the vessel and will gently be distributed into the vessel via rotating mechanism.
- 5. Incubate and Inhibitor Addition:** After 15 minutes of incubation, an enzyme inhibitor will be pumped into the vessel. (This step is optional)
- 6. Mechanical Agitation:** Automatic vertical shaking of the vessel is done to further detach the cells from the carriers.
- 7. Add in Medium:** Culture medium that contains serum or trypsin inhibitor are pumped in to flush the cells.
- 8. Collect:** Gather the solution with suspended cells into the harvest bag.
- 9. REPEAT STEP 5-6 about 5 times.** Obtain cell pellet through centrifugation.

Product Specifications

CelCradle X®	
Base Units	CelCradle X Standalone Bioreactor (CCX-SB) Inclusive of: - CelCradle X incubator chamber - Siemens HMI control tower - Integrated load cell, pumps
	CelCradle X-Isolator Integration (CCX-ISIN) Inclusive of: - Dockable CCX unit - Integrated control
Standard Consumables	
CCX-SUMAV-BN_	Matrix vessel pre-packed with BioNOC carriers
CCX-SUMAV-BM_	Matrix vessel pre-packed with BioMESH carriers
CCX-SUMIV	Single use mixing vessel inclusive of magnetic impeller
pH sensor dot	Single use optical pH sensor
DO sensor dot	Single use optical DO sensor
CCX-FHB-AC	Feed/Harvest bag with sterile tubing connections
CCX-BG-AC	100 mL glucose or alkali bag

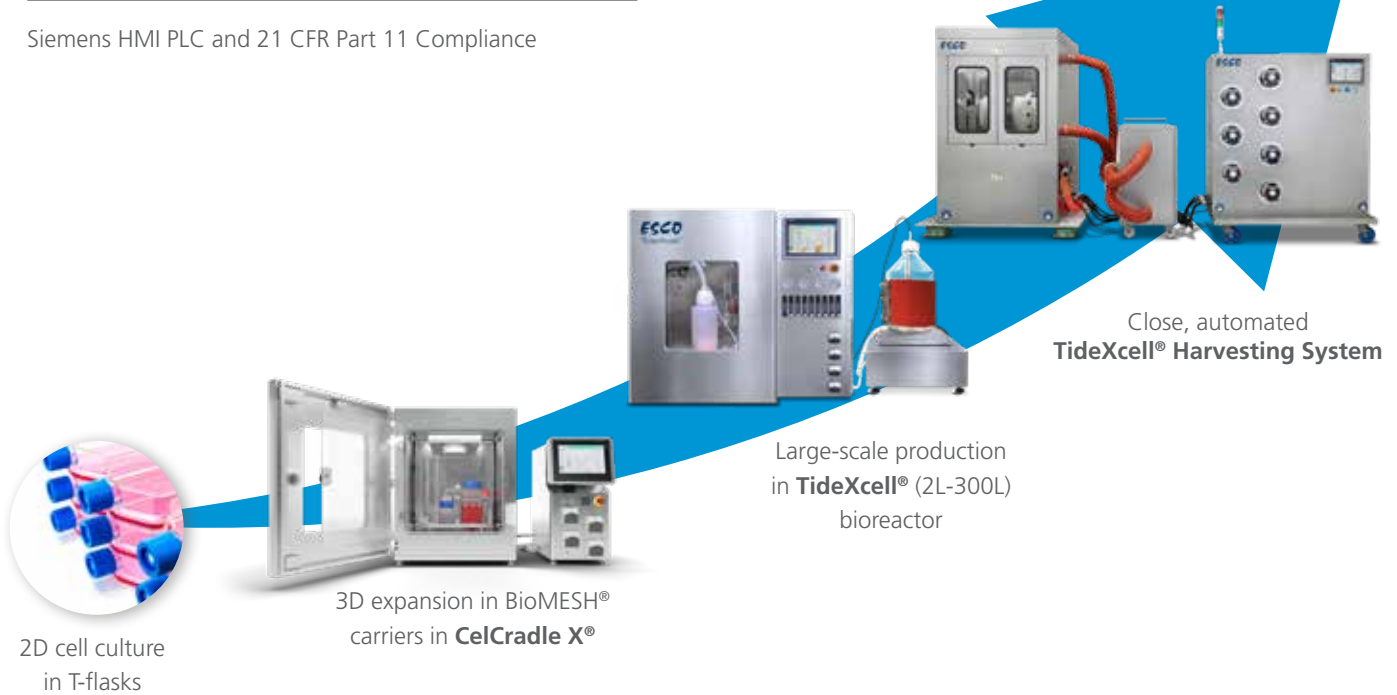
**specifications subject to change*

CelCradle X® Harvesting System (CCXHS)	
External Dimension (W x D x H)	Chamber: 543 x 640 x 759 mm (21.38 x 25.20 x 29.88 in.) Harvest System: 928 x 380 x 822 mm (21.38 x 25.20 x 29.88 in.)
Power	Single Phase 220 V, 50 Hz
Motor	Shaker Motor
Capacity	CCX Matrix Vessel
Control	HMI 7" color

**specifications subject to change*

Scale Up Strategy For Manufacturing

Siemens HMI PLC and 21 CFR Part 11 Compliance



Small Scale Autologous Production

Large Scale Allogenic Production



CelCradle X[®] Harvesting System (CCXHS)



CelCradle X[®] and TideXcell[®] bioreactors can be integrated with Cell Processing Isolators

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