Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Specification Sheet

ekko™ Acoustic Cell Processing System

Hear the sound of freedom with the ekko™ System, acoustic wave technology for cell therapy processing

The ekko™ Acoustic Cell Processing System is an automated and closed platform designed to support unmatched flexibility and ease-of-use. The system was developed for cell therapy organizations focused on research programs through manufacturing. It was designed for organizations in need of an industrialized, adaptable cell processing system uniquely capable of gentle, scalable, and reproducible processing required to achieve the promise of advanced therapies.

Concentrate and wash steps throughout the cell therapy process can be particularly challenging for a variety of reasons – low cell recovery and viability, open-processing steps, and operator error can plague this unit operation. With the ekko™ Acoustic Cell Processing System, our touchless technology frees users from traditional mechanical and filtration-based methods, increasing cell quality. With ekko™ Architect, our protocol development tool, total control is at your fingertips to help support your program goals.

Key Features and Benefits

- High cell recovery and viability with residual removal of >95%
- Simple and ergonomic installation of ekko™ Single-Use Assemblies
- ekko™ Software and ekko™ Architect, our flexible protocol development tool, is designed for easy navigation and use
- Freedom from process limitations - for use in multiple unit operations across a variety of cell types
- Low volume processing enabling collection of 5 mL cell concentrate
- 21 CFR Part 11 compliance-ready and developed under GAMP5 guidelines

Specifications

ekko™ System Control (SCU) and Fluid Handling (FHU) Units

ekko™ System	
Power Supply Voltage	SCU: 120-240 VAC, 50/60 Hz, 10/6.3 Amps
	FHU: 120-240 VAC, 50/60 Hz, 6.3/3.15 Amps
Dimensions (Height x Width x Depth)	System with hangers extended H: 549 mm (21.6 in) W: 1158 mm (45.6 in) D: 542 mm (21.4 in)
	SCU, only H: 293 mm (11.5 in) W: 457 mm (18 in) D: 522 mm (20.5 in)
	FHU, only H: 256 mm (10.2 in) W: 457 mm (18 in) D: 542 mm (21.4 in)
	Panel PC with Touchscreen H: 260 mm (10.2 in) W: 402 mm (15.8) D: 39.7 mm (1.6 in)
Weight	Total System: 63.6 kg (140.2 lb)
	SCU: 28.2 kg (62.2 lb)
	FHU (dry): 34.5 kg (76.0 lb)
	Electrical cables: 0.9 kg (2 lb)
Bag Hangers, Hooks	2 Bag Hangers support 4 Hooks and 2 Auxiliary Hooks
Operating Noise Level	Operator: 70 dBA
	Bystander*: 60 dBA
Shipping Temperature	0 °C – 50 °C (32 °F – 122 °F)
Shipping Crate Interfaces (located on bottom of each unit)	SCU: 2
	FHU: 2
System Control Unit (SCU)	
Air Inlet, Front Panel	2
Fans with Fingerguards, Rear Panel	2
Connections	
USB 2.0 Type A Female	
Front Panel	1
Rear Panel	3
Interface Control to FHU RJ45, Rear Panel	2
Fault Monitoring to FHU DB9 Female, Rear Panel	2
RF to FHU BNC Jack, Rear Panel	2
Power Inlet Receptacle IEC320-14, Rear Panel	1
Power Outlet Female Socket IEC320-C13, Rear Panel	1

Fluid Handling Unit (FHU)	
Piezoelectric Transducer, Front Panel	1
Piezoelectric Transducer Dimensions (Height x Width x Depth)	H: 50.3 mm (2.0 in) W: 92.1 mm (3.6 in) D: 28.4 mm (1.1 in)
Peristaltic Pump, Front Panel	1
Peristaltic Pump Flow Rate, Pump Capacity	≤ 190 mL/min
Peristaltic Pump Flow Rate, Operating Range	10-120 mL/min**
Valves, Front Panel	9
Bubble Sensors, Front Panel	4
Temperature Sensors, Front Panel	2
Latches for ekko™ Single Use Assembly	4 quarter-turn
Cooling Loop Pump Flow Rate	1.2 L/min
Cooling Loop Temperature	15°C
Cooling Loop Volume, Maximum	1 L
Cooling Loop Volume, Operating Range	800 mL - 950 mL
Fans with Fingerguards, Rear Panel	2
Connections	
Interface Control to SCU RJ45, Rear Panel	1
Fault Monitoring to SCU DB9 Female, Rear Panel	1
RF to SCU BNC Jack, Rear Panel	1
Power Inlet Receptacle IEC320-C14, Rear Panel	1
Panel PC, ekko™ Software and ekko™ Architect	
Operating System	Windows 10 Enterprise Build 14393
CPU	Intel Celeron J1900
Frequency	2.0 GHz Quad Core
Cache	2 MB
Memory	4 GB
USB 2.0 Type A Female	1 (can be disabled)
Ethernet GigE RJ45	1 (can be disabled)
Power Connector 12V/ 7A ITE	1
Report Generator	Yes
Protocol Editor	Yes, ekko™ Architect
Protocol Version Control	Yes
Definable User Access	Yes
Alarm and Notification System	Yes
Materials of Construction	
SCU and FHU Covers	Stainless Steel, AISI 304
Bag Hangers and Hooks	Stainless Steel, AISI 304
Latches	Stainless Steel, AISI 304
Shipping Crate Interface	Stainless Steel, AISI 304

*Bystander distance defined as 1 M from the system

**Cell and process dependent

ekko™ Single Use Assembly

Dimensions (Height x Width x Depth)	Cartridge with Acoustic Chamber Cover, only H: 210 mm (8.3 in) W: 297 mm (11.7 in) D: 59 mm (2.3 in)
Weight	1.05 kg (2.31 lb)
Chamber Volume	84 mL (5.13 in3)
Operating Fluid Temperature	4°C – 37°C
Acoustic Chamber Capacity per Load*	4e9 cells **
Recommended Input Volume Range	50 mL - 5 L**
Minimum Output Volume	5 mL
Shipping Test Meets	ISTA Integrity-Plus Test Procedure 3A
Shelf Life	1 year
Sterilization Method	Gamma irradiation to a dose level of 25–40 kGy

*The ekko™ Chamber can be filled multiple times a process run

**Cell and process dependent

Materials of Construction	
Acoustic Chamber Cover	Polycarbonate
Acoustic Chamber	Polycarbonate
Cartridge Base and Back Panel	Polycarbonate
Membrane	Polyetheretherketone (PEEK)
Assembly Tubing, Cartridge	Thermoplastic Elastomer (TPE)
Assembly Tubing, Tails	Polyvinyl chloride (PVC), DEHP-free
Assembly Tubing Connectors	Polypropylene and Polycarbonate
Pump Tubing	Platinum-cured (PC) Silicone

Component Material Testing

Materials of construction for the ekko™ Single Use Assembly meet, post-gamma irradiation:

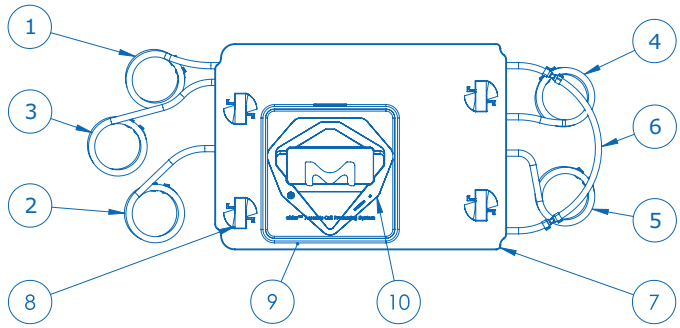
Tests	Properties
USP<88>	Biological Reactivity Test in Vivo for Class VI
USP<87>	Biological Reactivity Test in Vitro, Cytotoxicity
USP<661>	Plastic Containers Physiochemical
Dimethyl Sulfoxide (DMSO) Compatibility	Compatible with 10% DMSO

ekko™ Single Use Assembly Tubing Specifications

Location	Tubing	Tubing Label Reference	Material	Inner Diameter	Outer Diameter	Tubing Length	Tubing Connection	End Connection
Top, Left	Cell Input Line	A	TPE	3.2 mm (0.125 in)	6.4 mm (0.250 in)	305 mm (12 in)	Straight Connector, 3.2 mm (0.125 in) ID	Seal
			PVC		4.8 mm (0.188 in)	305 mm (12 in)		
Bottom, Left	Cell Recirculation Line	B	TPE	3.2 mm (0.125 in)	6.4 mm (0.250 in)	305 mm (12 in)	Straight Connector, 3.2 mm (0.125 in) ID	Seal
			PVC		4.8 mm (0.188 in)	305 mm (12 in)		
Middle, Left	Solution Line	C	TPE	3.2 mm (0.125 in)	6.4 mm (0.250 in)	305 mm (12 in)	Straight Connector, 3.2 mm (0.125 in) ID	Seal
			PVC		4.8 mm (0.188 in)	305 mm (12 in)		
Top, Right	Waste Line	D	TPE	3.2 mm (0.125 in)	6.4 mm (0.250 in)	305 mm (12 in)	Straight Connector, 3.2 mm (0.125 in) ID	Seal
			PVC		4.8 mm (0.188 in)	305 mm (12 in)		
Middle, Right	Product Line	E	TPE	3.2 mm (0.125 in)	6.4 mm (0.250 in)	305 mm (12 in)	Straight Connector, 3.2 mm (0.125 in) ID	Seal
			PVC		4.8 mm (0.188 in)	305 mm (12 in)		
Right	Pump Line	Not Labeled	Silicone	3.2 mm (0.125 in)	6.4 mm (0.250 in)	190 mm (7.48 in)	Straight Connector, 3.2 mm (0.125 in) ID	N/A

ekko™ Single Use Assembly

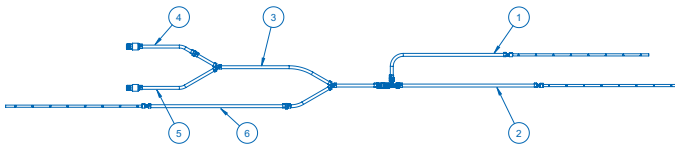
Position Number	Description
1	Cell Input Line [A]
2	Cell Recirculation Line [B]
3	Solution Line [C]
4	Waste Line [D]
5	Product Line [E]
6	Pump Line
7	Cartridge
8	Latch Interface
9	Acoustic Chamber Cover
10	Acoustic Chamber



ekko™ Single Use Maintenance Assembly Tubing Specifications

Location	Tubing	Tubing Label Reference	Material	Inner Diameter	Outer Diameter	Tubing Length	End Connection
Top, Left	Cleaning Solution Line	A	PVC	3.2 mm (0.125 in)	4.8 mm (0.188 in)	305 mm (12 in)	Seal
Bottom, Left	Water Line	B	PVC	3.2 mm (0.125 in)	4.8 mm (0.188 in)	305 mm (12 in)	Seal
Bottom, Right	Waste Line	C	PVC	3.2 mm (0.125 in)	4.8 mm (0.188 in)	305 mm (12 in)	Seal
Top, Middle	Pump Line	D	Silicone	3.2 mm (0.125 in)	6.4 mm (0.250 in)	255 mm (10 in)	N/A
Top, Right	Cooling Loop Top Line	E	Silicone	3.2 mm (0.125 in)	6.4 mm (0.250 in)	170 mm (6.7 in)	Coupling
Middle, Right	Cooling Loop Bottom Line	F	Silicone	3.2 mm (0.125 in)	6.4 mm (0.250 in)	178 mm (7 in)	Coupling

ekko™ Single Use Maintenance Assembly



Position Number	Description
1	Cleaning Solution Line [A]
2	Water Line [B]
3	Pump Line [D]
4	Cooling Loop Top Line [E]
5	Cooling Loop Bottom Line [F]
6	Waste Line [C]

Regulatory Information

ekko™ System	
Enclosure Rating	IP2X
CE	This product is CE marked in compliance with European laws and regulations that apply to the products scope. See the products Declaration of Conformity for more details.

ekko™ System	
ekko™ Software	Designed to support compliance to 21 CFR Part 11 and developed under GAMP5 guidelines*
Animal Origin Statement	All component materials in the wetted path of this device are animal free.

*Independent audit of the 21 CFR Part 11 Regulations and GAMP5 Guidelines ensure conformity set forth by the FDA and ISPE Guidelines, respectively.

Ordering Information

System	
ekko™ Instrument	**ACWHW001FXX***
Single Use Assembly	
ekko™ Single Use Assembly	**ACWSUF2001R**
ekko™ Single Use Maintenance Assembly	**ACWSUF2001RM**
Services	
Installation and Commissioning	**SSVQUAW001**
Preventative Maintenance	**SSVPRMW001**
Warranty	**SSVWTYW001**
Training	**SSVTRNW001**

*XX defined by region

To place an order or receive technical assistance

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