

# Sepax™ C-Pro cell processing instrument

## SEPAX C-PRO CELL PROCESSING SYSTEM

The Sepax C-Pro cell processing system is an automated and functionally closed technology for cell processing when developing and manufacturing cell therapy products. The system, which includes the instrument, Sepax C-Pro application software, and kits, is a multipurpose solution which allows you to combine multiple processing steps in a versatile manner. These steps include but are not limited to enrichment, magnetic bead incubation, spinoculation, concentration, washing, dilution, and splitting. Using Chronicle™ automation software, Sepax C-Pro system can be integrated with other cell therapy instruments from Cytiva and third-party instruments.

- **Facilitate your operations.** Compact design and user-friendly interface that can automate multiple steps of your processes to optimize resource requirements.
- **Support your requirements and system implementation.** Automated and functionally closed system to support GMP compliance.
- **Maintain flexibility.** Sepax C-Pro system is a multipurpose solution, allowing you to maintain the autonomy of each step.
- **Simplify record keeping.** Sepax C-Pro system can transmit instrument data and alarms for remote monitoring or for incorporation into a Chronicle automation software eSOP.

2.1.1- sistema gali būti integruota su kitais ląstelių terapijos instrumentais iš Cytiva ar trečiųjų šalių.

3.2.3

3.5

3.1



Fig 1. Sepax C-Pro instrument. The centrifugation chamber is in the middle, and the touchscreen is at the top.

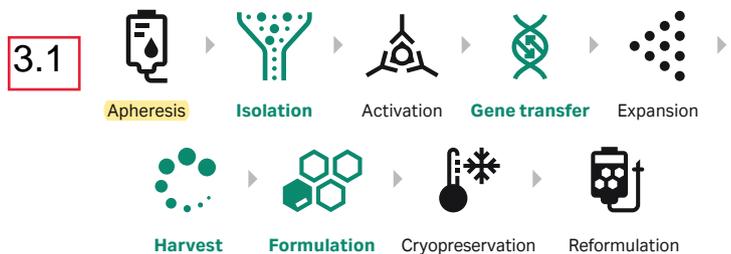


Fig 2. General workflow for cell therapy manufacturing. The Sepax C-Pro cell processing system provides solutions for the steps highlighted in green.

## Applications and related products

App soft	3.1.1 - Ląstelių koncentravimas pašalinant plazmą iš šviežio aferezato
PeriCell C-Pro	CT-49.1 Concentrate cells from apheresis product via plasma depletion
PlateletFree C-Pro	CT-60.1 Concentrate cells and remove platelets from apheresis product
BeadWash C-Pro	CT-60.1 or CT-90.1 Concentrate and wash cells from fresh or thawed apheresis products, incubate magnetic beads in cell fraction obtained and wash unbound beads
NeatCell C-Pro	CT-90.1 Enrich mononuclear cell fraction from cellular products via a density gradient medium
SpinOcultation C-Pro	CT-60.1 Concentrate, wash, and transduce isolated cells by spinocultation
CultureWash C-Pro	CT-60.1 or CT-90.1 Dilute, concentrate, and wash fresh or thawed cellular products
Dilution C-Pro	CT-49.1, CT-60.1, or CT-90.1 Dilute and split cellular products into multiple bags

Experience the versatility of Sepax C-Pro system in its entirety; our comprehensive software pack comprises all Sepax C-Pro application software.

## Product specifications

Feature	Description
Core technology	Electric centrifugation motor and pneumatic circuitry for piston drive Pressure monitoring sensor Optical line sensor
Traceability	Barcode reader 3.3 - barkodų skaitytuvas Data management with PDF reports and procedural graphs — data saving capacity on the instrument 32 log files, 50 PAT files, and 50 report files (PDF)
User interface	Color touchscreen with an intuitive graphical user interface (GUI)
Software	Compatible with Sepax C-Pro software only Windows® XP embedded and proprietary GMAP application software
Unified digital platform	Chronicle automation software connects Cytiva instruments and third-party instruments
Connectivity	Four USB slots and two ethernet ports
Dimensions	W: 27 cm, L: 40 cm, H: 46 cm (10.6" x 14.7" x 18.1"), 16.3 kg (35.9 lb)
Power	1000 W, 100–240 VAC, 50/60 Hz

## Safety and compliance

Sepax C-Pro system is manufacturing equipment with the CE mark (Machinery Directive 2006/42/EC) intended for cell therapy manufacturing in good automated manufacturing practice (GAMP™) compliant environments. It is compliant with IEC-61010, IEC-61326, and IEC-62304 standards.

Sepax C-Pro system is not intended for any therapeutic or diagnostic use in humans. Only for use with Sepax C-Pro system kits.

Country	Compliance
China	Instrument complies with specific Chinese standard 2
3.1.2 - Mononuklearų frakcijos išgavimas iš mišraus sąstato ląstelių suspensijos naudojant tankio gradientio terpes	UL 61010-2-020 :2016-12 05/R :2015-07
3.1.3 - Šviežių ir atšildytų ląstelių suspensijų skiedimas, koncentravimas ir plovimas	ICES-001
	CAN/CSA-C22.2 NO. 61010-1 :2012
Japan	PSE mark (Electrical safety): Electrical Appliance and Material Safety Law (Denan Law): Not applicable EMC (VCCI Mark (voluntary mark): Not applicable J-MOSS (JIS C 0950 The marking for presence of the specific chemical substances for electrical and electronic equipment): Not applicable here as Sepax C-Pro is not in the scope of JIS C0950 standard
South Korea	Sepax C-Pro system is registered in South Korea (registration number: r-r-bsa-29264741) under the clause 3, article 58-2 of Radio Waves Act. Certificate 374a-ad20-b2a8-b37e. Registration date: 31.10.2018 EMC test report e42830-01-01mk issued on 13.11.2018

## Storage requirements

Only operate the Sepax C-Pro instrument on a flat, stable, horizontal, and clean surface. Use it in an open environment to allow sufficient ventilation. Operate and store within the following conditions:

2.1.2 ir 3.2.2 - Spalvotas jutiklinis ekranas (vartotojo sąsają per jį) su intuityviu grafiniu vartotoju sąsaja (GUI) - integruotas kompiuteris

Temperature	7°C to 27°C	0°C to 50°C
3.2.1 - Windows pagrindu operacinė sistema	75% ndensing	20% to 75% non-condensing

3.5 - Galimybė prijungti prie aukštesnės organizacijos procesų valdymo ir atsekamumą integruojančios informacinės sistemos

3.4 - 4 USB jungtys ir 2 Ethernet jungtys

4. stalinio tipo įrenginys su nurodytais matmenimis bei svoriu: 27 x 40 x 46 cm ir 16,3 kg

3.2.3 - programinė įranga

5. maitinimas pritaikytas Lietuvoje galiojančiam standartui - 220 VAC, 50/60 Hz

# Ordering information

Product	Product code
Sepax C-Pro cell processing instrument	29264741

Related products	Product code
Sepax C-Pro application software pack	29734656
CT-49.1 Sepax C-Pro cell processing kit	29264738
CT-60.1 Sepax C-Pro cell processing kit	29264739
CT-90.1 Sepax C-Pro cell processing kit	29264740
CPAK-100 sampling line	29275109
CPAK-101 sampling line	29275108

2.1.3 - sterilių vienkartinių priemonių sąrašas, kurį galima įsigyti naudojimui su Sepax-C-Pro prietaisu

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