

Large-scale Continuous Flow Ultracentrifuge



himac CC40 SERIES

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CC40/CC40S

The above photo shows the model CC40 with options.

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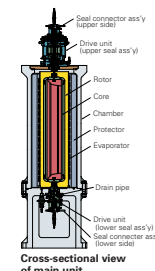
himac CC40 series is designed expressly to purify large-volume samples such as vaccines. Depending on the optional cores and sample feed systems selected, the CC40 series can be used to purify the active components of viruses by continuous flow centrifugation or by batch centrifugation using the density gradients solution, and even rough separation of large-volume samples for pelleting.



CE

Model CC40

This model is designed expressly to purify large-volume corpuscle samples such as vaccines. Its high performance is defined by an 8.0 L maximum capacity with batch centrifugation and 7.7 L maximum capacity with continuous flow centrifugation, speeds of up to 40,000 rpm and a maximum RCF of 118,000 x g.



The most reliable drive system in the world

Drive system of the CC40 series is himac original and the latest high-frequency induction motor. We have experience over 25 years to use the high-frequency induction motor for drive system of the large-scale continuous flow ultracentrifuge since our 1st model was launched into the market. This drive system does not require an extra space for a separate air turbine compressor which widely used in conventional type of large-scale continuous flow ultracentrifuge in the market. Our drive system keeps on sophisticated continuously; it has established reputation of the most reliable drive system nowadays.



Specifications of the main body

Specifications and features of the CC40

Model	CC40
Max. speed (rpm)/max. RCF (x g)	40,000/118,000
Speed control accuracy	±100 rpm
Rotor temperature control accuracy	±2°C (0 to 40°C)
Vacuum system/ultimate vacuum	Oil rotary vacuum pump/26.7 Pa (0.2 Torr)
Drive motor	Induction motor
Dimensions (mm)	1,750 (W) x 1,150 (D) x 2,950 (H), height to the control panel: 1,270
Weight (kg)	880 (main unit: 630, control unit: 250)
Power requirements	Single phase AC 200/208/220/230/240 V ±10%, 30A, 50/60 Hz

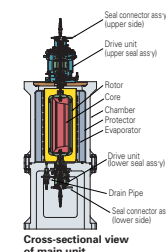
Notes: 1. Installation charge is not included.
2. The rotor is an option



CE

Model CC40S

With approximately one-half the capacity of the CC40, the CC40S is ideal for research, development and small-volume production of pharmaceuticals. This model has a maximum continuous centrifugation capacity of 1.6 liters, maximum speeds of 40,000 rpm and maximum RCF of 118,000 x g.



Designed with safety in mind

CC40 series comply with international standards and or requirements, such as EN60204-1, EN61000-6-4, EN61000-6-2. Of course CC40 series carry the CE mark with them.

Stable High Speed and High Centrifugal Force

Our reliable drive system stably offers maximum speed of 40,000 rpm and maximum RCF of up to 118,000 x g to support a wide variety of separation and density gradient centrifugation applications, even if titanium-made core is used.

Quiet Operation

The high-frequency induction motor reduces operating noise to 68dB at 40,000 rpm.

Specifications and features of the CC40S

Model	CC40S
Max. speed (rpm)/max. RCF (x g)	40,000/118,000
Speed control accuracy	±100 rpm
Rotor temperature control accuracy	±2°C (0 to 40°C)
Vacuum system/ultimate vacuum	Oil rotary vacuum pump/26.7 Pa (0.2 Torr)
Drive motor	Induction motor
Dimensions (mm)	1,750 (W) x 1,150 (D) x 2,160 (H), height to the control panel: 1,270
Weight (kg)	750 (main unit: 500, control unit: 250)
Power requirements	Single phase AC 200/208/220/230/240 V ±10%, 30A, 50/60 Hz

Notes: 1. Installation charge is not included.
2. The rotor is an option

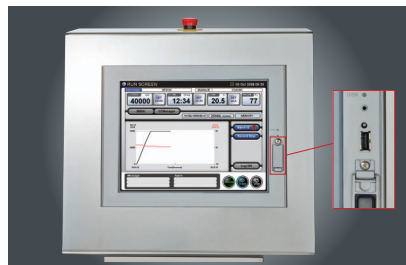
Now two types of control unit are available for your options.

Conventional Control Unit (Standard)



If you are looking for a cost-effective model, the conventional control unit equipped with LED display and keypad operation controller is available. This conventional control unit offers simplified operation to users. The operational data, such as speed, time temperature etc., can be output to an optional chart recorder which supports FDA 21 CFR Part11 and construct the data logging system comprehensively. In addition, you can upgrade controller to Windows® based touch sensitive LCD panel PC controller at option, so that CC40 series offer the same ability to manage operating log data as well as New optional control unit does.

New Control Unit (Option)



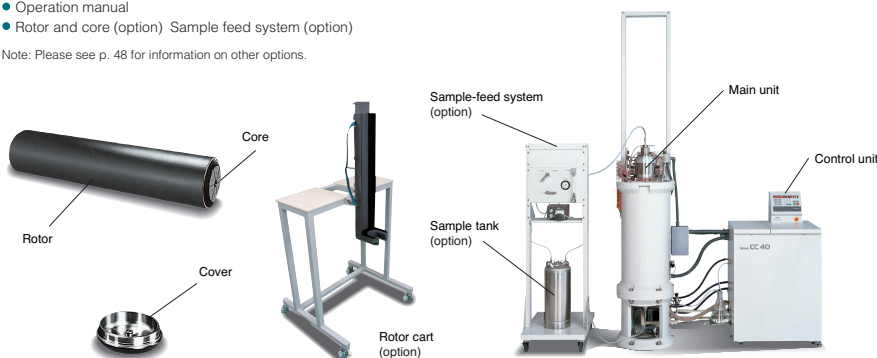
Windows® based touch sensitive LCD panel PC controller enclosed in an IP65 industrial housing offers simplified operation to users. Our intelligible screen design with GUI (graphic user interface) and high contrast against back screen enables users to identify operating status at a glance and operate the system easily. All operations such as parameter setting are done by touching icons or pop-up keyboard on the LCD. Access level of users is securely controlled by ID and password. Of course, the new control unit supports FDA 21 CFR Part 11 so that operating data is handled with the highest security and prevented from corruption. In addition, operating log data can be output in CSV format via USB port for your data management or analysis by commercially available data base or spreadsheet software. Ethernet communications is also accommodated.

* Screen design is subject to change due to upgrade of software without advanced notice.

Configuration

- Control unit (controller, refrigeration unit and vacuum pump)
- Main unit (vacuum chamber, motor and lift)
- Rotor cart for installing and replacing the rotor (option)
- Maintenance tools and spare parts
- Operation manual
- Rotor and core (option) Sample feed system (option)

Note: Please see p. 48 for information on other options.



Various options to conform to customers' usage purpose

The CC40 series have many options to offer maximum flexibility to conform to customers' usage purpose. We are very flexible to customize the CC40 series upon request of users. Following is examples of options available for the CC40 series;

Mechanical Option

Stainless Steel Construction

Control unit housing and rotor lift, including oil box conforming to IP65 housing, of the main unit are also made of the stainless steel to offer the cleanest environmental in the pharmaceutical manufacturing facility. Of course, you can select stainless steel material for rotor chamber as well as an optional rotor cart, a sample feed system and a template at your option. In addition, all sample-contacting metallic parts of the CC40 series can be changed to corrosion-resistance stainless steel according to U.S. FDA current Good Manufacturing Practice (cGMP) requirement.

Remote Operation

Installation of the CC40 series is very flexible. Control unit can be placed at either sides of the main unit. In addition to install both units in the same room, such as the clean room, it is possible to install the main unit in the clean room and the control unit outside of clean room for remote operation. An additional control panel can be placed beside the main unit. (patent approved)

Vacuum Filter

To prevent from any contaminations into the working room, vacuum filter can be assembled in the vacuum suction line.

Sterilize-in-Place (SIP)

To sterilize the rotor and the parts in contact with sample, steam or chemical sterilization in installed placed is possible.

Sanitization of FSCL (Face Seal Cooling Line)

To keep FSCL in hygienic after sterilization, FSCL can be modified for direct sanitation using hot water.

After installation Option

Documentation support

To support your official inspection or audit of cGMP, we can provide documentation of the CC40 series that supports your cGMP documentation. Of course, FAT (factory acceptance test) is conducted and its documentation is provided.

IQ/OQ Validation

Do you feel that IQ/OQ validation is so complicated? Do not worries about it, our engineers help you to set up protocols and validate IQ/OQ on your request.

Service Support

Operation of the CC40 series is very stable and reliable. However, in case of any malfunction; our certified well-trained service engineer will fix and repair the malfunction upon your call. Regular maintenance program or extended warranty program is also available to keep your systems always perfect conditions.

Application Support

If you need any support in application, such as scale up to production volume from process developing volume, our well-experienced application scientists are ready to support your preparation for commercial production using CC40 series upon your request.

Wide Selection of Rotors and Cores*1

Rotors

Two types of rotors are available for each CC40 and CC40S. One is a regular flow type and the other one is a high flow type. Both types of rotors are made of titanium alloy that shows strong corrosion resistance and high heat resistance.

Titanium alloy made cores

There are several types of cores available for method of centrifugation or target volume. The titanium alloy shows high heat resistance and is suitable for SIP option. Patent approved himac original super light titanium cores*1 are lighter than NORLY® made cores in the same size. This light weight of core realized the highest RCF 118,000 x g at 40,000 r.p.m. versus other similar cores available in the market; also it makes its operation easy.

*1: available in core (D), core (H), core (A) and core (AH)

NORLY® made cores

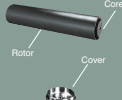
NORLY® resin (PPO) is a superior material in terms of strength and chemical resistance. It shows satisfactory characteristics in saline solution in the range of pH4 to pH10. However, it can be damaged by hydrocarbon fluids and cannot be used in their presence. In addition, unique himac original scale-up rotors are available, if you begin process development with small volume and move to the manufacturing scale later.

O-ring

O-rings are made of FDA approved material. This material was chosen for its high safety with regard to pharmaceutical supply products and so on.

For details about rotors and core types, please refer to the specification chart.

Specification of Rotor and Cores CC40

Rotor model	C40CT4*1						
	Type of cores	Core (H) (High Flow Type)	Ti Core (H) (High Flow Type)	Core (D)	Ti Core (D)	Core (E)*2	Core (F)
 Rotor Models • C40CT4 • C40CT3	External appearance of cores						
	Max. speed (rpm)	40,000					
	Max. RCF (x g)	118,000					
	Max. revolving radius: Rmax (mm)	66					
	Rotor weight (kg)	31					
	Rotor material	Titanium alloy					
	RCF (x g) at outside radius of center body	97,500					
	Radius of center body: Rmin (mm)	54.5					
	Core length (mm)	761					
	Core material	Norly®	Titanium	Norly®	Titanium	Norly®/Polyetherimide (Registered by General Electric)	Titanium
 Rotor Models • C40CT4 • C40CT3	Core weight (kg)	7.7	7.6	7.7	7.5	2.8	7.5
	Capacity (l)	3.2					
	Max. flow rate (l/hr)	50					
	O-ring material	EPDM (Ethylene-propylene rubber, USP Class VI compliant)					
	Applications	Density gradient centrifugation of virus, liposome, etc. (For high viscosity sample)					
		Density gradient centrifugation of virus, liposome, etc.					
		Batch centrifugation of HBsAg, etc.					
		Density gradient centrifugation of virus, liposome, etc. The prefractionator core permits separation of cells and fractions.					
		Rough separation of large-volume samples for pelleting.					
		With prefractionator core					

Notes: *1. The C40CT4 rotor assembly, using Core (H) and Titanium core (H), is designed with 30% lower flow restriction compared to the C40CT3 rotor assembly using the same cores. Which allows for a higher flow rate for viscous samples.

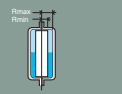
*2. The Core (E) is not for continuous flow but for batch centrifuge operation.

*3. The shape and size are the same as Core (H).

*4. The shape and size are the same as Core (D).

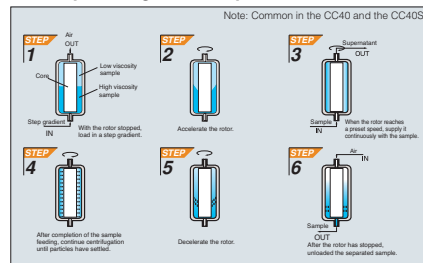
*5. For details about himac scale-up rotors, please kindly contact us.

Specification of Rotor and Cores CC40S

Rotor model	C40CT4*1			
	Type of cores	Core (AH) (High Flow Type)	Ti Core (AH) (High Flow Type)	Core (B)
 Rotor Models • C40CT4 • C40CT3	External appearance of cores			
	Max. speed (rpm)	40,000		
	Max. RCF (x g)	118,000		
	Max. revolving radius: Rmax (mm)	66		
	Rotor weight (kg)	15		
	Rotor material	Titanium alloy		
	RCF (x g) at outside radius of center body	97,500		
	Radius of center body: Rmin (mm)	54.5		
	Core length (mm)	382		
	Core material	Norly®	Titanium	Norly®
 Rotor Models • C40CT4 • C40CT3	Core weight (kg)	4.0	4.3	4.2
	Capacity (l)	1.6		
	Max. flow rate (l/hr)	50		
	O-ring material	EPDM (Ethylene-propylene rubber, USP Class VI compliant)		
	Applications	Density gradient centrifugation of virus, liposome, etc. (For high viscosity sample)		
		Density gradient centrifugation of virus, liposome, etc.		
		Batch centrifugation of virus, liposome, etc. The prefractionator core permits separation of cells and fractions.		
		Density gradient centrifugation of virus, liposome, etc. The prefractionator core permits separation of cells and fractions.		
		With prefractionator core		
		Prefractionator 0.15		

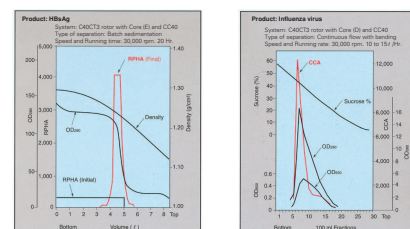
Note: *1. The C40CT4 rotor assembly and Core (AH) is designed with 30% lower flow restriction compared to the C40CT3 rotor assembly and Core (H). Which allows for a higher flow rate for viscous samples.

Example of a gradient separation



Applications

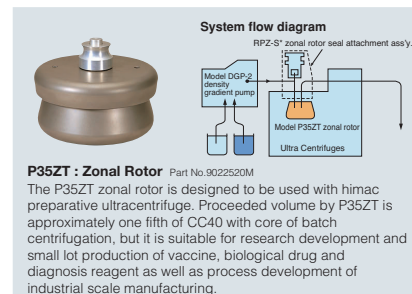
Note: The followings are examples of the application for CC40. Please inquire concerning the application for CC40S.



Zonal centrifugation system

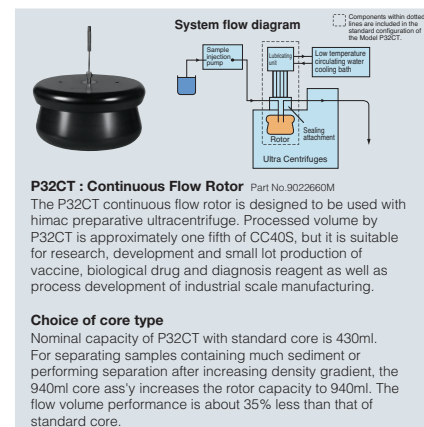


In zonal centrifugation, a density gradient is developed within the zonal rotor running at low speed. Next, the samples to be separated are loaded through the center of the zonal rotor and are separated at a preset high speed. After separation, the gradient is unloaded and collected through the center by injecting high-density fluid from the outside wall of the zonal rotor while the rotor is running at 3,000 rpm. The desired fractions are moved into the fraction collector via a spectrophotometer using a flow cell which monitors and records the optical density of the fractions.



P35ZT : Zonal Rotor

Part No. 9022520M
The P35ZT zonal rotor is designed to be used with himac preparative ultracentrifuge. Proceeded volume by P35ZT is approximately one fifth of CC40 with core of batch centrifugation, but it is suitable for research development and small lot production of vaccine, biological drug and diagnosis reagent as well as process development of industrial scale manufacturing.



P32CT : Continuous Flow Rotor

Part No. 9022660M
The P32CT continuous flow rotor is designed to be used with himac preparative ultracentrifuge. Processed volume by P32CT is approximately one fifth of CC40S, but it is suitable for research, development and small lot production of vaccine, biological drug and diagnosis reagent as well as process development of industrial scale manufacturing.

Choice of core type

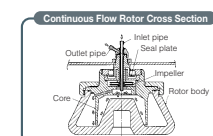
Nominal capacity of P32CT with standard core is 430ml. For separating samples containing much sediment or performing separation after increasing density gradient, the 940ml core ass'y increases the rotor capacity to 940ml. The flow volume performance is about 35% less than that of standard core.

Type	Model	Part No. (automatic)	Max. speed (rpm)	Max. RCF (xg)	Nominal capacity (ml) x number of samples	K-factor
Zonal	P35ZT	9022520M	35,000	122,000	1,690ml	303
Continuous flow	P32CT	9022660M	32,000	102,000	430ml	42

R18C/R13C/R10C : Continuous flow rotors for himac High-speed Refrigerated Centrifuges

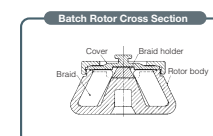


This continuous flow rotor series is designed to separate for micron-size particles, such as bacteria and yeast. This continuous flow rotor series can be used in two ways, the one is continuous flow separation and the other is batch separation for pelleting.



Continuous flow rotors

The sample is introduced into the rotor through the inlet pipe. The supernatant liquid after separation is taken up by the impeller (like a vane wheel of a centrifugal pump) and discharged from



Batch rotors

Batch rotors centrifugally separate samples introduced directly into the rotor. There is no need to establish balance. Four blades protect the sample from disturbance.

Type	Item	Model	Part No.	Maximum speed (rpm)	Maximum RCF (xg)	Weight (kg)	For tubes		Standard accessories
							Nominal capacity (ml) x number of tubes	Tube dimensions (dia. x mm)	
Continuous rotor	R18C	90431900	18,000 (16,000)	34,960 (27,630)	7.5	1,000	□	□	□
		R18C seal unit (E) for CR22G III/21G III (Part No. S203036A), 18 batch unit for CR22G III/21G III (Part No. S217247A)							
	R13C	90432000	13,000	21,260	9.2	2,200	□	□	□
		R13C seal unit (E) for CR22G III/21G III (part No. S203037A), 13 batch unit for CR22G III/21G III (part No. S217248A)							
	R10C	90432100	10,000	14,590	11.8	3,200	□	□	□
		R10C seal unit (E) for CR22G III/21G III (part No. S203038A), 10 batch unit for CR22G III/21G III (part No. S217250A)							