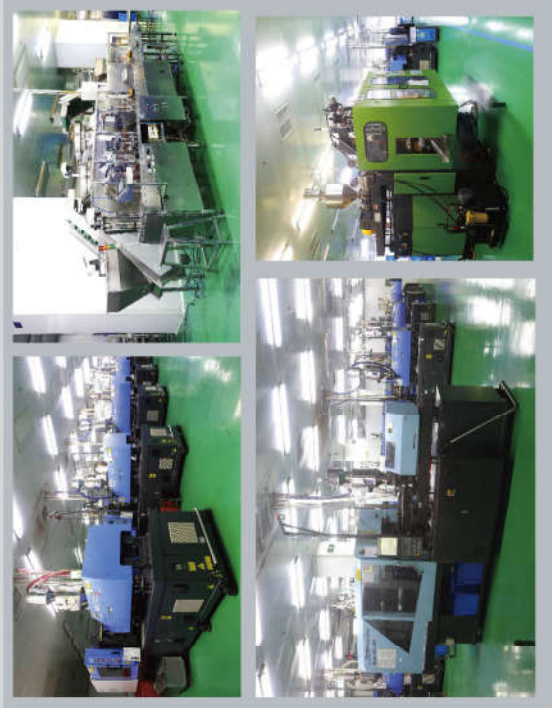




上海市达华医疗器械有限公司
Shanghai Dahua Medical Apparatus Co., Ltd



Manufacturer Information
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Introduction of Dahua Medical

Established in 2000, Shanghai Dahua Medical Apparatus is a modern high-tech enterprise which is engaged in researching, developing and technology introducing related to blood separation technology, medical apparatus and assorted consumptive materials. From 2003 to now, Shanghai Dahua Medical Apparatus enjoys the reputation of Shanghai high-tech enterprise. Several products manufactured by Shanghai Dahua are entitled as national and municipal key products, Shanghai high-tech achievements conversion projects, Shanghai Torch plan, small and medium size enterprises technology innovation projects and Shanghai progress prize in science and technology.

Dahua has over 20 years of management and production experience of disposable medical equipment. It has a high quality and well-experienced team of science and technology development, production and management that familiar with GMP standard and quality guarantee. It has strong technical development capabilities as well as strong management ability in project research and development and industrialized implementation. It is a big production enterprise in domestic blood transfusion technique field.

It possesses 51 patents including 15 invention patents. A number of products are named Shanghai and national key new product. The company has two factories in Chongming with a land area of 61,270 square meters. The new factory is located at Chongming Industrial Park, one of the municipal industrial parks in Shanghai, with a land area of 33,333 square meters and a floor space of 40,000 square meters.

DAHUA is executive director of the Association of the National Medical Polymer, director of the Chinese Society of Blood Transfusion; member of the Standards Committee of the Chinese family planning appliances; China the medical polymer Standards Committee members; Shanghai Medical Device Industry.

◆ Association executive

Experience from cooperating with international organization
Dahua has accumulated rich experience in market development and quality control from cooperating with Bill and Melinda Gates Foundation and PATH in woman condom project.

◆ Certificates:

- Compy to ISO13485:2016 / ISO9001:2015
- GMP certification of medical device by Chinese SFDA
- CE Marking of TUV company, Germany
- SABS Marking of South Africa
- UNFPA/WHC Pre-qualification
- ANVISA GMF certificate of Brazil
- Cuba MOH registered
- Belarus MOH Registered
- Pakistan MOH Registered
- Iran MOH Registered
- Ukraine MOH Registered

Plasma Collection Machine



◆ **Type**
DH-I

◆ Intended use

The DH-I plasma collection machine with the software is combined with a disposable plasma separator and a tubing to form a plasma collection system for non-in-vitro plasma collection of the human body. The collected plasma will be used in the production of human serum albumin or to supplement coagulation factors or massive blood loss of patients. At the same time, the device can also be used for therapeutic plasma exchange and component therapy.



Disposable Centrifugal Plasma Separator System

◆ Advantage

- multi-languages
- Touchable display screen and reliable operation panel
- Clear human-machine interface, excellent human-machine communication
- Stable speed of centrifuge, 7000 +/- 50 RPM to ensure the quality of the plasma
- Shorter Collection time to improve the work efficiency
- Control system modularization, A relative small dimension; easy for maintaining
- Display main working parameter
- Automatic electronic scale correction function to ensure high collection standard.
- Complete warning system
- Remote control and data transmission: through net and scan function, human can monitor running state, operational parameter of storage device and print statistic report.(optional)
- Scanning function to automatically record the operator and donor's ID, Disposable information (optional)
- Printing function to print collection data without human writing to ensure the accurate data(optional)
- Remote fault diagnosis: through remote fault diagnosis, engineer can maintain device.
- The design of outlook is to ensure user can use device easily, safely, Light appearance does not occupy space; suit for collection vehicle.V

◆ Specification

Size Length*Width*Height	50*34*37(cm)	Package size : 73*51*43 (cm)
Weight	Net : 32kg Gross : 36kg	
Input	Voltage range :	230VAC;frequency range50/60Hz;input power : 420W
	Atmospheric pressure	86kPa ~ 106kPa
	Ambient temperature	+10°C ~ +30°C
	Relative humidity	≤70%
Working condition	The RF signals emitted by the high-power communication base station and similar equipment may cause interference and influence to the DH-PCM. Therefore, the similar equipment should not be too close to the DH-PCM, User should avoid using those equipment during the DH-PCM running.	



◆ Product intended use

Plasma collection system is formed by Disposable centrifugal plasma separator system and plasma collection machine ,which is used to collect the plasma of human body

The collected plasma will be used in blood biologics to produce human albumin or to supplement the patient's blood coagulation factors or massive blood loss. At the same time, the product can also be used for therapeutic plasma exchange and component therapy.

◆ Matched model

This product is suitable for the Disposable Centrifugal Plasma Separator System of Dahua or Haemonetics PCS2 type or similar function.

◆ Applicable people

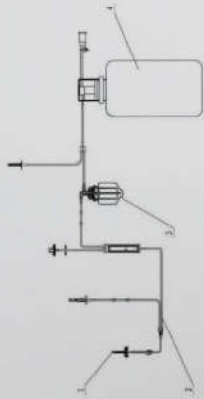
Healthy people (except infants, pregnant and lactating women)

◆ **Product model**

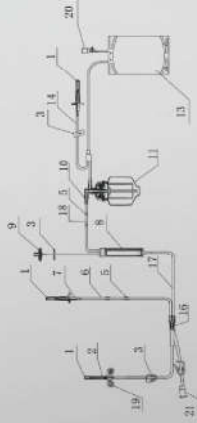
FLQ-4J-1-15; FLQ-1J-1-8; total 23 models

◆ **Product specifications**

1000ml (bottle or bag capacity)



1. Apheresis needle	2. Apheresis Tubing set
3. Plasma collecting bowl	4. Plasma collection container



1. Cover	2. 15G, 16G, 17G (needle)	3. Clamp
5. Clip	6. Pump tubing	7. Puncture outfit
8. Blood Filters	9. DPM	10. Two-way connect
11. Plasma separator cup	12. Sampling tube	13. Plasma bags
14. Tubing	16. Lure three-ways	17. Tubing
18. Pump tubing	19. Needle handle	21. Sampler

Disposable Platelet Apheresis System

◆ **Product Intended use**

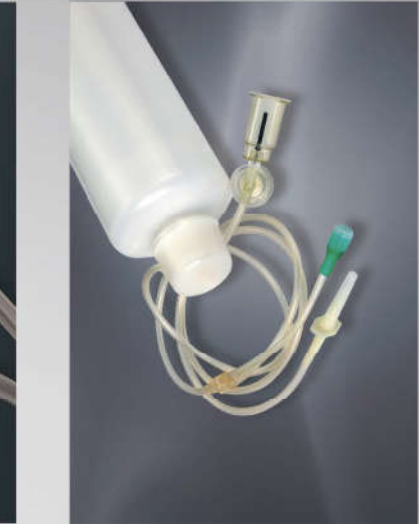
This product is matched with the full-automatic centrifugal blood cell collection instrument, which is used to collect the blood of human body, separate and store human platelets, and also transfuse cells.

◆ **Matched model**

This product is suitable for the automatic centrifugal blood cell collection equipment of Dahua or Haemonetics MCS+ type or similar Brand.

◆ **Applicable people**

Healthy people (except infants, pregnant and lactating women)



◆ **Product mode**

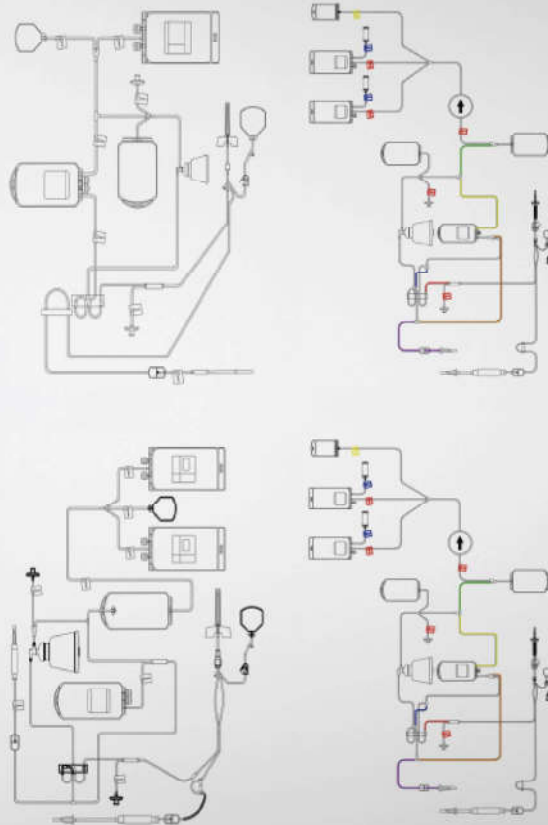
Product Type	Equipment Type
XXBFLQ1-800+XXBFLQ2-300	HaemoneticsMCS+ 3P
XXBFLQ1-800-1+XXBFLQ2-300	HaemoneticsMCS+System
XXBFLQ1-800-2+XXBFLQ2-300	HaemoneticsMCS+
XXBFLQ1-800-3+XXBFLQ2-300	HaemoneticsMCS+ System
XXBFLQ1-800-4+XXBFLQ2-300	HaemoneticsMCS+ 3P
XXBFLQ1-5-800+XXBFLQ2-300	HaemoneticsPCS+

◆ **Product composition**

Centrifugal cup, Platelet apheresis tubing set

◆ **Product Structure**

See Typical product



Disposable hemodialysis set

◆ **Product Intended use**

Hemodialysis treatment is to treat acute or chronic renal failure patients, artificial simulation of the working principle of renal function, through dialysis treatment, that is, to clear the toxins in the body, correct various disorders caused by toxins and drain the accumulated water in the body, so that the physiological indicators of the patients return to normal state.



◆ **Matched model**

This product is suitable for Fresenius, Gambro, B. Braun or similar hemodialysis equipment

◆ **Product model**

Model	Pump tube size (arterial line) (inner * outer * length)	Outer diameter of blood filter/ Outer diameter of the bubble filter	Arterial line Prime volume	Venous line Prime volume
A004/V604	8*12*300mm	φ22mm/φ22mm	105ml	76ml
A006/V601	6.35*9.75*380mm	φ22mm/φ22mm	95ml	78ml
A007/V607	8*12*370mm	φ22mm/φ22mm	96ml	76ml
A008/V608/V609	3.3*6.3*185mm	φ20mm/φ20mm/φ20mm	65ml	25ml/25ml
A010/V610	8*12*380mm	φ20mm/φ20mm	86ml	33ml
A013/V613	8*12*300mm	φ22mm/φ22mm	103ml	80ml
A014/V616	8*12*380mm	φ22mm/φ22mm	105ml	72ml
A015/V613	6.35*9.75*420mm	φ20mm/φ20mm	88ml	80ml
A016/V616	6.35*9.75*300mm	φ20mm/φ22mm	95ml	72ml
A017/V600	8*12*360mm	φ22mm/φ22mm	105ml	80ml
A018/V612	6.35*9.75*380mm	φ20mm/φ20mm	64ml	76ml
A019/V616	8.0*12.0*360mm	φ22mm/φ22mm	100ml	72ml
A020/V611	6.35*9.75*175mm	φ22mm/φ22mm	90ml	63ml
A029/V607	8.0*12.0*300mm	φ22mm/φ22mm	103ml	76ml
A030/V613	8.0*12.0*420mm	φ22mm/φ22mm	88ml	80ml
A031/V602	6.35*9.75*370mm	φ22mm/φ22mm	105ml	76ml
A032/V611	6.35*9.75*370mm	φ22mm/φ22mm	96ml	63ml
A035/V613	8.0*12.0*380mm	φ22mm/φ22mm	105ml	80ml

◆ **See Typical product**

