



## MODULAR PLASMA SOURCE ESTABLISHMENT

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- » Blood plasma and plasmapheresis
- » Safety during the plasma donation
- » Function of a plasmapheresis station
- » Design of a modular plasma source establishment
- » Advantages of the modular design

## MODULAR PLASMA SOURCE ESTABLISHMENT

### *Blood plasma and plasmapheresis*

Blood plasma is a plain transparent yellowish liquid that accounts for approx. 55 % of human blood. It contains 91 % of water and more than 120 different proteins, apart from a small level of nutrients, hormones, minerals, and other transport substances.

With their specific characteristics, these 120 proteins have an effect on vital body functions such as blood coagulation, the immune system, and the transport of various substances. Because of its variety of contents along with essential functions, blood plasma is an important therapeutic agent. More than one quarter of its contained proteins can be directly used for disease treatment. Therapy is performed either as a direct transfusion from the donor to the patient or, as in most cases, it is administered via medication with drugs that are produced from blood plasma.

As blood plasma currently cannot be produced synthetically, donations from volunteers are relied on when it comes to the production of these preparations and their direct therapeutic use.

Blood plasma is collected either indirectly by the extraction of the plasma portion from already donated whole blood, or directly during the donation. The process of blood plasma separation during the donation is also called plasmapheresis. For this purpose, peripheral blood is taken from the donor, then treated so that it cannot clot and fractionated into its two main components – solid matter (erythrocytes, leucocytes, and platelets) and liquid (plasma). The plasma is retained and collected, and then the solid blood contents are returned to the donor. The removed plasma is volumetrically replaced by an isotonic saline solution.

Plasmapheresis is an automatic process wherein the donor is connected to an apparatus via a hypodermic needle and tube throughout the duration of the donation. Compared to a whole blood donation, plasmapheresis is gentler to the donor and is more efficient. As the human organism is



Medical examination for the donor's general health and blood analysis before the first donation



Express analysis in the collecting station's laboratory

able to recreate all the components of the donated plasma within just two days, a blood plasma donation can occur at an interval of every three days (versus 6 weeks for a whole blood donation).

In contrast to a whole blood donation, a plasma donation hardly affects the haemoglobin portion. Therefore, many of those people whose haemoglobin value previously was possibly too low for a whole blood donation would still be able to donate blood plasma.



Blood and plasma samples from donors



Frozen blood plasma in bags



Example of finished medicine produced from blood plasma



Plasma donation by means of the plasmapheresis apparatus

### *Safety during the plasma donation*

There are international guidelines from the World Health Organization WHO for the extraction and processing of blood plasma. These are enforced and governed by means of national laws, for the EU by the European Directorate for the pharmacopeia, the European Community, and the Council of Europe. The "Richtlinien zur Gewinnung von Blut und Blutbestandteilen und zur Anwendung von Blutprodukten" (Guidelines for the Preparation of Blood and Blood Components and for the Use of Blood Components (Hemotherapy)), which is issued by the scientific advisory board of the Bundesärztekammer (German medical association) and the Paul Ehrlich Institute, are valid in Germany. The safety for donors, pharmaceuticals, and medical personnel has top priority. The safety concept completely covers all the process steps, starting with the first anamnesis of a donor up to the delivery of the finished medication. It applies equally to all collecting stations, storage and production facilities, and includes technical and organisational conditions:

- » Thorough examination and selection of donors before their first donation and in regular intervals thereafter
- » Repeat examinations of donors' health prior to each additional donation in respect of suitability
- » Laboratory analysis of each donation
- » Compliance with strict hygienic standards in collecting stations
- » Deep freeze storage of the donations without interruption of the cold chain
- » Quarantine storage of each plasma donation up to the release confirmation
- » Undertaking of RT-PCR tests for HIV
- » Processes for the inactivation of viruses for plasma fractionation
- » Exclusive use of tested and approved materials, equipment, and technologies
- » Monitoring of all the processes via a computer network running certified software
- » Redundant equipment for all vital process steps
- » Ongoing training and assessment of the personnel involved



## FUNCTION OF A PLASMAPHERESIS STATION

Plasmapheresis stations must not be confused with blood banks that collect and store human whole blood from donors and deliver it to medical facilities for blood transfusions. The function of plasmapheresis stations is to collect blood plasma for the purpose of further processing in pharmaceutical works on an industrial scale. For this purpose, a sufficiently large collection area with good transport connections is required to:

- » Have a sufficient number of healthy donors who can be reached and persuaded to donate on a regular basis
- » Ensure short distances to the collecting station
- » Provide optimal logistics for a stable supply of auxiliary materials and media, as well as for the transport of the plasma donations

Collecting stations are particularly successful in urban areas, in the vicinity of large companies or colleges and universities where a large volume of young and healthy donors are available. The higher the proportion of regular donors the more efficient the collecting station will be.

Furthermore the people's response to appeals for donations also depends on the financial remuneration that donors receive for their blood plasma.

The capacity required for a collecting station depends on the potential of the catchment area. A standard-sized station has at most 10 collection places and can collect approximately 12,000 - 18,000 litres of blood plasma per year in an extended 1-shift operation (10 h). The work procedure for a plasma donation consists of the following steps:

- » Welcoming and registering the donor
- » Preparing the collection equipment
- » Donation
- » Shock freezing and storing the donation in a deep freeze store
- » Evaluate the laboratory analyses
- » Release of the negative tested donation and deliver it to a facility for further processing

The personnel required for this normally includes one (1) station manager, one (1) physician, four or five (4-5) qualified medical employees, two or three (2-3) medical assistants, as well as service staff (cleaning and technical support).



Each module has an individual steel frame



Transport of a module



Preparation of the strip foundation on-site



Positioning of the first module



Assembled building without cladding



Reception area



Room for plasma bag handling with deep-freeze cabinets and direct access to the deep-freeze storage room

The time required for a plasma collection is approx. 30 - 60 min. depending on the donor and the donated quantity of plasma, in addition to the preparation time of approx. 20 min.

Blood and plasma samples from donors undergo laboratory analyses for Immuno Assay and PCR according to the specified methods in compliance with all the national requirements, both in the collecting station (express analysis) and additionally in regional institutes or laboratories. The delivery of the released plasma for further processing, after the quarantine time, from the collecting station is carried out by a special deepfreeze transporter in order to maintain the cooling chain.



Completed building

### *Design of a modular collecting station*

The modular design of a collecting station with 10 donor places, as described herein, complies with the advanced state of medicine and pharmacological engineering EU with a view to the technical equipment and methodological sophistication of the process.

The collecting station includes two main areas:

- » Functional area (office, staff room, sanitary facilities, technical room, and auxiliary rooms)
- » Production area (waiting room, interview room, physician's room, donation room, shock-freezing area, and cold room)

These areas are equipped with following main equipment: diagnostic and laboratory equipment, automatic plasmapheresis machines, donor chairs, shock freezer, deepfreeze store, PC, and a facility for the decontamination of infectious and biological waste. Certified software for donor management and quality assurance can be provided upon request. All the systems necessary for the perfect function and to ensure the hygienic standards, are installed in the building: basic heating, air conditioning, electric power supply, refrigerant supply for the deepfreeze storage, telecommunications system, and a fire alarm system. To protect the health of the donors and to comply with the strict requirements for product quality, the station is equipped with an automatic emergency power supply.

A station with at most 10 donor places is installed in a single-

floor building with an area of approx. 384 m<sup>2</sup>. It consists of 13 self-supporting preinstalled room modules that can be arranged freely without grid restrictions. A grid-type strip foundation has to be provided on-site.

The only things to be additionally provided are the utility supplies: drinking water, heating medium (pumped hot water, gas, or oil), wastewater, electric power supply, and telecommunications. The number of collection places depends on the local conditions and can be increased at any time. Then, the building floor area will be correspondingly enlarged. If the necessary space is inadequate, e.g. in town centre areas, a multi-storey construction is also possible without any problems.

The modular system allows the construction of plasmapheresis stations of user-defined capacity, without major changing of the standard project.



Donation room

## ADVANTAGES OF THE MODULAR DESIGN

Normally, the prefabricated modules are transported to the site on special low-loader trucks. Specific requirements for the delivery that are associated with this (e.g. considering the road conditions, transport costs, etc.) are more than compensated for by the advantages of the modular design:

- » Modules are suitable for series production, but also allow for individual configurations, and are normally more cost-effective than a conventional new building.
- » Modules can be installed as self-contained single units or be combined for buildings of any size. With suitable cladding, they can be adapted to any local architecture and do not resemble a container home, neither outside nor inside. They have a minimum service life of 25 years.
- » The room modules or buildings can be extended, and partitioned. A complete moving to another site is possible,
- » if required, without any problems.
- » Collecting stations can be established within existing regional structures (e.g. polyclinics, hospitals, etc.) without disturbing their respective operations.
- » The modules are completely pre-installed by the manufacturer. Installation on-site takes very little time and can be done to a great extent independently from local resources (materials, special staff, etc.).
- » Minimized requirements for setting up the modules.

When a user operates multiple collecting stations as a chain or network, the use of modules offers additional advantages:

- » Reduction of investment costs by serial production of the modules
- » Optimized work processes in the collecting stations through standardized equipment and fittings
- » Standardized quality management
- » Better personnel training by multiplicity
- » Easier technical support for all the stations
- » Cost reduction through the centralized purchase of standardized materials and consumables
- » Easier certification of new collecting stations

**Glatt Ingenieurtechnik GmbH has applied for a patent on the modular plasmapheresis station.**



Technical and sanitary rooms



Technical equipment



Training of station personnel

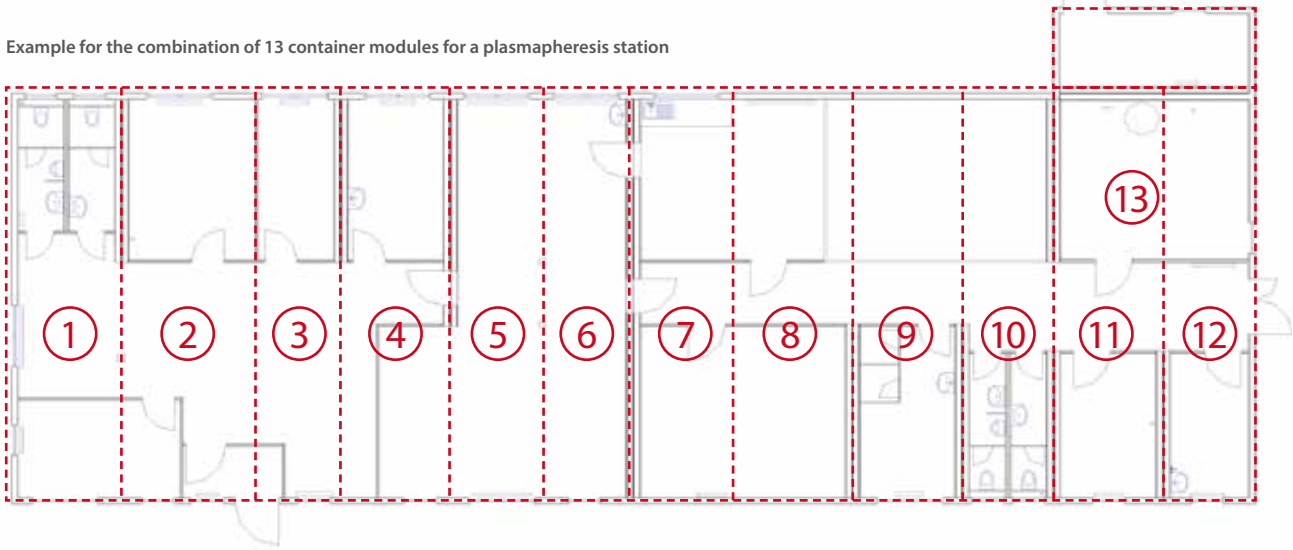


## TECHNICAL DATA: COLLECTING STATION WITH 10 COLLECTION PLACES

### Room modules

- » Suitable for standalone self-contained construction or for a combination of multi-floor buildings
- » Can be combined without grid restrictions, can be moved, extended, and partitioned at any time
- » Length/width/clear height of one module: up to 12 m / up to 5 m / up to 3 m
- » Environmental conditions (standard):  
summer: 32 °C, 35 % rel. humidity / winter: -40 °C, 50 % rel. humidity (depending on the equipment adjustable to each climatic zone)

Example for the combination of 13 container modules for a plasmapheresis station



### Internal media and systems

- » Electric power distribution: ..... completely preinstalled electrical installation
- » Drinking/waste water: ..... completely preinstalled piping
- » Air conditioning: ..... approx. 4,000 m<sup>3</sup>/h, exchange rate 80 %, direct exhaust air if required
- » Deep freezing: ..... -85 °C / -25 °C, (redundant systems)
- » Telephone, EDP, fire alarm system, burglar alarm system: ..... completely preinstalled network
- » Emergency power supply: ..... 23 kVA

### External prerequisites

- » Foundation: ..... grid-type strip foundation with peripheral insulation
- » Drinking water acc. to the valid standard: ..... pressure 4 bar (g)
- » Sewer system for rain and waste water: ..... DN70 / DN100; numerous connection points
- » Heating medium: ..... pumped hot water 90°C flow / 70°C return alternatively: gas or oil supply
- » Electric power: ..... 400 V / 50 Hz, 70 KVA
- » ISDN telecommunication: ..... 3 separate lines
- » Transport: ..... suitable site access road for special low-loader truck crane (25 tonnes capacity) for unloading

### Russian certificates

Declaration of Conformity No. ROSS DE SL 19S00025 of OS "Sewsapstrojsertifikacija"



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