



APHERESIS TECH
PLASMA INNOVATION

PFM-500 / PFM-800

MEMBRANE FILTER FOR PLASMAPHERESIS

PFM-500 and PFM-800 are sterile, single-use membrane plasma filters designed to separate whole blood into plasma and erythrocyte mass. Their multicamera architecture with a flat track-etched membrane prioritizes more predictable circuit performance, supports SOP compliance, and enables control of critical variables (citrate anticoagulation, inlet pressure, setup safety, and per-session traceability).

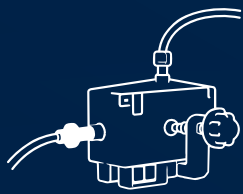




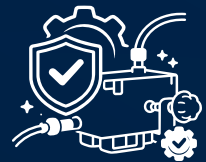
Use: Donation (plasma/autoplasm) and therapeutic applications (according to medical indication and protocol).



Design: Alternating flat chambers (blood/plasma) with flow separators and inlet/outlet manifolds.



Membrane: Flat track-etched PET (10 μm) with 6–10% porosity and an approximate pore size of 0.5 μm , as specified in the technical manual.



Operational safety: Mandatory usage rules (citrate anticoagulation, pressure control, PC-PFM).



Quality management: Per-session traceability (reference + lot + expiration date), FEFO control, incident logging, and internal auditing.



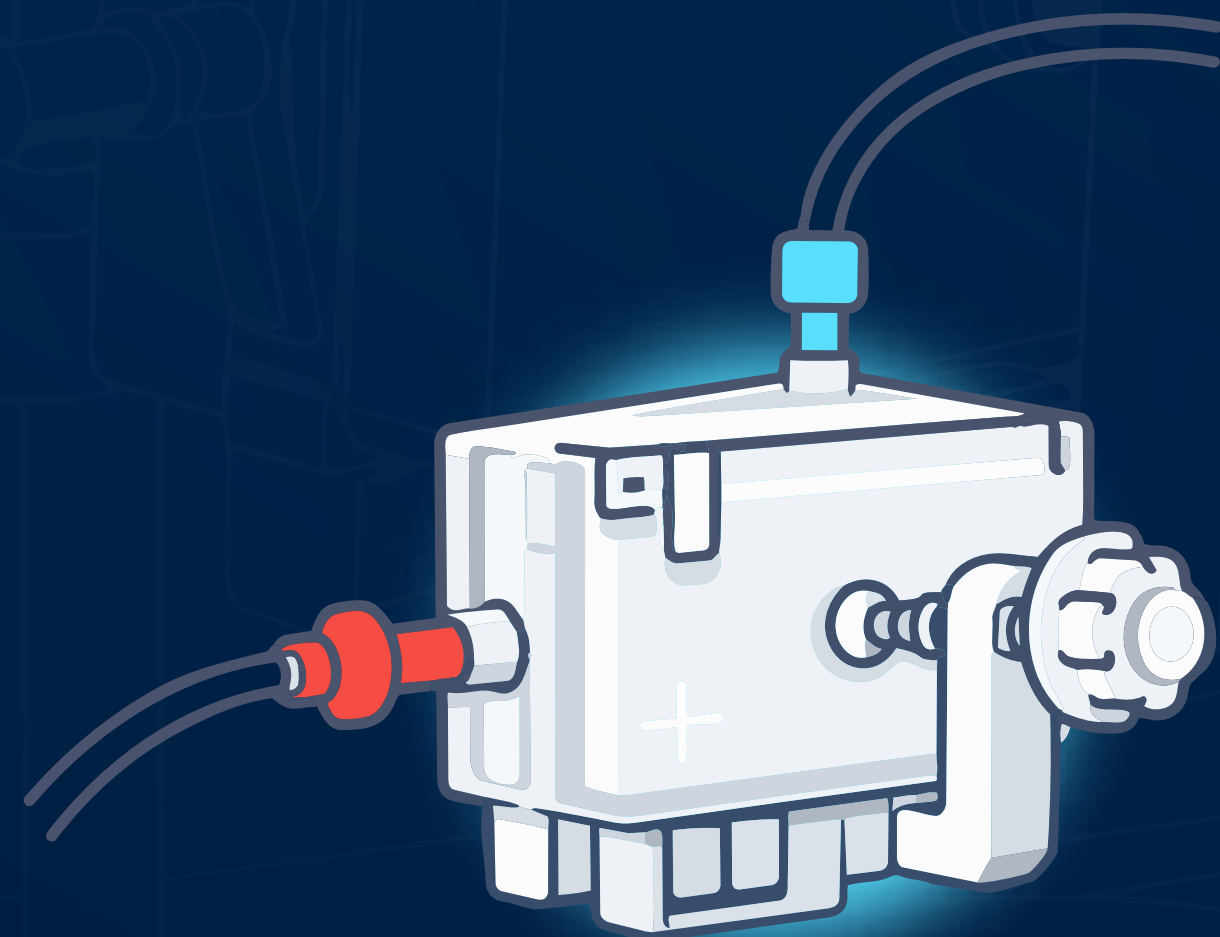
Supply Chain & Logistics: Availability of filters, disposables, and anticoagulants to sustain uninterrupted program operation.



Regional logistics: Warehouses in Ecuador, Panama, and the United States to enable faster distribution of equipment and consumables, ensuring operational continuity in line with each center's planning.

FILTER ARCHITECTURE: Multichamber module for consistent separation.

The central component is a multichamber separation module: alternating slotted flat chambers for blood and plasma, separated by a track-etched membrane. This design organizes flow paths and facilitates procedural reproducibility when setup is standardized through SOPs.



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- ***Alternating chambers:*** Physical separation of blood and plasma compartments for controlled flow.
 - ***Internal separators:*** Stabilize the flow profile and promote consistent separation.
 - ***Peripheral manifolds:*** Blood inlet with dedicated outlets for erythrocyte mass and plasma.
 - ***Institutional value:*** Facilitates step-by-step training, reduces variability between shifts, and supports standardized setup documentation.
 - ***Best practices:*** Assembly checklist and pre-start verification (integrity, connections, and orientation).

Track-etched membrane: technology with calibrated cylindrical pores

The track-etched membrane is produced by irradiating a polymer film with accelerated heavy ions, followed by a subsequent physicochemical treatment. The result is a thin membrane with calibrated cylindrical pores, designed for stable filtration and low flow resistance.

Geometry: cylindrical, calibrated pores for more predictable behavior.

Smooth surface: reduces unwanted interaction and trauma to formed elements (according to the manual).

Low adsorption: reduced capture of dissolved substances compared to rougher surfaces (in general terms).

No extractables: described as absence of extractable substances (according to the manual).

Operational impact: supports consistent SOPs and reduced variability between sessions.



Verifiable membrane specifications (procurement / biomedical committee)

For institutional evaluation, verifiable data are essential. The manual specifies material, thickness, porosity, and pore size, which are useful for internal control, biomedical acceptance, and documentation standardization.



- ***Material:*** polyethylene terephthalate (PET).
- ***Thickness:*** 10 μm (PFM filter membrane).
- ***Porosity:*** 6–10%.
- ***Pore size:*** $\sim 0.5 \mu\text{m}$.
- ***Use in documentation:*** internal consumable datasheet, change control, and per-session traceability.



Hemocompatibility and TMP tolerance: procedural continuity

The manual highlights that the smooth surface and cylindrical pore shape reduce traumatic effects on formed elements and allow tolerance to elevated transmembrane pressure without hemolysis. For daily operation, this provides a safety margin and stability, always within the SOP.

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- ***TMP:*** up to 200 mmHg without hemolysis (according to the manual).
 - ***Reduced trauma:*** due to smooth surface and calibrated pores (according to the manual).
 - ***Stable operation:*** supports scenarios with vascular access variability when pressure control is in place.
 - ***Risk management:*** integrate thresholds, actions, and event logging into the center's SOP.
 - ***Quality:*** document pressures, incidents, and corrective actions per session.

Hydrodynamics: tangential flow and plasma separation

Blood is fed through the inlet manifold, distributed into blood chambers, and flows tangentially along the membrane. A portion of the plasma is filtered into plasma chambers and collected in the plasma manifold, while formed elements are retained.



Inlet: blood chamber manifold.

Tangential flow: movement along the membrane toward the erythrocyte mass outlet.

Filtration: plasma passes through the pores into plasma chambers and is collected at the plasma outlet manifold.

Retention: formed elements remain within the blood circuit.

Advantage: clear sequence for SOPs, training, and troubleshooting (setup/priming/verification).

Clinical–operational interpretation: what is separated (without clinical claims)

From a mechanistic perspective, the filter separates the plasma fraction from the blood while retaining the formed elements. This section helps communicate the principle in a professional manner, without implying specific clinical indications beyond the medical protocol.

Obtained: plasma (liquid fraction) for collection or therapeutic handling according to protocol.

Returned: erythrocyte mass / formed elements to the patient's or donor's blood circuit.

Applications: donation (plasma/autoplasm) and therapeutic use (detoxification, immunocorrection, rheocorrection) as described in the manual.

Clinical governance: selection criteria and parameters defined by the treating team.

Documentation: record protocol, volume, consumables, and events per session.



Functional specifications: operation planning and scheduling

Functional characteristics (priming, flow rate, inlet pressure, and performance) help plan timing, consumables, and SOPs. For procurement, these values allow consumption forecasting and program sizing.

- ***Priming volume (max):*** 20 mL (PFM-500) / 25 mL (PFM-800).
- ***Nominal flow rate:*** 50 mL/min (both).
- ***Inlet pressure (max):*** 90 mmHg (both).
- ***Minimum plasma yield:*** $\geq 30\%$ of inlet flow.
- ***Planning:*** map per-session consumption, minimum stock, and planned replenishment.

Biosafety and shelf life: traceable institutional consumable

The manual defines the filters as single-use products that maintain sterility, apyrogenicity, and non-toxicity throughout the guaranteed storage period. This approach supports biosafety, audits, and inventory management with FEFO control.



- ***Single use:*** reduces cross-contamination and simplifies post-session workflow.
- ***Sterility / apyrogenicity / non-toxicity:*** declared throughout the guaranteed period (manual).
- ***Shelf life:*** at least 3 years (manual).
- ***Traceability:*** record reference + lot + expiration per session.
- ***Inventory:*** FEFO rotation, expiration alerts, and stockout control.

Mandatory minimum SOP: citrate, pressure, and PC-PFM fixation

The manual defines general operating rules that must be mandatory within the SOP. For a large organization or center, this becomes an audited operational standard: procedures performed consistently across all shifts.

- **Anticoagulant:** mandatory use of sodium citrate (manual).
- **Pressure control:** mandatory monitoring of inlet pressure at the filter (manual).
- **Setup:** mandatory use of the PC-PFM device for normal operation (manual).
- **Checklist:** setup, priming, verification, and per-session documentation.
- **Management:** incident handling and internal escalation when SOP pressure thresholds are exceeded.



PC-PFM: setup consistency and visual process control

The PC-PFM secures the filter on an infusion stand, does not come into contact with blood, and is reusable. Its transparent material allows visual control of filling and separation. From an institutional procurement perspective, the PC-PFM is valued for its impact on setup consistency and error reduction.

- **Reusable:** no blood contact; multi-use accessory (manual).
- **Transparency:** facilitates visual verification of filling/separation (manual).
- **Installation:** friction-based fixation, without additional compression (manual).
- **Benefit:** standardizes circuit setup and reduces recurrent incidents.
- **Training:** mandatory SOP step to ensure operator uniformity.



Compatibility and integration with platforms (incl. Gemma/GEMA)

The manual describes the use of the filter in different configurations (device-based and non-device-based) and on systems such as "Gemma." This enables integration of the consumable into programs with varying resource levels, while maintaining SOPs and traceability.

UAM-01 (device-based):
closed circuit, two-needle, continuous flow; integration with pumps and pressure/air safety features according to the platform (manual).

UBM-01 (gravity-based):
single-needle; exfusion/reinfusion phases

Syringe-based version:
single-needle, closed circuit

Gemma: two synchronized peristaltic pumps (blood/anticoagulant), 1-2 needles; level sensors, air sensor, safety valve, and microprocessor control.

Hemos-PF: ventricular pump, single-needle; anticoagulant dosing by drip and defined protection levels



INSTITUTIONAL PROCUREMENT, IMPLEMENTATION, AND CONTINUITY

For institutional procurement, the filter must be integrated into a complete system: SOPs, traceability, inventory, and logistics. This reduces improvisation, improves quality, and ensures continuity.

- **Implementation:** SOP + checklist + role-based training (clinical/technical/biomedical).
- **Management:** per-session traceability, FEFO control, internal auditing, and operational indicators.
- **Continuity:** minimum stock levels, planned replenishment, and stockout control.
- **Supply Chain & Logistics:** availability of filters, disposables, and anticoagulants to sustain the program without interruptions.
- **Regional logistics:** warehouses in Ecuador, Panama, and the United States for faster distribution of equipment and consumables, ensuring operational continuity according to the center's planning.
- **Perceived quality:** orderly, reproducible, and well-documented operation — a large-enterprise standard.