GEMMA

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Membrane Plasmapheresis System

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PLASMA EXCHANGE SOLUTION FOR LATIN AMERICA

Technical-Commercial Brochure | Membrane-Based Clinical Platform

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Integrated Solutions for Clinical Centers and Networks

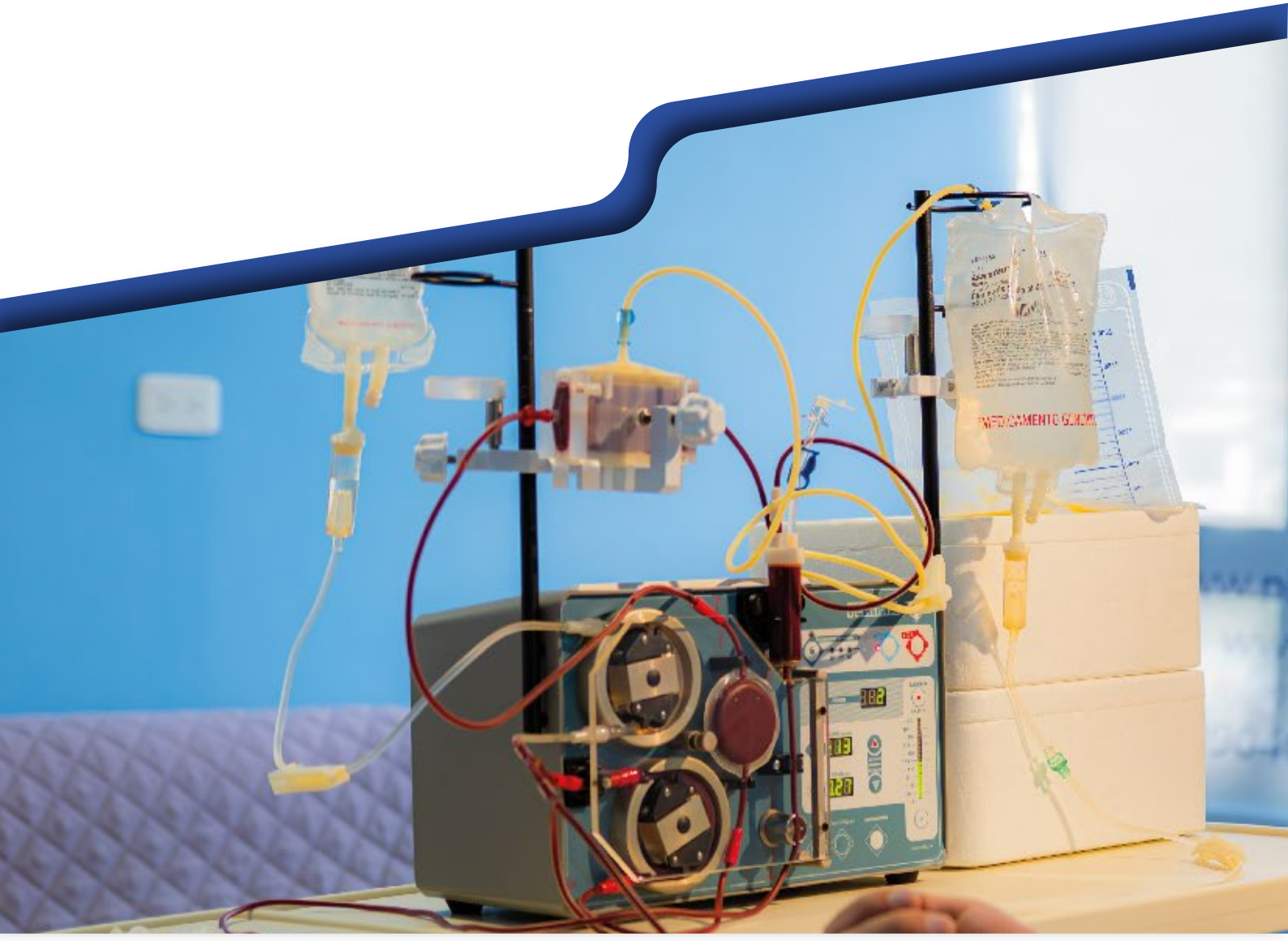
GEMA integrates membrane separation, fine hemodynamic control, and modular consumables in a single platform to perform both therapeutic and donor plasmapheresis with the same device. It is designed for real clinical work: patient bedside, ICU, therapy rooms, ambulatory operation, and field deployment. Portability and low power consumption allow the unit to be moved between departments, reducing transfers and downtime.

OPERATIONAL METRICS

• ≥ 95% equipment availability (operational goal) • ≤ 10 min standard line installation (training objective)
• ≤3 alarm events/100 sessions and ≤ 5 min average recovery
• ≥ 8 h continuous operation; MTBF ≥ 5,000 h
•≤ 60 VA power consumption; ≤ 8 kg; 320×200×200 mm (true portability)
• Clinical ranges: 2–200 mL/min
(flow), 5:1–25:1 (blood:AC), pressure up to 300 mmHg

GEMA Platform — Clinical Plasma Filtration Device

GEMA operates with one or two needles and allows adding a second stage (hemosorption or selective filtration) without changing the platform. The direct interface and live indicators prioritize safety and hemodynamic stability in hospital and prehospital environments.



Membrane Technology and Hemodynamic Control

The parameter control in GEMA allows each session to be adapted to the patient's physiology and clinical objective.The total flow can be adjusted between 2 and 50 mL/min with a resolution of 1 mL/min, and from over 50 to 200 mL/min with a resolution of 5 mL/min.
The blood-to-anticoagulant ratio is configurable from 5:1 to 25:1 to balance safety and performance according to hematocrit, venous access, and citrate tolerance.

The device monitors and displays pressure up to 300 mmHg; in single-needle mode, it defines the return pressure range between 60 and 240 mmHg, and in dual-needle mode, it allows threshold settings between 60 and 300 mmHg to protect the access.
The draw volume in single-needle mode can be adjusted between 3 and 10 mL, stabilizing fragile patients or those with limited access.

The indicators FLOW, K, VOLUME, and MODE display flow rate, anticoagulant mix, blood/AC volumes, and cycle status for immediate bedside decision-making.
Visual and acoustic alarms are triggered when a parameter exceeds safe limits, and the stop/resume logic guides the operator through the correct intervention before continuing.

This approach reduces errors, shortens downtime, and improves both patient and operator experience, even in ICUs or mobile deployments.
It operates between 10 and 35 °C with up to 80 % relative humidity.
Typical power consumption is ≤ 60 VA at 220 V / 50 Hz.
The weight is ≤ 8 kg and the dimensions are 320 × 200 × 200 mm.
Continuous operation exceeds 8 hours, and the specified MTBF is 5,000 hours.
The SM PF 01 and SM PF 01U lines are sterile, single-use, and non-pyrogenic.

Use Cases (Objective Action Result

ICU / Hemodynamic Stability

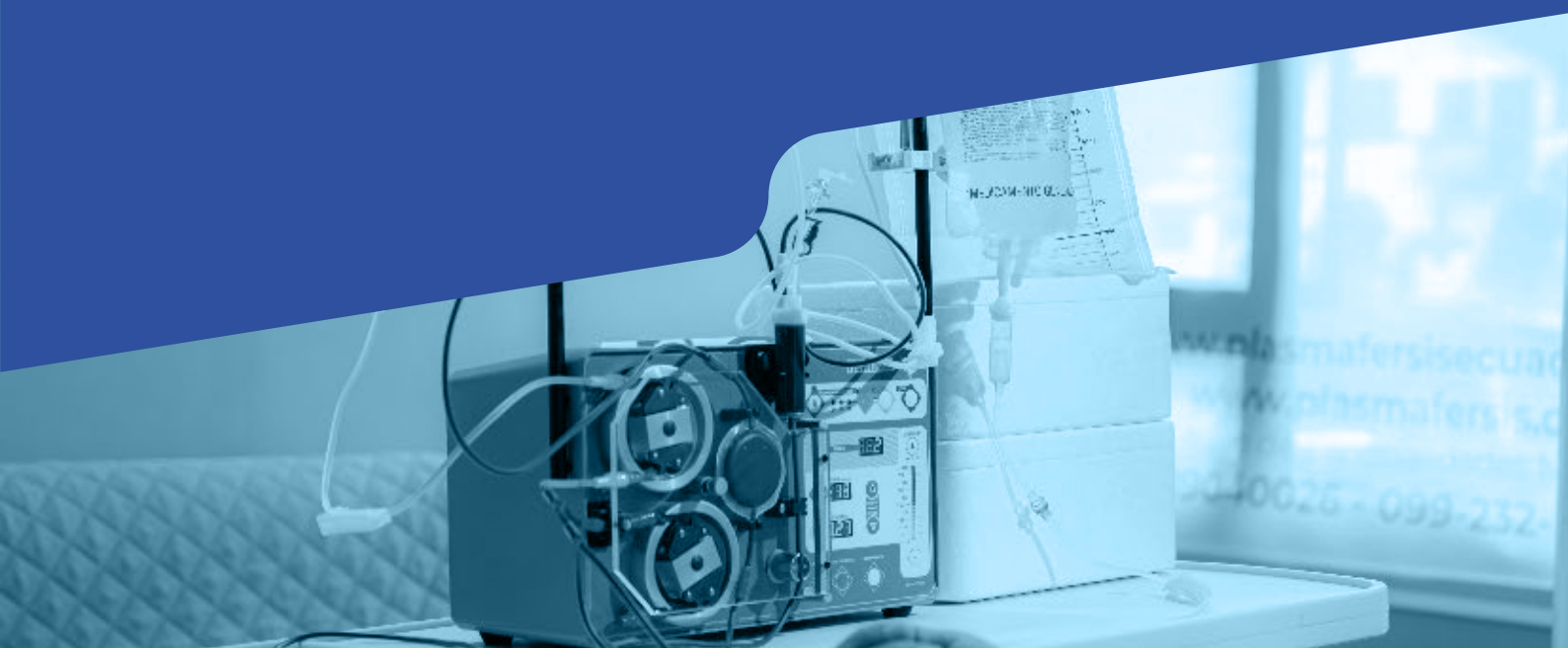
Objective: Exchange with citrate tolerance in a fragile patient.
Action: Single-needle mode with 3–10 mL per draw and return pressure of 60–240 mmHg; real-time adjustment of K (blood:AC) ratio.
Result: Stable session with no unsafe reinfusions; predictable total bed time.

Therapeutic with Second Stage

Objective: Plasmapheresis + hemosorption in a single procedure.
Action: SM-PF-01U with PFM-800/500 and mass transfer module in series.
Result: Expanded clinical indication without changing equipment or retraining staff.

Field Operation

Objective: Bring the procedure to the patient to reduce transfers.
Action: Deployment with ≤ 8 kg weight and ≤ 60 VA power consumption; electrical validation at 110–120 V; mobility SOPs applied.
Result: Greater availability; sessions performed closer to the point of care.



ACTIVE SAFETY AND COMPLIANCE

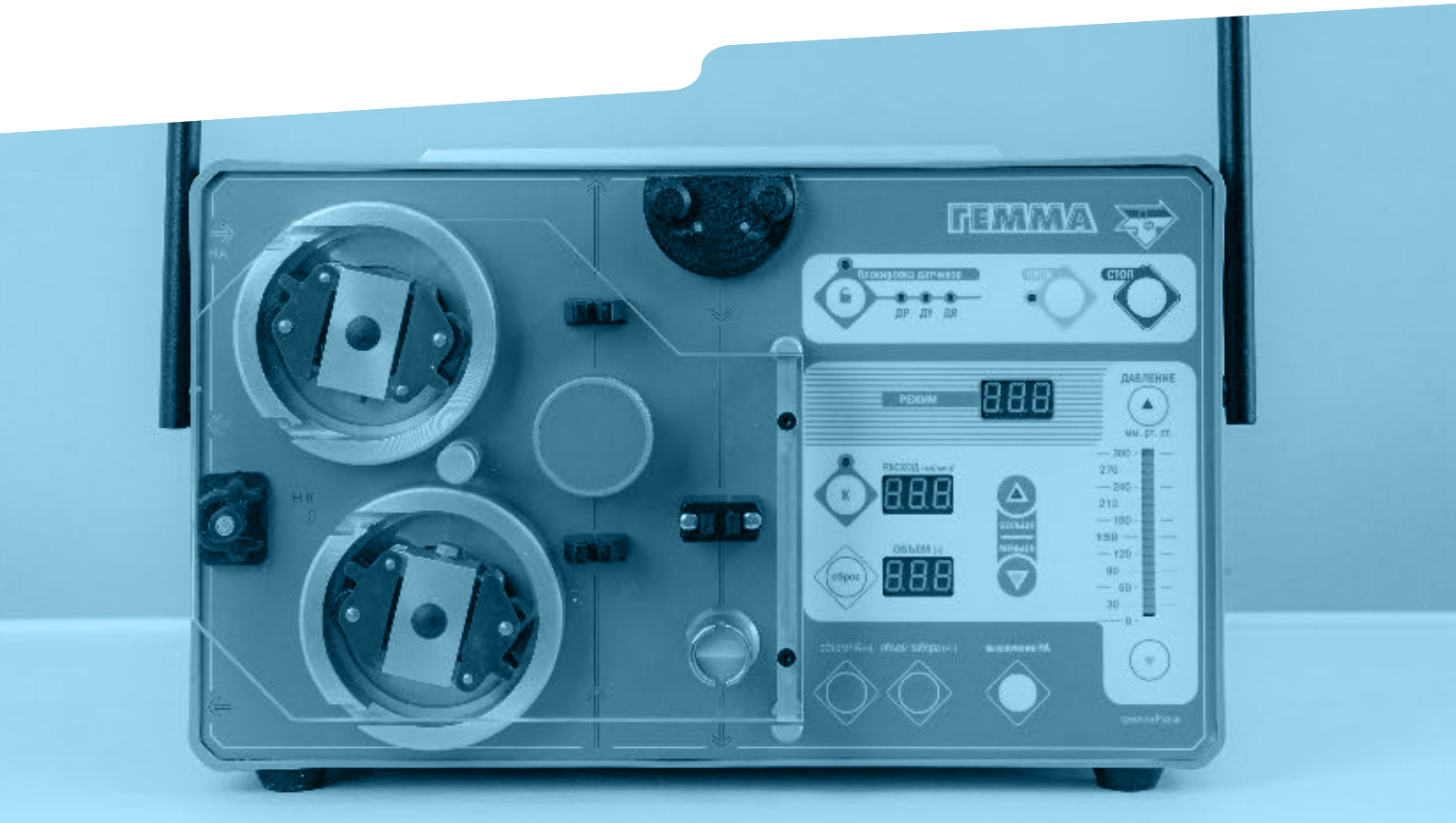
Safety in GEMA is preventive and redundant. It incorporates DR sensors to detect vacuum or air in the aspiration line, DV sensors to identify air in the return line, and a level sensor in the air trap. In addition, a solenoid valve blocks reinfusion in case of risk. The protective cover features an interlock system, and the device verifies its closure before starting operation. Under

mmHg), pressure threshold exceedance, or maximum phase duration, the pumps stop automatically and the screen displays instructions for safe resolution. Once the cause is corrected, the system allows automatic or operator-confirmed resumption depending on the event. The maintenance guidelines include sensor lens cleaning, occlusion adjustment, and calibrations to minimize false alarms

and protect blood integrity. Documentation of origin, warranty, and certificates of acceptance/sale/start-up reinforce the traceability required by clinical and biomedical committees. Operates between 10 and 35 °C with up to 80% relative humidity.

Compliance and Safety (Callout)

Class I, Type CF equipment; operating range 10–35 °C, RH ≤ 80%; ≥ 8 hours of continuous operation; MTBF ≥ 5,000 hours. Active safety features include DR/DV/level sensors, solenoid valve, and protective cover interlock. Provides safe stop and guided restart in case of vacuum limits (−60 to −200 mmHg), pressure thresholds, or maximum phase times. Single-use sterile lines and compatible cleaning protocols (peroxide / “Lotus” / chloramine). Includes warranty documentation and certificates of acceptance, sale, and commissioning.



Clinical Software and On-Site Traceability

GEMA prioritizes decision-making directly on the device, providing live data and direct controls without depending on a donor-oriented BECS/CRM ecosystem. The clear indication of flow, pressure, and anticoagulant mixture allows each session to be personalized and documented according to the institution's format.

For clinical networks, record templates, bilingual SOPs, and decision matrices are provided to standardize the process across facilities and shifts. When required, information can be integrated with existing hospital systems through validated operational procedures and formats, ensuring traceability and local regulatory compliance.

Operates between 10 and 35 °C with up to 80% relative humidity. Typical power consumption is ≤ 60 VA with 220 V / 50 Hz input. The weight is ≤ 8 kg, and the dimensions are 320 × 200 × 200 mm. Continuous operation exceeds 8 hours, and the specified MTBF is 5,000 hours.

The SM PF 01 and SM PF 01U lines are sterile, single-use, and non-pyrogenic. The PFM 800 and PFM 500 filters are selected according to the clinical objective of the procedure. The indicators FLOW, K, VOLUME, and MODE facilitate quick decisions during the session.

Frequently Asked Questions (FAQ)

Do you need BECS/CRM to be efficient?
No. At the bedside or in the ICU, efficiency comes from direct control and portability. GEMA does not rely on BECS to deliver results.

How is the procedure personalized?
Through configurable parameters: 2–200 mL/min (flow), 5:1–25:1 (blood:AC), up to 300 mmHg (pressure), and the FLOW / K / VOLUME / MODE indicators.

Does the second stage require another device?
No. With the SM-PF-01U, hemosorption or selective filtration can be integrated on the same platform.

What maintenance and cleaning are required?
Use compatible cleaning agents (peroxide / "Lotus" / chloramine), perform calibrations, and adjust occlusion as per the manual to maintain ≥ 8 hours of availability.

How to start in LATAM/Costa Rica?
With the startup package, which includes a 110–120 V kit, tests and calibrations, 8–12 hours of training, SOPs, and a consumables/maintenance plan.

CLINICAL IMPLEMENTATION AND OPTIMIZATION SERVICES

To accelerate adoption, we offer an on-site startup package that includes electrical validation, sensor and pressure testing, and initial calibrations. Clinical training (8–12 hours) covers line setup, safety checklist, 1- and 2-needle modes, alarm handling, and preventive maintenance.

We provide SOPs in Spanish and English, along with decision matrices for citrate management, venous access, and pressure/flow control. Consumable sizing and a semiannual maintenance schedule ensure operational continuity.

For Costa Rica and LATAM, we offer a 110–120 V electrical integration kit that guarantees power stability and equipment protection. This approach reduces operational friction, standardizes results, and facilitates internal audits.

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CONFIGURATIONS AND PACKAGES

GEMA Base (SM-PF-01): Membrane-based platform with 1/2-needle access; FLOW / K / VOLUME / MODE indicators; 2–200 mL/min; 5:1–25:1; up to 300 mmHg.

GEMA Universal (SM-PF-01U): Universal trunk to integrate a second stage (hemosorption / selective filtration / cascade) without changing equipment.

Filters: PFM-500 / PFM-800 (selected according to clinical objective); single-use sterile lines.

Field / Prehospital Kit: Environmental validation (10–35 °C; RH ≤ 80%), packaging, quick checklist, and mobility accessories.

ICU Kit: Decision matrices (citrate, venous access, pressure/flow), record formats, and alarm guidelines.

LATAM Startup (110–120 V): Electrical integration kit, sensor/pressure tests, calibrations, 8–12 hours of training, SOPs, and a maintenance plan.

Notes, Availability, and Contact

The technical information is based on the manufacturer's official manuals and may be updated without prior notice. The availability of configurations and consumables is subject to local regulatory requirements.

It is recommended to verify on-site electrical and environmental operating conditions before commissioning. For commercial inquiries, technical support, and on-site validation, please contact us.

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