

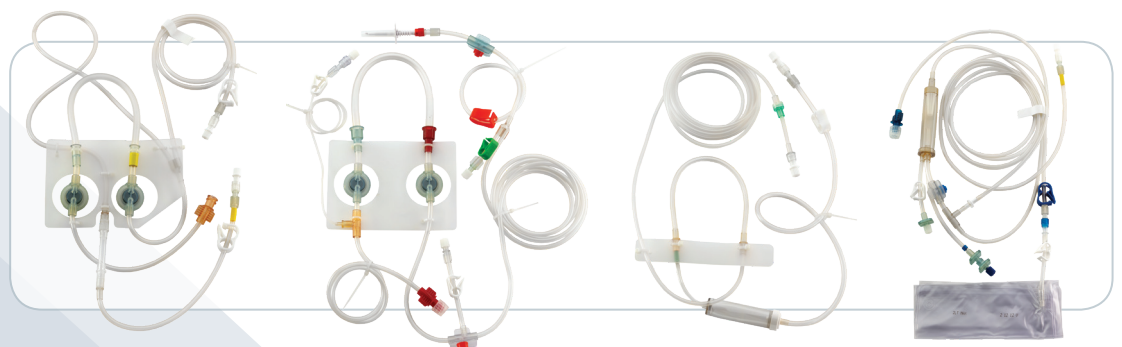
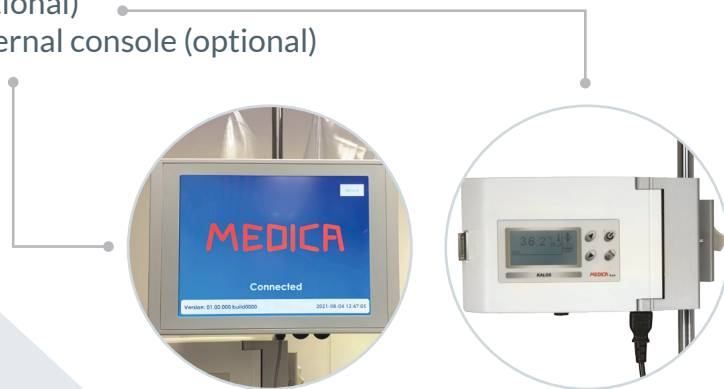
AFERsmart Plus™ Therapeutic apheresis system

AFERsmart Plus™ allows to perform the following treatments:

- Therapeutic Plasma exchange (Plasmapheresis)
- Double filtration plasmapheresis
- Selective apheresis
- Double filtration plasmapheresis and adsorption
- Hemoperfusion

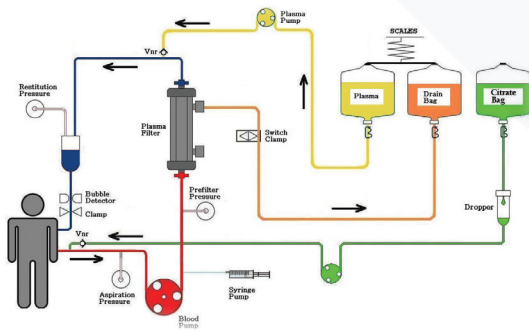
AFERsmart Plus™ Main features:

- Air-free pressure transducers (type DOME)
- Pre-assembled line kit
- Three peristaltic pump
- One syringe pump
- Double scale
- Heparin and/or citrate anticoagulant
- Proprietary self-adjusting clamp for plasma flow control (plasmapheresis)
- Automatic rinsing procedure of the plasma fractionator
- KALOS heater for blood/replacement fluid (optional)
- External console (optional)



AVAILABLE TREATMENTS

THERAPEUTIC PLASMA EXCHANGE



APPLICATION FIELD

Therapeutic Plasma Exchange (TPE) treatment can be used to remove toxic substances with high molecular weight from the plasma, such as:

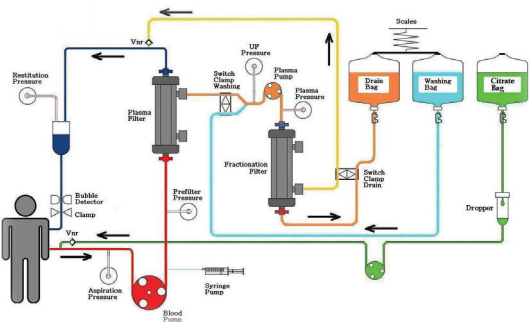
- Pathogen autoantibodies
- Immune complexes
- Cryoglobulins
- Endotoxins
- Cholesterol-containing lipoproteins

TARGET POPULATION

Therapeutic Plasma Exchange (TPE) treatment is indicated for patients affected by various diseases, including:

- Vasculitis (Goodpasture syndrome and Wegener syndrome)
- Thrombotic thrombocytopenic purpura (TTP)
- Cryoglobulinemia
- Micromolecular and macromolecular myeloma
- Lupus erythematosus
- Hemolytic uremic syndrome
- Guillain-Barré syndrome

DOUBLE FILTRATION PLASMAPHERESIS



APPLICATION FIELD

Double filtration treatment can be used to remove multiple molecules, which can be classified as follows:

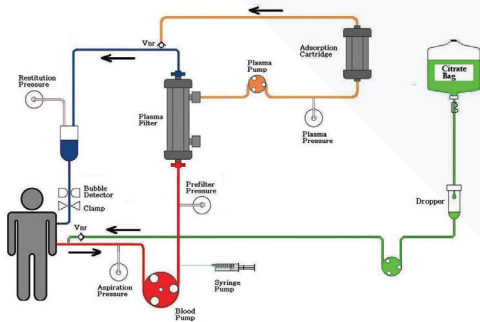
- Antibodies
- Pathogenic substances
- Metabolic factors (example: LDL)
- Inflammatory mediators

TARGET POPULATION

Double filtration apheresis treatment is indicated for patients with various diseases, including:

- Goodpasture syndrome
- Myasthenia gravis
- Chronic inflammatory neuropathy
- Guillain-Barré syndrome
- Neutrophil cytoplasmic autoantibody-associated vasculitis (ANCA = Anti-Neutrophilic Cytoplasmic Autoantibody)
- Acute antibody-mediated rejection (in the post-solid organ transplant), both for ABO-incompatible transplants and in patients with anti-HLA antibodies
- High HCV (hepatitis C virus) load
- Familial hypercholesterolemia, heterozygous, homozygous
- Lp(a) hyperlipoproteinemia
- Multiple sclerosis
- Autoimmune encephalitis
- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Lambert-Eaton syndrome
- Morvan syndrome
- Dilated cardiomyopathy
- Nephritis
- Nephropathy membranous
- Rapidly progressive glomerulonephritis (RPGN)
- Goodpasture syndrome
- Recurrent focal segmental glomerulosclerosis (FSGS)
- Pemphigus vulgaris

SELECTIVE AIPHERESIS



APPLICATION FIELD

Selective apheresis treatment can be used to remove multiple types of molecules:

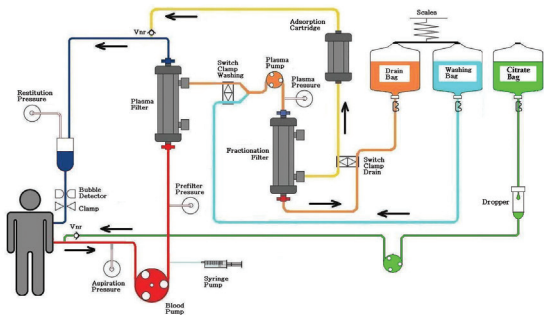
- Apo-B-containing lipoproteins [example: LDL, Lp(a)]
- Inflammatory mediators
- Anti-DNA antibodies
- Anti-cardiolipin
- Immune complexes

TARGET POPULATION

This treatment is indicated for patients with multiple pathologies, including:

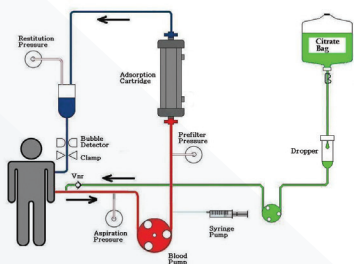
- Familial hypercholesterolemia
- Peripheral arterial occlusive syndrome
- Focal segmental glomerulosclerosis
- Systemic lupus erythematosus
- Goodpasture's syndrome
- Cryoglobulinemia
- Thrombotic thrombocytopenic purpura (TTP)
- Devic's neuromyelitis optica
- Transplantation:
 - HLA-incompatible transplantation
 - ABO-incompatible blood group transplantation
 - Acute antibody-mediated rejection

DOUBLE FILTRATION AIPHERESIS AND ADSORPTION



This technique allows the treatment of patients with septic shock in which it is necessary to remove pro-inflammatory cytokines, released in large quantities in the case of sepsis.

HEMOPERFUSION



APPLICATION FIELD

Hemoperfusion (HP) treatments have demonstrated their effectiveness in all those cases where there is a need to selectively remove known molecules, directly from the blood, such as:

- Pro- and anti-inflammatory mediators
- Apo-B lipoproteins [e.g. LDL, Lp(a)]
- B-2 Microglobulin
- In case of high levels of cytokines and/or bilirubin and/or myoglobin

TARGET POPULATION

This treatment can be adopted for patients with various pathological conditions, including:

- Sepsis / Severe Sepsis / Septic Shock / Multiple Organ Failure Syndrome (MOF)
- Familial Hypercholesterolemia
- Dialysis-Related Amyloidosis (DRA)
- Lp(a) Hyperlipoproteinemia
- "Systemic Inflammatory Response Syndrome" (SIRS)
- Treatment of rhabdomyolysis
- Hyperbilirubinemia

Operating conditions	Temperature from 15°C to 35°C Relative humidity from 35% to 75% Atmospheric pressure from 700 to 1060 hPa
Transport conditions	Temperature from -10°C to +50°C Relative humidity from 35% to 85% Atmospheric pressure from 500 to 1060 hPa
Power supply	230 VCA (±10%) 110 VCA (±10%) 50Hz/60Hz
Power adsorption	Power adsorption in the worst conditions is 110 VA
Mechanical structure	Height: 365 mm Width: 375 mm; Depth: 300 mm Trolley dimensions: Trolley Base: 440 x 500 mm Maximum height pole: 1970 mm Weight with trolley: 36Kg
Blood pump	Maximum flow range: [0 to 450] ml/min Resolution: 5 ml/min
Plasma pump	[0 to 200] ml/min Adjustable flow range (by the operator): [0 to 30] % in relation to blood pump speed Resolution: 1ml/min
Citrate pump	Reachable flow range: [0 to 2000] ml/h Resolution: 1 ml/min
Syringe pump	Supported syringes: 30 ml Flow rate: [0.20] ml/h Sensitivity: 0.1 ml Accuracy: +/- 0.2 ml or 2%
Venous pressure	Range: [-100, +500] mmHg Sensitivity: 1 mmHg Displayed resolution: 5 mmHg
Arterial pressure (type DOME)	Range: [-300, +300] mmHg Sensitivity: 1 mmHg Displayed resolution: 5 mmHg
Pre-filter pressure (type DOME)	Range: [-100, +500] mmHg Sensitivity: 1 mmHg Displayed resolution: 5 mmHg
Plasma pressure (type DOME)	Range: [-100, +500] mmHg Sensitivity: 1 mmHg Displayed resolution: 5 mmHg
UF pressure (type DOME)	Range: [-300, +500] mmHg Sensitivity: 1 mmHg Displayed resolution: 5 mmHg

Bubble detector	Ultrasonic sensor. Sensitivity: 0.1 ml (at the flow rate of 100 ml/min)
Washing and draining scale	Range: [0.6] kg Sensitivity: 1 g Accuracy: ±20 g or ±1%
Washing clamp	Switch clamp with 4 independent ways Maximum closing pressure: 600 mmHg
Drain clamp	Switch clamp with 2 independent ways Maximum closing pressure: 600 mmHg
Blood and hemoglobin detector	Detects traces of blood or hemoglobin in the ultra-filtered fluid <ul style="list-style-type: none"> Optical sensor based on the spectroscopic analysis Sensitivity: 0.5% of blood or 0.5% of hemoglobin
Blood detector	Optical sensor able to detect blood inside the venous line. Sensitivity: 0.5%
Drip sensor	Check the citrate flow by counting the drops. Drop volume = 50uL + -10%
User interface	The UI consists of a colourful, integrated 5.7" display, a rotary selector to set the parameters and a membrane keyboard containing 3 keys for the most critical functions: blood pump's start and stop, alarm reset, assistance on the current operating alarm.
Serial port RS232	Used to communicate with the external console and for software upgrades
External console (optional)	A 10" external console. Reads data about the device treatment and pictures the most important informations for the operator. Saves the informations in an internal register and provides the automatic download of it on a USB stick.

PRODUCT CODES

M90414	AFERsmart Plus™
M90420/R/RH	AFERsmart Plus™ DFPP line with plasma heating bag
M90422	AFERsmart Plus™ selective apheresis line
M90424	AFERsmart Plus™ double filtration adsorption line
M90426	AFERsmart Plus™ HEMOPERFUSION line
M90428	AFERsmart Plus™ PLASMA EXCHANGE line

MANUFACTURER

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