Medtronic

Technical Data Sheet

Preassembled device for Coupled Plasma Filtration and Adsorption (CPFA) treatment with Amplya™ system

Product description

The preassembled device for coupled plasma filtration and adsorption (CPFA) treatment is a sterile, single-use, non-pyrogenic with integrated extracorporeal circuit, a hemofilter, a plasmafilter, and a heater bag for use with the Amplya™ system.

These preassembled devices are composed by the tubing lines (blood, infusion, and ultrafiltration) with two cassettes for extracorporeal circulation, a hemofilter (HFT 14), a plasmafilter (MPS05), and a heater bag. The componenets are preconnected and fastened to a thermoformed support for easy installation of the medical device on the machine.

The CPFA treatment is an extracorporeal blood purification treatment that combines plasma separation and adsorption of inflammatory mediators and/or toxins with hemofiltration.

The tubing lines that compose the preassembled device consist of a line for replacement fluid infusion, a line for extraction of the waste fluid (ultrafiltrate), a line for plasma clearence and its reinfusion once treated, and possibly a pre-diluition line, two cassettes.

The devices contain a hemofilter HFT 14, that consists of an outer cylindrical polycarbonate body containing a bundle of microporous, high-permeability hollow fibers. The hollow-fiber bundle is secured at at the end with hot melt polyurethane resin. The hemofilters have nominal filtering area of 1.4 m^2.

The plasmafilter MPS05 is a filter used in association with the preassembled devices for coupled plasma filtration and adsorption (CPFA) treatment. The MICROPLAS plasmafilter is composed by MicroPES membrane and by luer lock connections to the blood and plasma circuits. The MICROPLAS is a plasmafilter to separate plasma from blood.

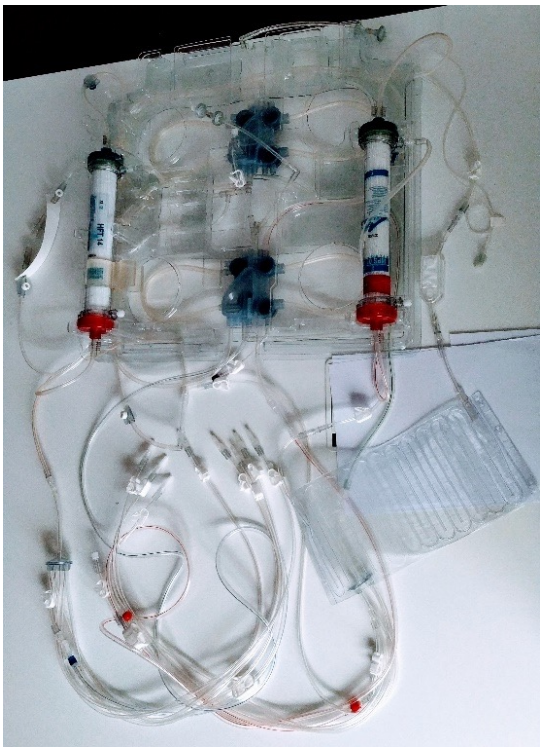

Figure 1: Preassembled CPFA photo device

Applicable therapies

Coupled plasma filtration and adsorption (CPFA) is continuous treatment. CPFA is an extracorporeal blood purification treatment that combines plasma separation and adsorption of inflammatory mediators and/or toxins with hemofiltration.

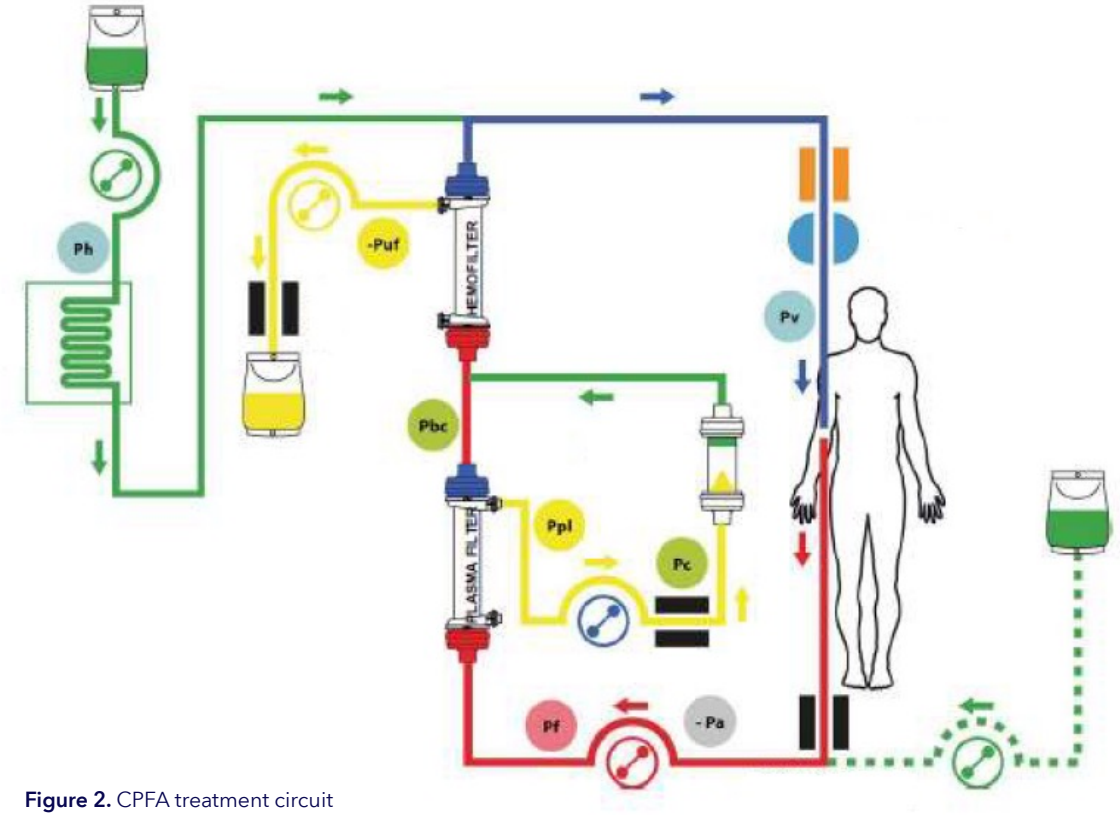

Figure 2. CPFA treatment circuit

Description of the image above:

The blood pump and the blood flow on the access in red.
The blood flow on the return side in blue.
The infusion pump, the bags and the infusion flow in green on the left.
The pre-dilution pump, the bags and the pre-dilution flow in green on the right.
The ultrafiltration or ultrafiltration pump, the bags and ultrafiltration (plasma water) flow in yellow on the left.
In the center, the plasma flow into the Mediasorb cartridge in yellow, the plasma flow out of the Mediasorb cartridge in green, and the plasma pump in blue.
The hemofilter, the plasma filter and the Mediasorb cartridge.
The heater, the sensors and the venous electoclamp.
The pressures measured directly or indirectly access (-Pa), return (Pv), plasma filter inlet (Pf), hemofilter inlet or plasma filter outlet or Mediasorb outlet (Pbc), infusion pump outlet (Ph), ultrafiltration pump inlet (-Puf), Mediasorb inlet (Pc), plasma pump inlet (Ppl).

Intended use

The device has been designed for extracorporeal blood circulation in:

- Treatment in cases of sepsi and/or multiple organ dysfuncion.

Code available

CFN	Models	Filter	Description	CND	GMDN
IB0086000	ABL14P05	HFT 14 + MPS05	Preassembled device for CPFA for Amplya™ system	F020199	61674

Sterilization method and validity

Sterile and non-pyrogenic.

Sterilizing agent: gamma radiation.

Shelf life: 12 months.

Do not resterilize.

Technical characteristics

The technical characteristics of the preassembled devices for CPFA treatments with Amplya™ system are reported below.

HFT 14 - Hemofilter	
Components	**Materials**
Membrane	Polyethersulfone
Housing	Polycarbonate
Header	Polycarbonate
Caps	Polycarbonate
Potting	Polyurethane
O-ring	Silicone rubber

MPS05 - Plasmafilter	
Components	**Materials**
Membrane	Polyethersulfone
Housing	Polycarbonate
Header	Polycarbonate
Luer cap	High density polyethylene
Protective caps	Polypropylene
Potting A[1]	Polyol
Potting B[1]	Isocyanate
O-ring	Termoplastic Elastomer TPE
Luer joint for gluing	Polycarbonate
Sterilization cap	Polypropylene
Side Caps	Polyethylene

[1]Potting A and Potting B are the materials that mixed together make up potting component.

Tubing lines	
Components	**Materials**
Cassette body	Rigid Polyvinyl chloride
Cassette Membrane	Ethylene-propylene diene monomer
Venous filter	High density polyethylene
Tubing lines	Soft Polyvinyl chloride
T connector	Rigid Polyvinyl chloride
Y connector	Rigid Polyvinyl chloride
Seal and caps	High density polyethylene
Luer lock and dialyzer connection	Rigid Polyvinyl chloride - Acrylonitrile butadiene styrene
Transducer protector	Rigid and Soft Polyvinyl chloride
Laminate Membrane	Expanded Polytetrafluoroethylene
Check valve	Acrylonitrile butadiene styrene or Silicone rubber
Cuvette	Polyethylene terephthalate glycol copolyester for the body - Polyvinyl chloride for the connection
Bowl	Rigid Polyvinyl chloride

Heater bag	
Components	**Materials**
Film	Polyvinyl chloride
Tube	Polyvinyl chloride

Technical characteristics HFT14 - Hemofilter								
Model	**Surface area (m^2)**	**Fiber wall thickness (µm)**	**Fiber internal diameter (µm)**	**Filling volume blood compartment (ml)**	**Blood compartment pressure drop[2] (mmHg)**	**Weight (g)**	**Total length[3] (mm)**	**External diameter[3] (mm)**
HFT 14	1.4	30	200	85	< 45	191	305	55

[2] Bovine blood: Hct 32±3%, proteins 60±5 g/l, Q_B = 200 ml/min

[3] Outer body characteristics

Technical characteristics MPS05 - Plasmafilter									
Model	**Surface area (m^2)**	**Number of fibers**	**Fiber wall thickness (µm)**	**Fiber internal diameter (µm)**	**Maximum pore size (µm)**	**Filling volume blood compartment (ml)**	**Plasma compartment priming volume (ml)**	**Total length[4] (mm)**	**External diameter[4] (mm)**
MPS05	0.45	2000	100	300	0.5	50	125	305	55

[4] Outer body characteristics

Technical characteristics preassembled device	
Model	**Priming volume hematic circuit (hemofilter and plasmafilter excluded) (ml)**
ABL14P05	103

Performance

The measurements in the charts below are taken in accordance with EN ISO 8637-2. The values indicated are to be considered approximate and may vary due to measurement methods, inherent variations of the membrane, manufacturing, and storage conditions. During the treatment, performance on the individual patient may vary due to variable clinical parameters of the patient.

The reported performances below refer to each hemofilter present in preassembled device for CPFA treatment.

UF Coefficient[5]	
Model	**Ultrafiltration (ml/h*mmHg)**
HFT 14	41

[5] Qb = 300 ml/min; bovine blood (Hct 32±3%; proteins 60±5 g/l)

Packaging

Model	Primary packaging	
	Pouch material	**Pouch weight (g)**
ABL14P05	Low density polyethylene and Tyvek	132,44

Storage and disposal conditions

Storage conditions: store at temperatures between +0 and +30 degrees Celsius.

Disposal: dispose of the device after treatment in accordance with applicable government and health center regulations.

Biocompatibility

Biocompatibility tests of the preassembled devices for CPFA treatments with Amplya™ system have been performed according to ISO 10993-1 and related applicable standard series.

Bellco S.r.l.
Via Camurana, 1 - 41037 Mirandola (MO) Italy www.bellco.net

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