Medtronic

Technical Data Sheet

Preassembled devices for renal replacement therapy treatments with Amplya™ system

Product description

The preassembled devices for renal replacement therapy (RRT) treatments are a sterile, single use, non-pyrogenic with integrated extracorporeal circuit, a hemofilter and a heater bag for use with the Amplya™ system.

These preassembled devices are composed of the different tubing lines (blood, infusion, and ultrafiltration) with two cassettes for extracorporeal circulation, a hemofilter, and a heater bag. All the componenets are pre-connected and fastened to a thermo-formed support for easy installation of the medical device on the system.

The devices contain different HFT hemofilters, these devices consist of an outer cylindrical polycarbonate body containing a bundle of microporous, high-permeability hollow fibers. The hollow-fiber bundle is secured at the end with hot melt polyurethane resin. The hemofilters have nominal filtering areas that range from 0.3 to 2.2 m^2.

The RRT treatments are defined as continuous when the treatment time is not established, and as intermittent when the treatment time is not more than 24 hours. There are four types of RRT treatments, including continuous and intermittent hemodiafiltration, continuous and intermittent hemodialysis, continuous and intermittent hemofiltration, and continuous ultrafiltration. Each of the RRT treatments share the same priming/rinsing procedure.

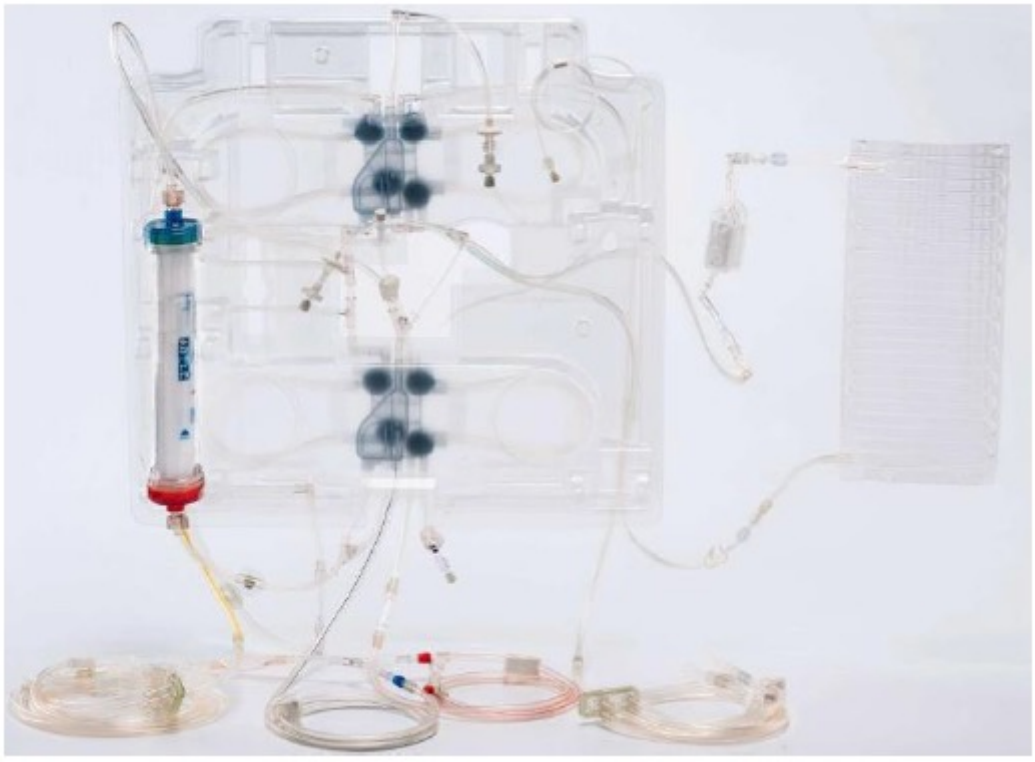

Figure 1. Preassembled RRT photo device

Applicable therapies

The RRT treatments are defined as continuous when the treatment time is not established, and as intermittent when the treatment time is not more than 24 hours. Each of the RRT treatments share the same priming/rinsing procedure.

The types of RRT treatment are:

- Continuous and intermittent hemodiafiltration.
- Continuous and intermittent hemodialysis.
- Continuous and intermittent hemofiltration.
- Continuous ultafiltration.

Hemodiafiltration

Hemodiafiltration is an RRT treatment and may be continuous or intermittent. The hemofilter sizes vary from 0.3 m^2 to 1.7 m^2 for increasing flow values.

The replacement fluids that can be used are medications produced for hemofiltration treatments. The single-use circuit includes a line for fluid infusion into the dialysate compartment of the filter, a line for replacement fluid infusion at the hemofilter outlet (post-infusion), and a line for extraction of the waste fluid (ultrafiltrate).

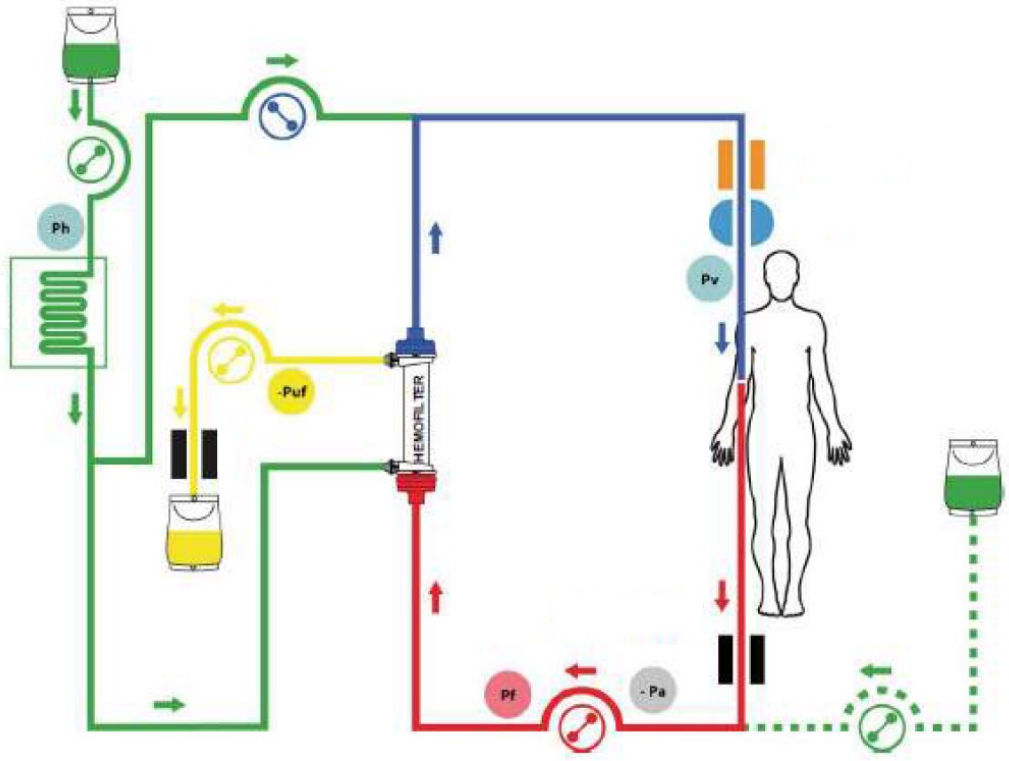

Figure 2: Hemodiafiltration Treatment Circuit

Description of the image above:

The blood pump and the blood flow on the access side in red
The blood flow on the return side in blue
On the left, the infusion pump in green, the post-infusion pump in blue, and the bags and infusion flow for the dialysate compartment of the filter and for post-infusion in green
The pre-dilution pump, the bags and the pre-dilution flow in green on the right
The ultrafiltration or ultrafiltration pump, the collection bags and the ultrafiltrate (plasma water) flow in yellow
The hemofilter
The heater, the sensors and the venous electoclamp
The pressures measured directly or indirectly: access (-Pa), return (Pv), hemofilter inlet (Pf), infusion pump outlet (Ph), ultrafiltration pump inlet (-Puf)

Hemodialysis

Hemodialysis is an RRT treatment and may be continuous or intermittent. The hemofilter sizes vary from 0.3 m^2 to 1.7 m^2 for increasing flow values. The replacement fluids that can be used are medications produced for hemofiltration treatments. The single-use circuit includes a line for fluid infusion into the dialysate compartment of the filter and a line for extraction of the waste fluid (ultrafiltrate).

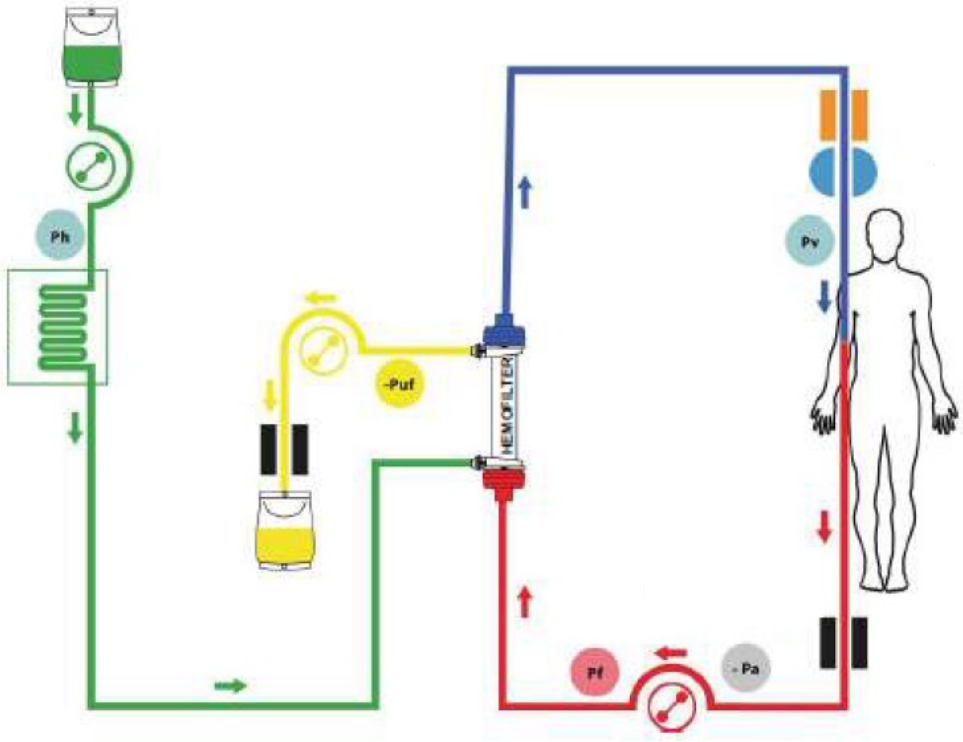

Figure 3: Hemodialysis Treatment Circuit

Description of the image above:

The blood pump and the blood flow on the access side in red
The blood flow on the return side in blue
The infusion pump, the bags and the infusion flow for the dialysate compartment of the filter in green on the left
The ultrafiltration or ultrafiltration pump, the collection bags and the ultrafiltrate (plasma water) flow in yellow
The hemofilter
The heater, the sensors and the venous electroclamp
The pressures measured directly or indirectly: access (-Pa), return (Pv), hemofilter inlet (Pf), infusion pump outlet (Ph), ultrafiltration pump inlet (-Puf)

Hemofiltration

Hemofiltration is an RRT treatment and may be continuous or intermittent. The hemofilter sizes vary from 0.3 m^2 to 2.2 m^2 for increasing flow values. The replacement fluids that can be used are medications produced for hemofiltration treatments.

The single-use circuit includes a line for replacement fluid infusion at the hemofilter inlet (pre-infusion), a line for replacement fluid infusion at the hemofilter outlet (post-infusion), and a line for extraction of the waste fluid (ultrafiltrate).

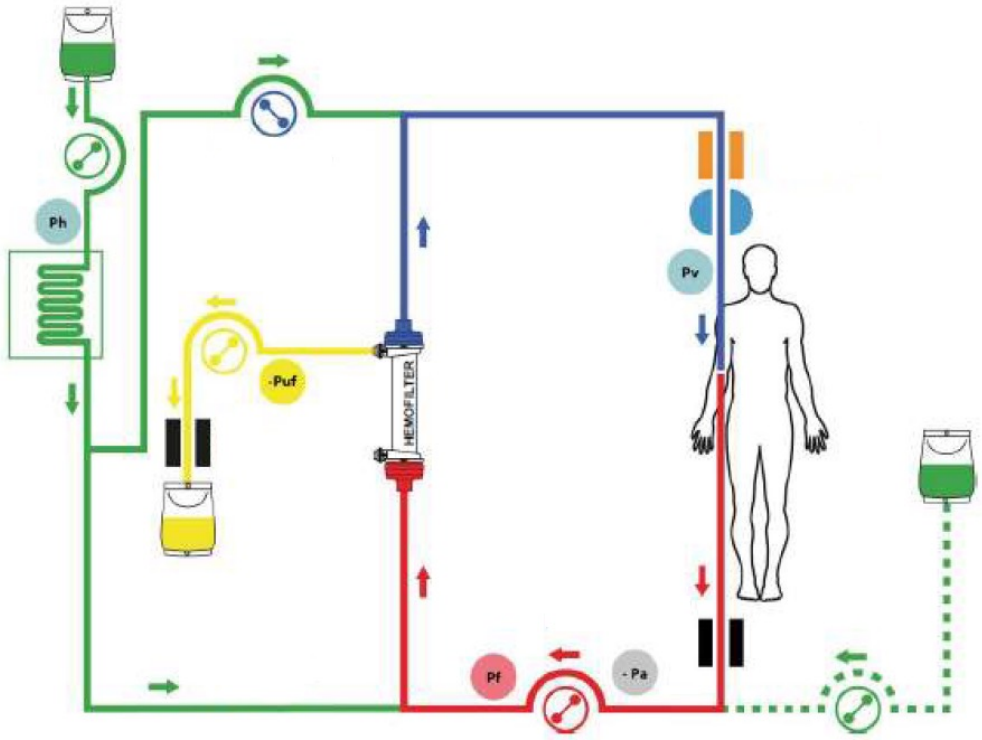

Figure 4: Hemofiltration Treatment Circuit

Description of the image above:

The blood pump and the blood flow on the access side in red.
The blood flow on the return side in blue.
On the left, the infusion pump in green, the post-infusion pump in blue, and the infusion bags and the pre- and post-infusion flow in green.
The pre-dilution pump, the bags and the pre-dilution flow in green on the right.
The ultrafiltration or ultrafiltration pump, the collection bags and the ultrafiltrate (plasma water) flow in yellow.
The hemofilter, the heater, the sensors and the venous electoclamp.
The pressures measured directly or indirectly: access (-Pa), return (Pv), hemofilter inlet (Pf), infusion pump outlet (Ph), ultrafiltration pump inlet (-Puf).

Ultrafiltration

Ultrafiltration is a continuous RRT treatment. The hemofilter sizes from 0.3 m^2 to 1.7 m^2 for increasing flow values. The single-use circuit includes a line for extraction of the waste fluid (ultrafiltrate).

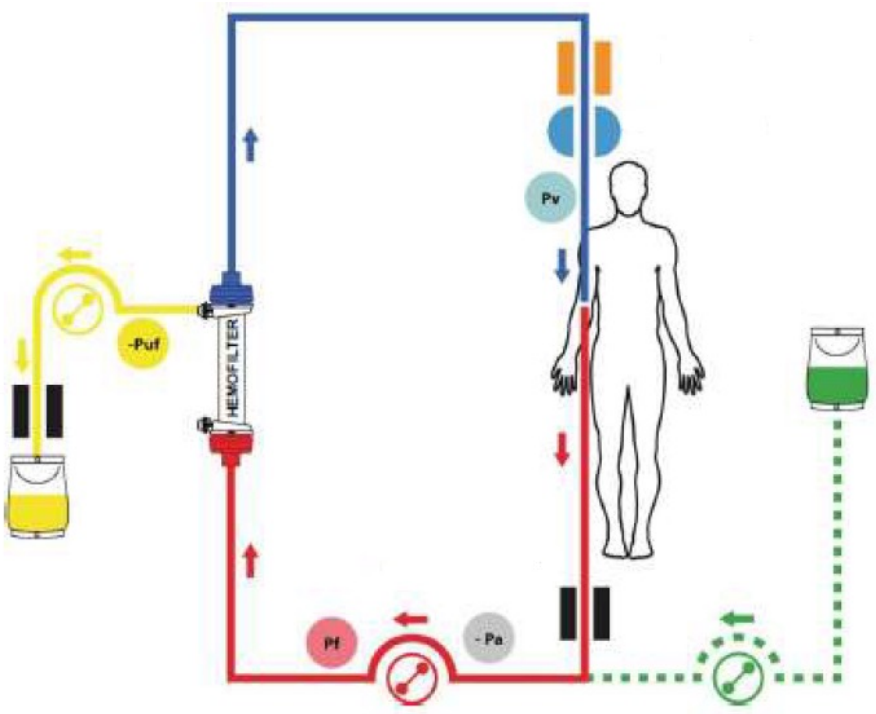

Figure 5: Ultrafiltration Treatment Circuit

Description of the image above:

The blood pump and the blood flow on the access side in red.
The blood flow on the return side in blue.
The pre-dilution pump, the bags and the pre-dilution flow in green.
The ultrafiltration or ultrafiltrate pump, the collection bags and the ultrafiltrate (plasma water) flow in yellow.
The hemofilter.
The sensors and the venous electroclamp.
The pressures measured directly or indirectly: access (-Pa), return (Pv), hemofilter inlet (Pf), ultrafiltrate pump (-Puf).

Intended use

The device has been designed for extracorporeal blood circulation in:

- Hemodialysis, hemodiafiltration and hemofiltration treatments in cases of chronic and acute renal failure.
- Blood clearance treatments in cases of acute intoxication with dialysable substances.
- Hemofiltration treatments in cases of water overload.

Codes available

CFN	Models	Filter	Description	CND	GMDN
IB0580903	ABLD03	HFT 03	Preassembled device for RRT for Amplya™ system	F0399	61674
IB0580905	ABLD05	HFT 05	Preassembled device for RRT for Amplya™ system	F0399	61674
IB0580908	ABLD08	HFT 08	Preassembled device for RRT for Amplya™ system	F0399	61674
IB0580914	ABLD14	HFT 14	Preassembled device for RRT for Amplya™ system	F0399	61674
IB0580917	ABLD17	HFT 17	Preassembled device for RRT for Amplya™ system	F0399	61674
IB0580922	ABLD22	HFT 22	Preassembled device for RRT for Amplya™ system	F0399	61674

Sterilization method and validity

Sterile and non-pyrogenic
Sterilizing agent: gamma radiation
Shelf life: 30 months
Do not resterilize

Technical characteristics

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

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

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
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 of Hemofilters								
Model	**Surface area (m^2)**	**Fiber wall thickness (µm)**	**Fiber internal diameter (µm)**	**Filling volume blood compartment (ml)**	**Blood compartment pressure drop[1] (mmHg)**	**Weight (g)**	**Total length[2] (mm)**	**External diameter[2] (mm)**
HFT 03	0.3	30	200	36	< 40	98	145	55
HFT 05	0.5	30	200	44	< 30	102	145	55
HFT 08	0.8	30	200	50	< 80	162	305	55
HFT 14	1.4	30	200	85	< 45	191	305	55
HFT 17	1.7	30	200	109	< 25	194	305	55
HFT 22	2.2	30	200	132	< 30	201	365	55

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

[2] Outer body characteristics.

Technical characteristics preassembled devices	
Model	Priming volume hematic circuit (hemofilter excluded) (ml)
ABLD03	109
ABLD05	
ABLD08	
ABLD14	
ABLD17	
ABLD22	

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 each preassembled device for RRT treatment.

Model	UF Coefficient[3]
	Ultrafiltration (ml/h*mmHg)
HFT 03	16
HFT 05	25
HFT 08	33
HFT 14	41
HFT 17	80
HFT 22	75

[3] Ultrafiltration coefficient: Q_B = 300 ml/min, bovine blood Hct= 32%, proteins = 60 g/l

Packaging

Model	Primary packaging	
	Pouch material	Pouch weight (g)
ABLD03 ABLD05 ABLD08 ABLD14 ABLD17 ABLD22	Low density polyethylene and Tyvek	132,06

Model	Secondary packaging – Box		
	Single Box	Weight[4] (kg)	Pcs[5]
ABLD03	White colored micro-triple Kraft cardboard, double wave EB Dimensions: 785 x 590 x 140 mm	4,6	2
ABLD05	White colored micro-triple Kraft cardboard, double wave EB Dimensions: 785 x 590 x 140 mm	4,7	2
ABLD08	White colored micro-triple Kraft cardboard, double wave EB Dimensions: 785 x 590 x 140 mm	5,3	2
ABLD14	White colored micro-triple Kraft cardboard, double wave EB Dimensions: 785 x 590 x 140 mm	4,7	2
ABLD17	White colored micro-triple Kraft cardboard, double wave EB Dimensions: 785 x 590 x 140 mm	4,7	2
ABLD22	White colored micro-triple Kraft cardboard, double wave EB Dimensions: 785 x 590 x 140 mm	5,4	2

[4] Single box weight.

[5] Number of preassembled devices in a single box.

Storage and disposal conditions

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

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

Biocompatibility

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

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