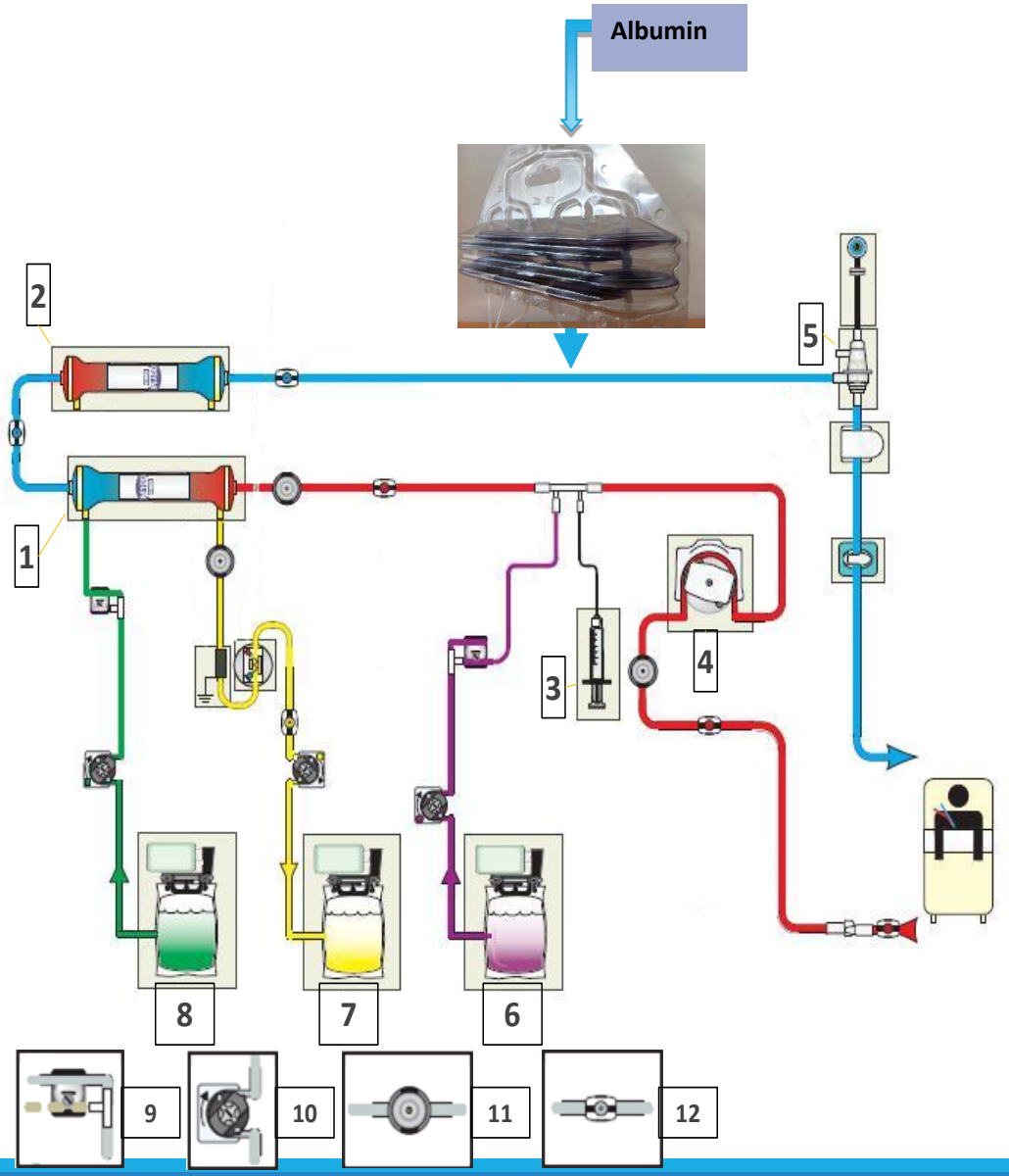
ALIVER Project overview
Development of DIALIVE, a novel Liver Dialysis Device for the treatment of patients with Acute on Chronic Liver Failure (ACLF)

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733057

1. Gambro Septex – Albumin Removal (Allocated “FILTER SET 1”)
2. Gambro oXiris– Bacterial Endotoxin Removal (Allocated “FILTER SET 2”)
3. Heparin Syringe pump
4. Blood pump
5. Bubble trap
6. Pre-Diluter Solution bag
7. Effluent bag
8. Dialysate bag
9. Safety valve
10. Pump
11. Pressure sensor
12. Sampling site



Extracorporeal Support Equipment	Regulatory Status
Prismaflex Monitor	CE 0086
Extension Tubing	CE 0086
Accessories	CE 0086

12-Adsorbent Cluster for Albumin Dialysis-CE Marked

NEW Albumin ReCycler for Albumin Dialysis/Plasmapheresis -will be CE marked at Phase II Study

NEW Albumin ReCycler for Albumin Dialysis/Plasmapheresis
-will be CE marked at Phase II Study – can be adapted to Albumin Volume

Set up of the ALIVER system

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Components of the system

The treatment system requires

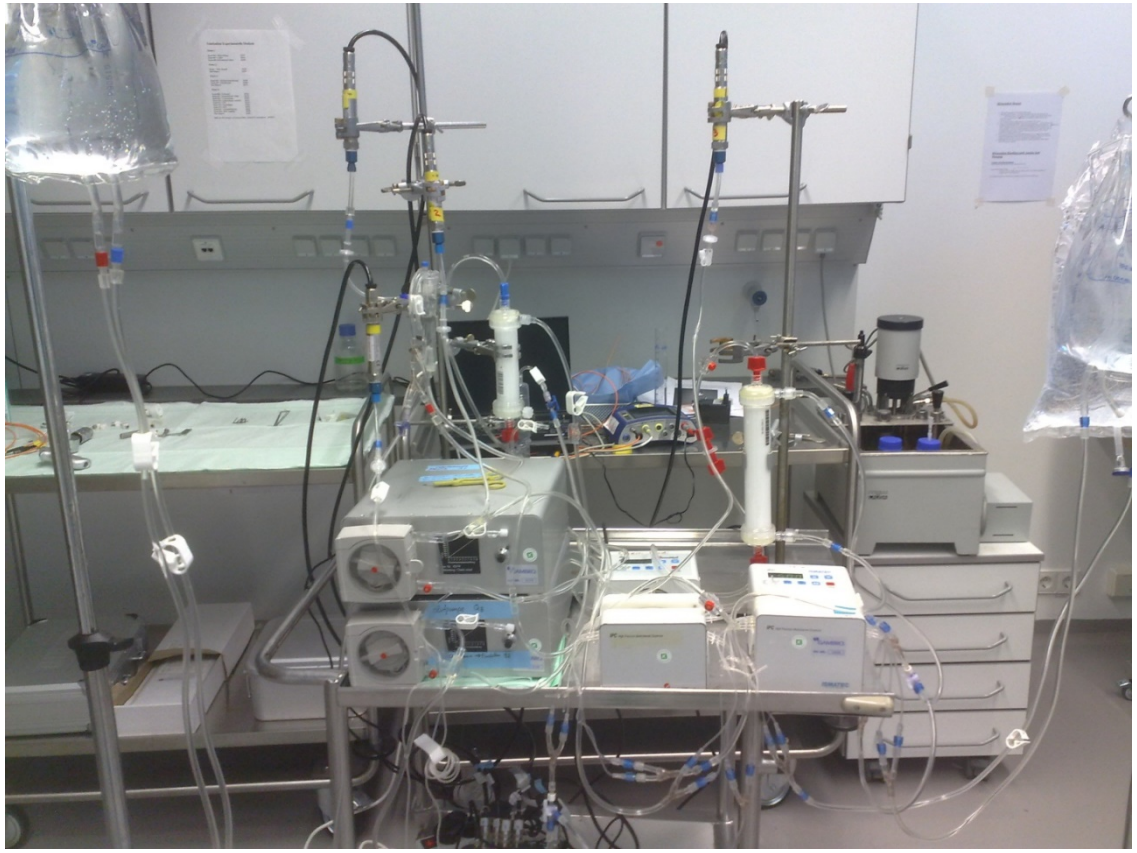
A Prismaflex monitor

1 septeX treatment kit

1 oXiris treatment kit

1 connecting tubing

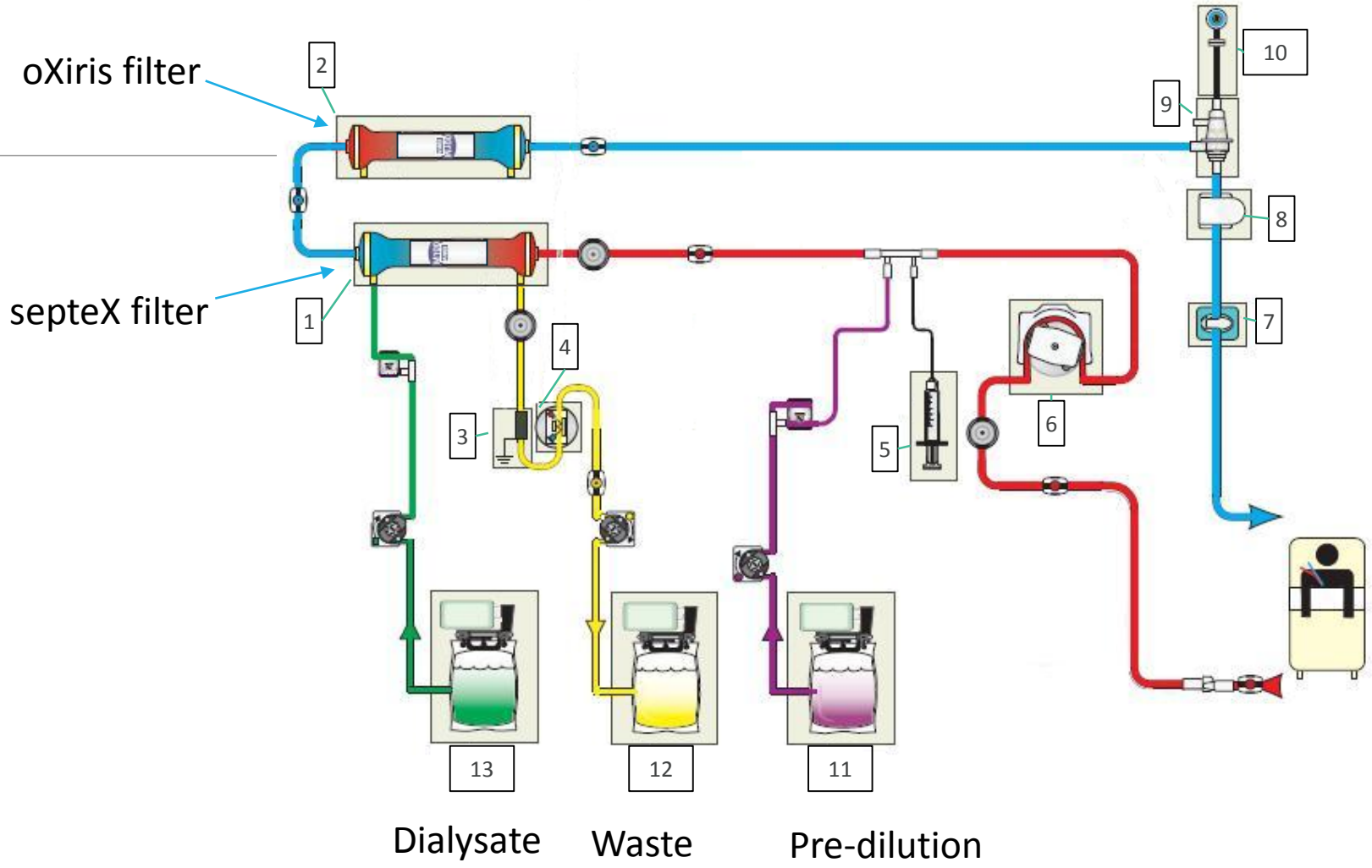
Where we started

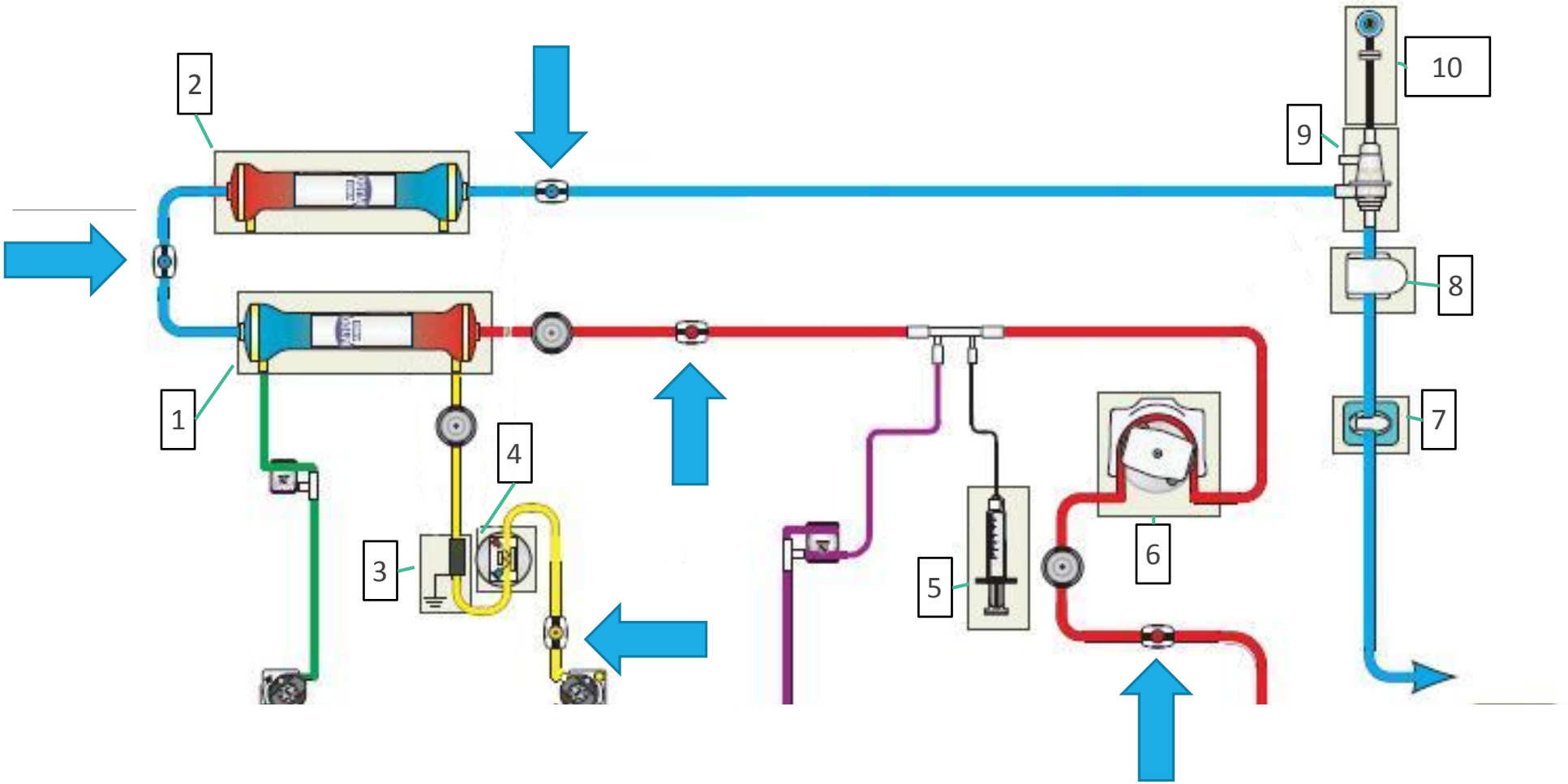


To treat the patient

The operator of the system should be trained and familiar with the Prismaflex system.

Set up involves the use of the two treatment kits placed in series.


oXiris filter
septeX filter
1
2
3
4
5
6
7
8
9
10
11
12
13
Dialysate
Waste
Pre-dilution


2
10
9
8
1
7
4
3
6
5

The practicalities of the system

septeX treatment kit

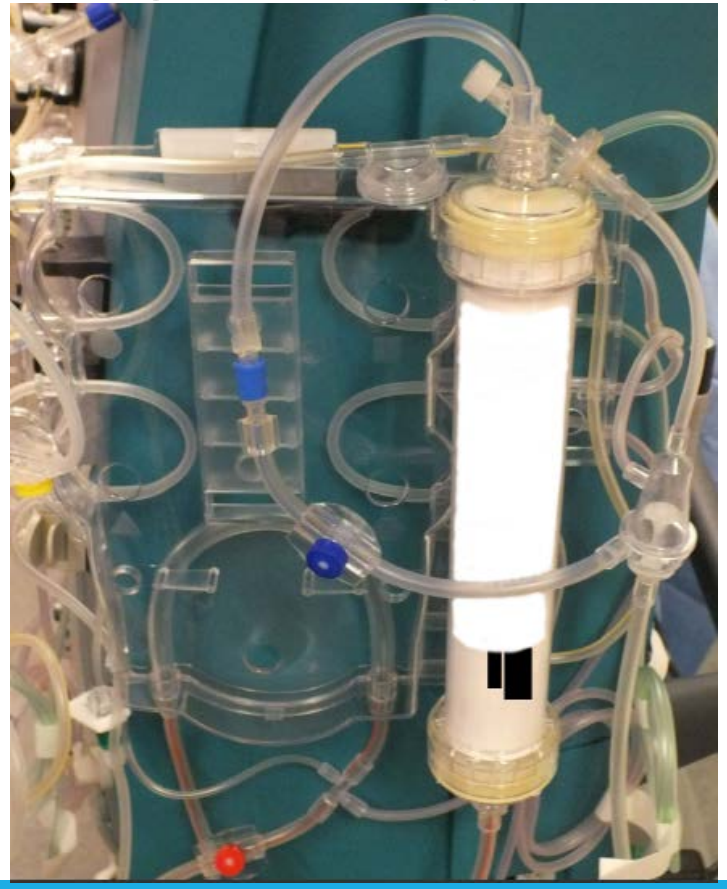
oXiris treatment kit

Set-up of the system

1. Load the septeX filter on the front of the machine using the automated system, then select the HF1000 protocol

Attach the second filter

2. Attach the oXiris filter using the black support on the RHS of the system



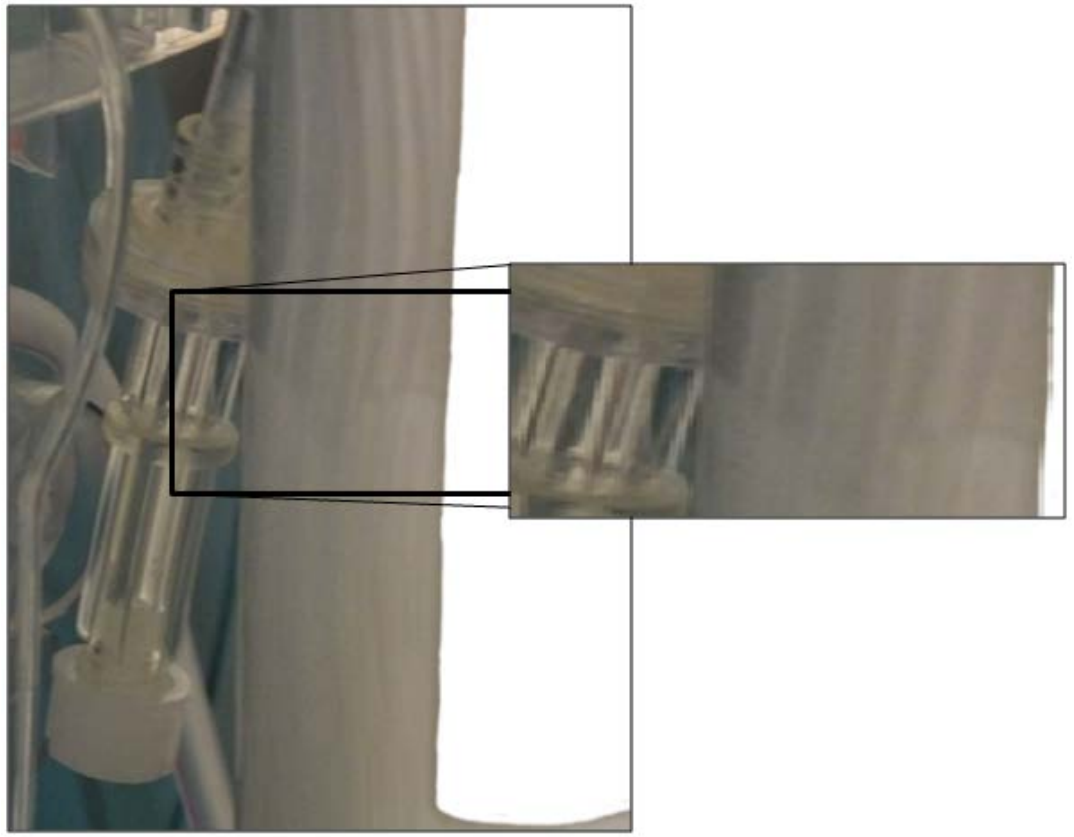
Connect the filter sets

3. Connect the septeX and oXiris filters using the custom tubing set

Completing the tubing set up

Attach the venous return line to the oXiris filter, and ensure bubble trap, pressure sensor and clamps are all in place.

Prime the system as normal



Additional priming

Add 1litre of saline using the manual priming function to ensure both filters are full.

Clamp off all of the dialysis and waste lines of the second filter, secure the second filter with a cable tie

System is now ready to run.

Advantages

The set-up and priming does not take longer than standard prismaflex protocols

All of the warning messages and alarms still function as normal

All of the clamps and safety systems still function as normal

Any staff with previous experience of running the prismaflex system will be able to monitor the patient for the duration of therapy

Schematic representation of a prototype of the Dialive LDD system

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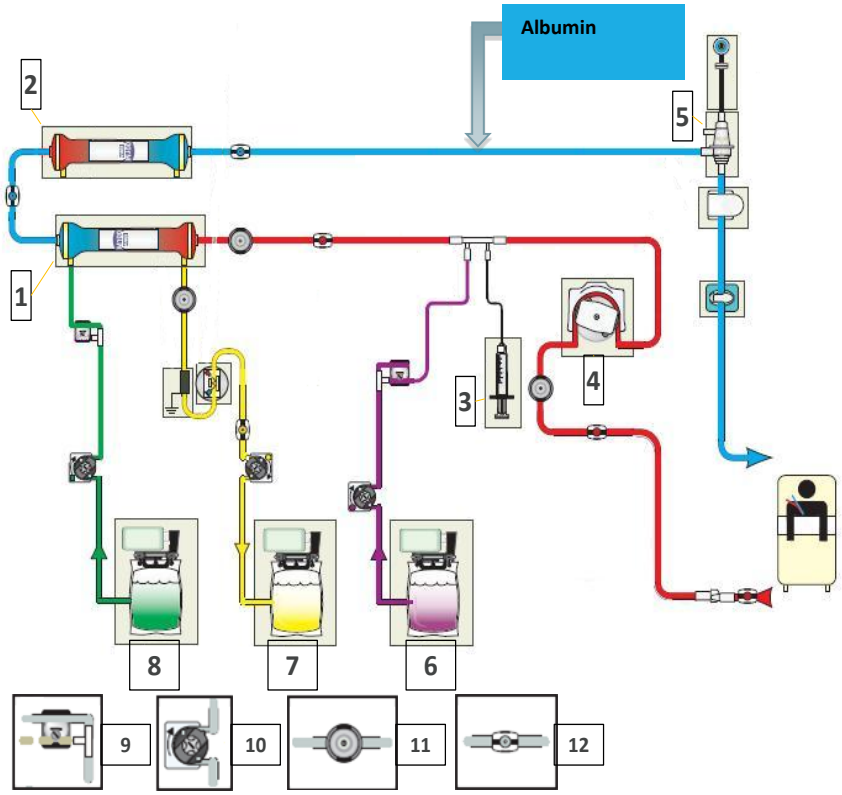

Important aspects of the DIALIVE LDD treatment

- Patients randomised to receive DIALIVE treatment will be treated in a high dependency setting (HDU), Intensive Care Unit (ICU) or Transplant unit.

- Vascular access will be obtained via a jugular or femoral vein using a double lumen catheter. Insertion of catheter will be undertaken under aseptic conditions in accordance with local clinical practices. Correction of clotting according to local clinical practice.

  The treatment will be delivered by the local site team, with the initial set-up and on-going support to be provided by the DIALIVE team.

  Anticoagulation of the device as per local protocol for CRRT

- Albumin replacement , ideally at the end of the treatment cycle, of the estimated loss of 25-30 mg after 12 h treatment., by infusing 200 mls of 20% HAS (local brand) over 2 hrs. Episode (s) of haemodynamic instability such as hypotension should preferably be treated by one or more non-albumin fluid solutions of your choice in the first instance.

- Routine monitoring of the patients during treatment cycles will be undertaken as per standard haemofiltration parameters.