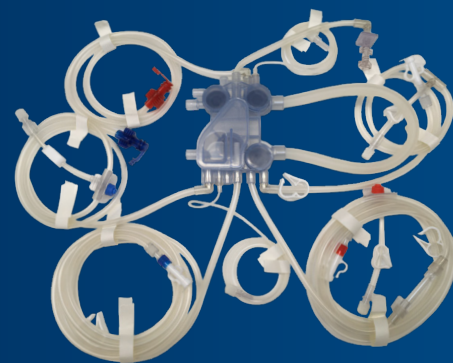


TECHNICAL DATA SHEET



Automatica™ BL 500 family – Extracorporeal circulation devices for use with with the Flexya™ machine

PRODUCT DESCRIPTION

The Automatica™ BL 500 family of devices, are single use products indicated for extracorporeal blood circulation. The family is comprised of different models that are manufactured using the same materials, methods and overall design. These extracorporeal circulation devices are for use exclusively with the Flexya™ machine.

The Automatica™ BL 500 extracorporeal circulation devices consist of the arterial bloodline, the venous bloodline, the heparin line and, depending on treatment, the infusion line. The device tubing system is connected to a plastic holder or cassette.

INTENDED USE

Device designed for extracorporeal blood circulation on Flexya™ machine.

CODES AVAILABLE

CFN /UPN	GTIN	Name	Description	CND	GMDN
BHD0000	08032979794460	Automatica™ BL 500	Extracorporeal circulation device for bicarbonate dialysis	F020102	34999, 32110
BHD0010	08032979794477	Automatica™ BL 500	Extracorporeal circulation device for single needle bicarbonate dialysis	F020101	34999, 32110
BHD1000	08032979794514	Automatica™ BL 500	Extracorporeal circulation device for bicarbonate dialysis with Hemox™	F020102	34999, 32110
HDF0000	08032979794538	Automatica™ BL 500	Extracorporeal circulation device for on-line hemodiafiltration in pre/post – pre+post dilution	F020102	34999, 32110
HDF1000	08032979794484	Automatica™ BL 500	Extracorporeal circulation device for on-line hemodiafiltration with Hemox™ in pre/post – pre+post dilution	F020102	34999, 32110
HFR0000	08032979794491	Automatica™ BL 500	Extracorporeal circulation device for HFR therapy	F020102	34999, 32110
HFR0100	08032979794378	Automatica™ BL 500	Extracorporeal circulation device for HFR therapy with Natrium™	F020102	34999, 32110
HFR1000	08032979794613	Automatica™ BL 500	Extracorporeal circulation device for HFR therapy with Hemox™	F020102	34999, 32110
HFR1100	08032979794521	Automatica™ BL 500	Extracorporeal circulation device for HFR therapy with Hemox™ and Natrium™	F020102	34999, 32110
MID0000	08032979794385	Automatica™ BL 500	Extracorporeal circulation device for MID-DILUTION therapy	F020102	34999, 32110
MID1000	08032979794507	Automatica™ BL 500	Extracorporeal circulation device for MID-DILUTION therapy with Hemox™	F020102	34999, 32110

STERILIZATION METHOD AND VALIDITY

Sterile and non-pyrogenic

Sterilizing agent: beta ionizing radiation (i.e. electron beam radiation)

Shelf life: 18 months

Do not resterilize.

TECHNICAL CHARACTERISTICS

The technical characteristics of the Automatica™ BL 500 family extracorporeal circulation devices in operating conditions are reported below.

Arterial pressure (mmHg)	-350
Prefilter pressure (mmHg)	770
Priming volume (mL)	148

The main components present in the extracorporeal circulation device are listed in the chart that follows. A representative circuit diagram is shown in figure 1; refer to the individual drawings below to identify the different configuration of each model.

Components	Materials
Tubing lines	Polyvinyl chloride (PVC) DEHP free
Blood pump segment	Polyvinyl chloride (PVC) DEHP free
Infusion pump segment	Polyvinyl chloride (PVC) DEHP free
Heparin line	Polyvinyl chloride (PVC) DEHP free
Cassette	Polyvinyl chloride (PVC)
Membrane	Ethylene-propylene diene monomer (EPDM)
Venous filter	High density polyethylene (HDPE)
Dialyzer connector	Polyvinyl chloride (PVC)
Luer lock	Polyvinyl chloride (PVC)
Infusion point top	Polypropylene (PP)
Infusion point body	Polyvinyl chloride (PVC)
Infusion point rubber	Isoprene
Infusion point cap	Polyethylene (PE)
T connector	Polyvinyl chloride (PVC)
Elbow connector	Polyvinyl chloride (PVC)
Blood catcher	Rigid polyvinyl chloride (PVC)
Transducer protector	Polyvinyl chloride (PVC) – Expanded polytetrafluoroethylene laminate (ePTFE)
Luer lock cap	High density polyethylene (HDPE)
Clamp	Polypropylene (PP)
Unloading hook	Polyethylene (PE)
Check valve	Acrylonitrile butadiene styrene (ABS) – Silicone rubber
Hemox™ cuvette ¹	Polyethylene terephthalate glycol (PETG)
Conductivity probe natrium ²	Acrylonitrile butadiene styrene (ABS) / Stainless steel
Joint 3-ways ³	Polyvinyl chloride (PVC) DEHP free
Y connector ³	Polyvinyl chloride (PVC)
Joint for hose ³ (raccordo terza pompa)	Polyvinyl chloride (PVC) DEHP free
Fast connector HFR ⁴	Polyvinyl chloride (PVC) DEHP free
Rigid tray	Polyvinyl chloride (PVC)

¹ This component is present in the following codes: BHD1000, HDF1000, HFR1000, HFR1100 and MID1000

² This component is present in the following codes: HFR1100 and HFR0100

³ This component is present in the following codes: HDF0000 and HDF1000

⁴ This component is present in the following codes: HFR0000, HFR1000, HFR1100 and HFR0100

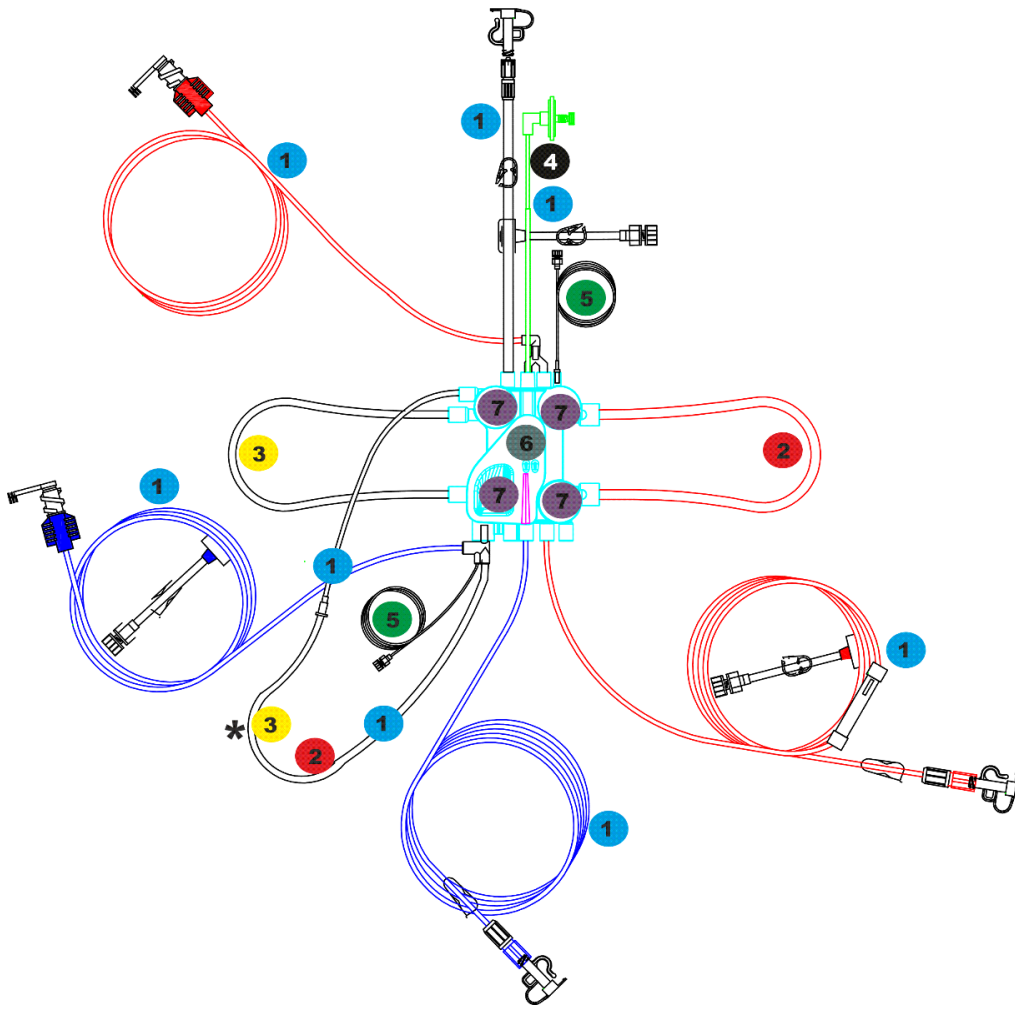
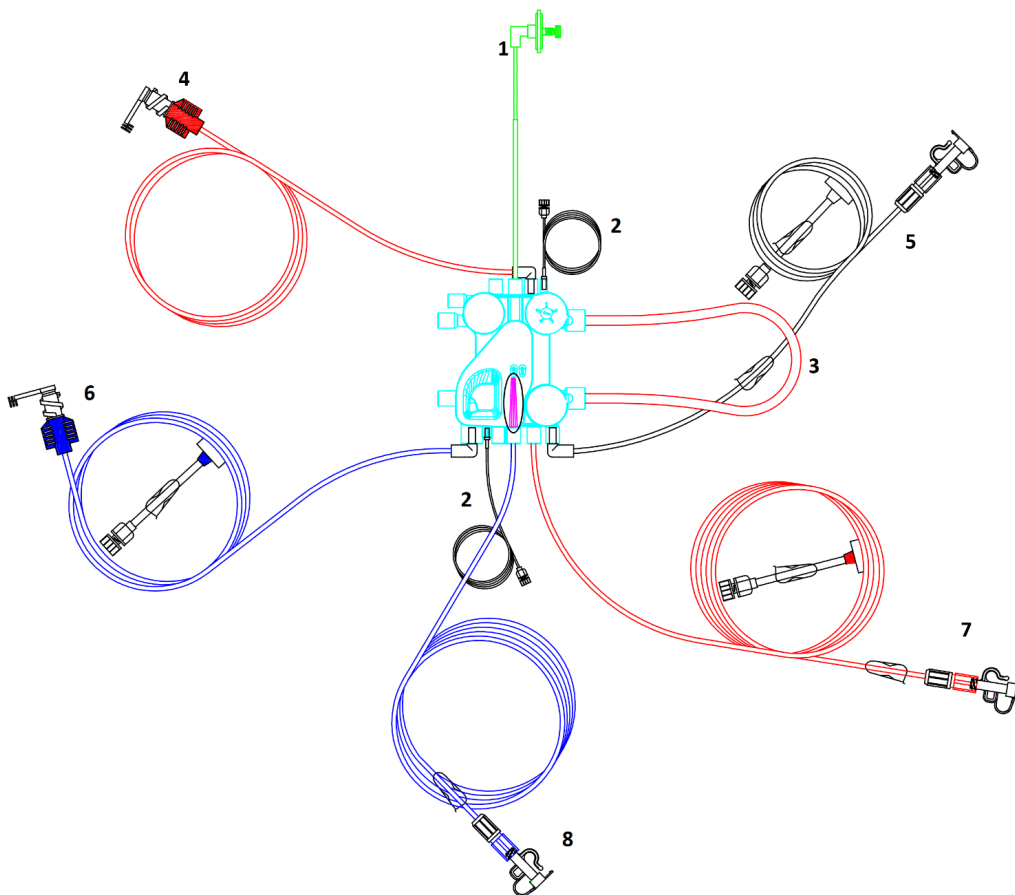


Figure 1 – legend:

- 1. Tubing lines
- 2. Blood pump segment
- 3. Infusion pump segment
- 4. Branches
- 5. Heparin line
- 6. Cassette
- 7. Membrane

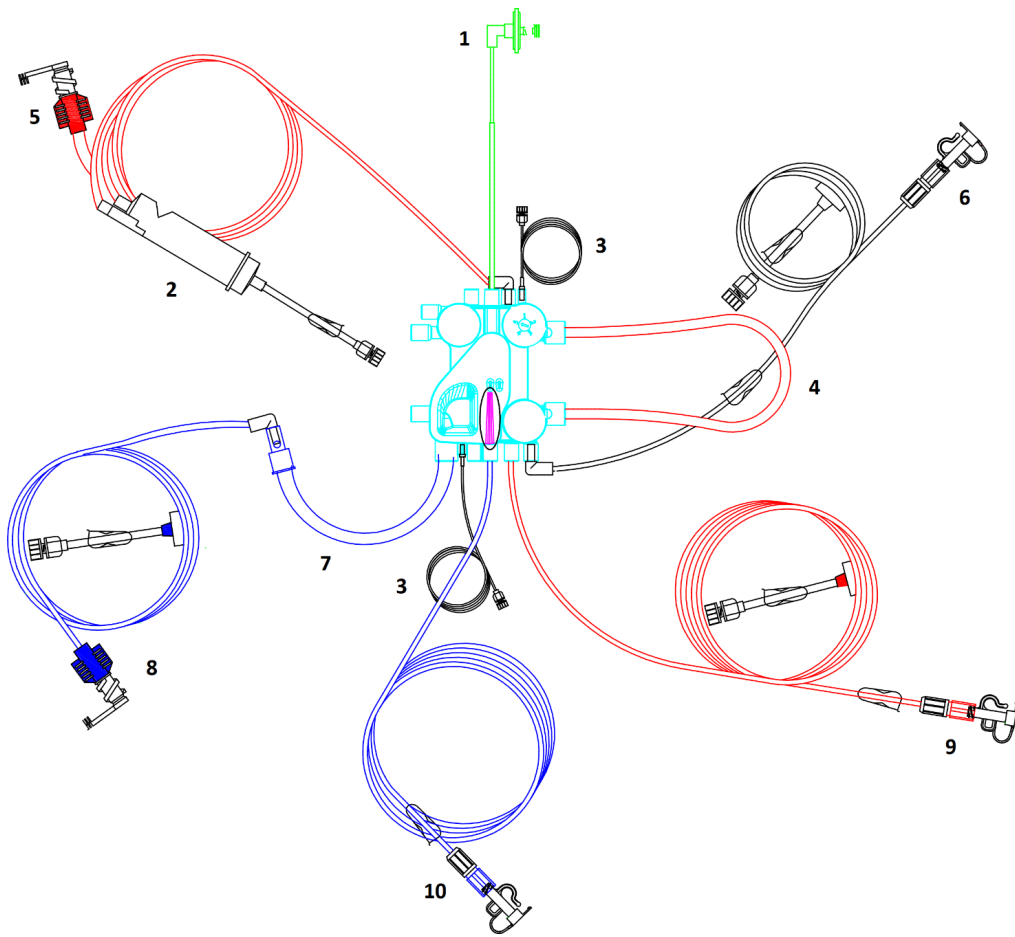
*This pump segment could be a blood or infusion pump segment depending on the model considered



BHD0000

Figure 2 – legend:

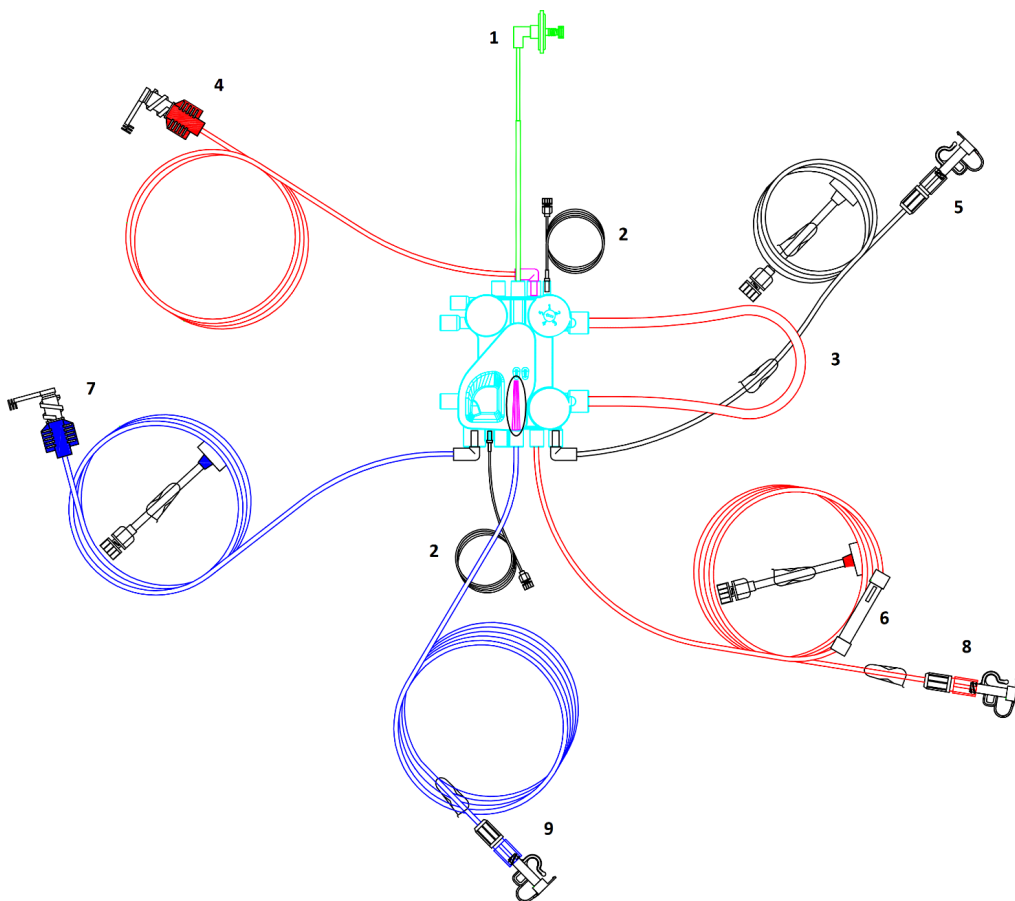
- 1. Transducer protector line
- 2. Heparin line
- 3. Blood pump segment
- 4. Arterial dialyzer line
- 5. Infusion line
- 6. Venous dialyzer line
- 7. Arterial patient line
- 8. Venous patient line



BHD0010

Figure 3 – legend:

1. Transducer protector line
2. Expansion chamber
3. Heparin line
4. Blood pump segment
5. Arterial dialyzer line
6. Infusion line
7. Dialyzer pump segment
8. Venous dialyzer line
9. Arterial patient line
10. Venous patient line



BHD1000

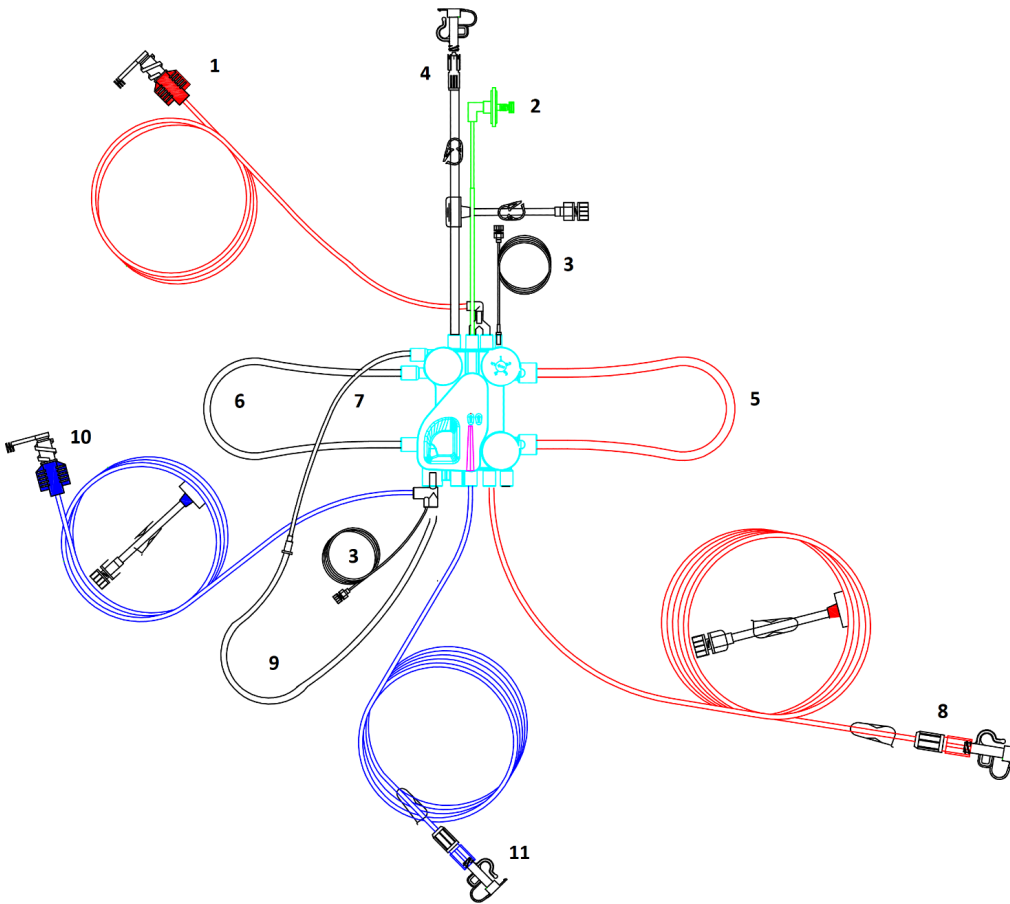
Figure 4 – legend:

1. Transducer protector line
2. Heparin line
3. Blood pump segment
4. Arterial dialyzer line
5. Infusion line
6. Hemox™ cuvette
7. Venous dialyzer line
8. Arterial patient line
9. Venous patient line

HDF0000

Figure 5 – legend:

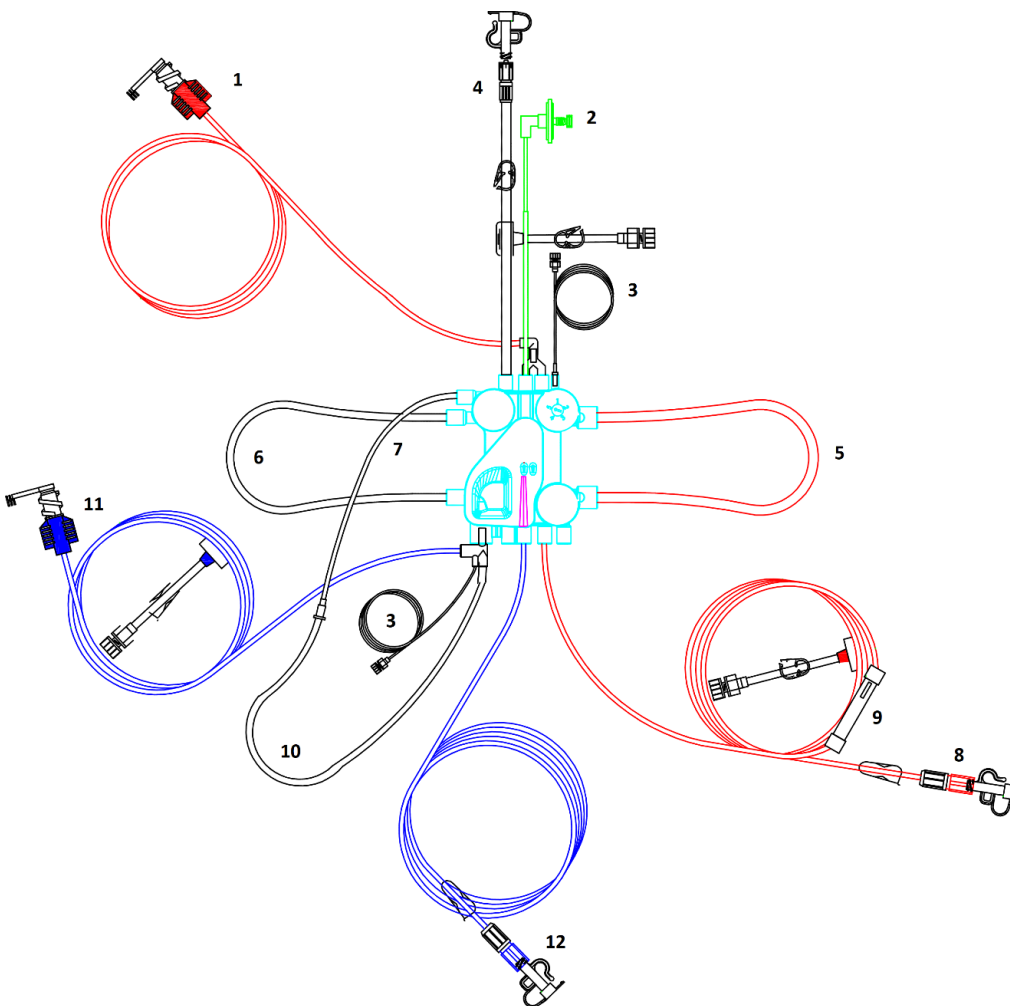
1. Arterial dialyzer line
2. Transducer protector line
3. Heparin line
4. Infusion line
5. Blood pump segment
6. Infusion pump segment
7. 3° pump segment top
8. Arterial patient line
9. 3° pump segment bottom
10. Venous dialyzer line
11. Venous patient line

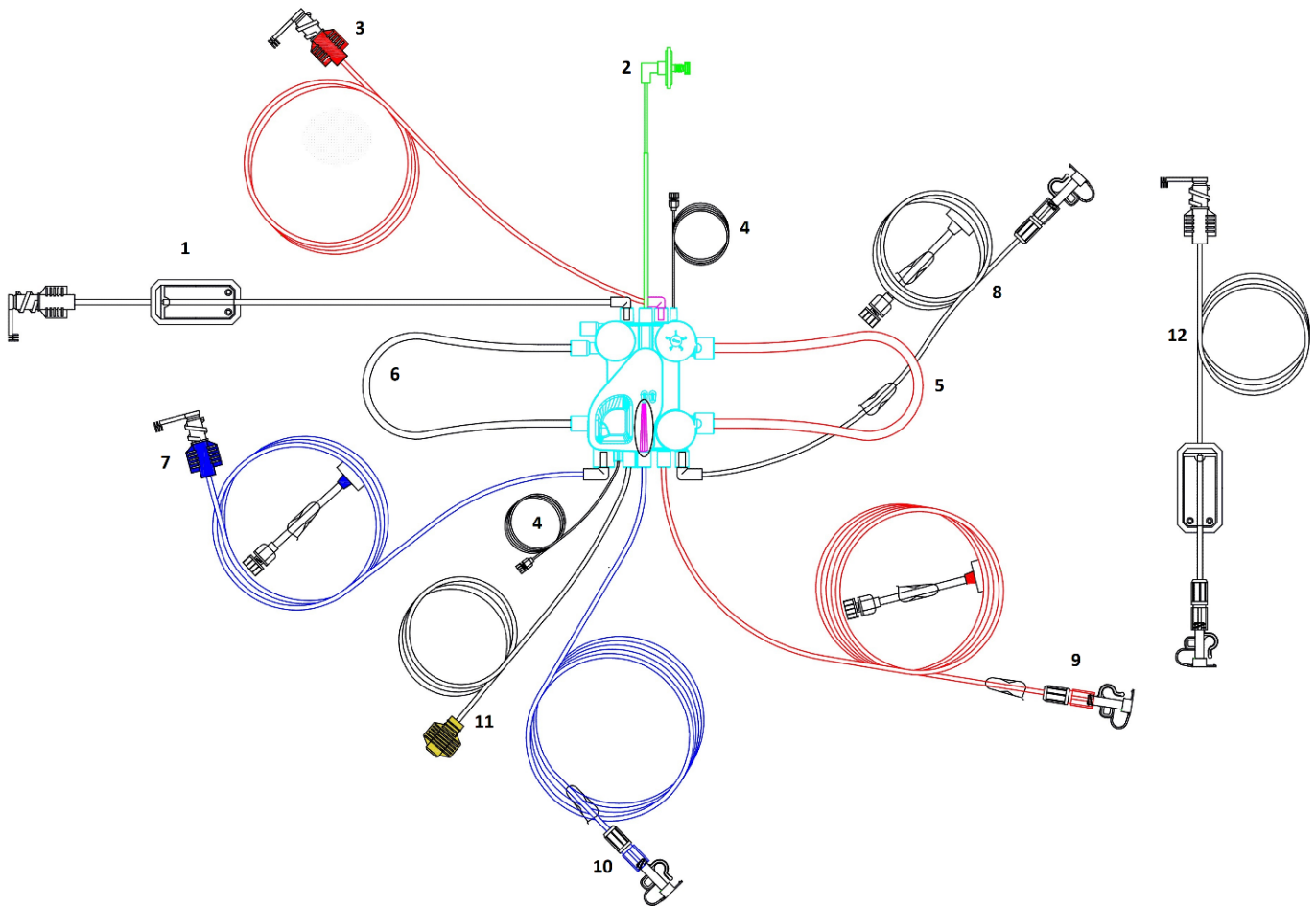


HDF1000

Figure 6 – legend:

1. Arterial dialyzer line
2. Transducer protector line
3. Heparin line
4. Infusion line
5. Blood pump segment
6. Infusion pump segment
7. 3° pump segment top
8. Arterial patient line
9. Hemox™ cuvette
10. 3° pump segment bottom
11. Venous dialyzer line
12. Venous patient line

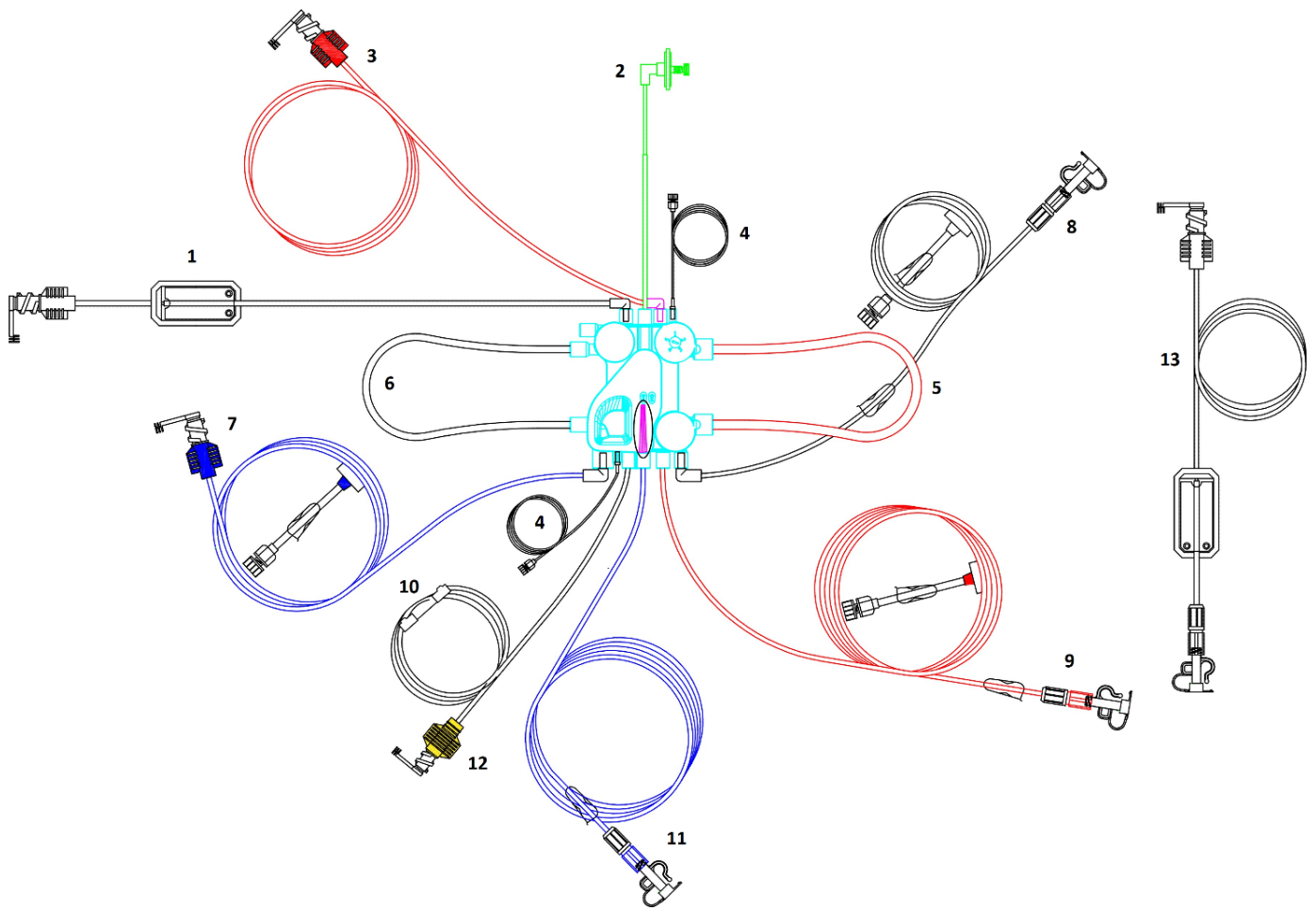




HFR0000

Figure 7 – legend:

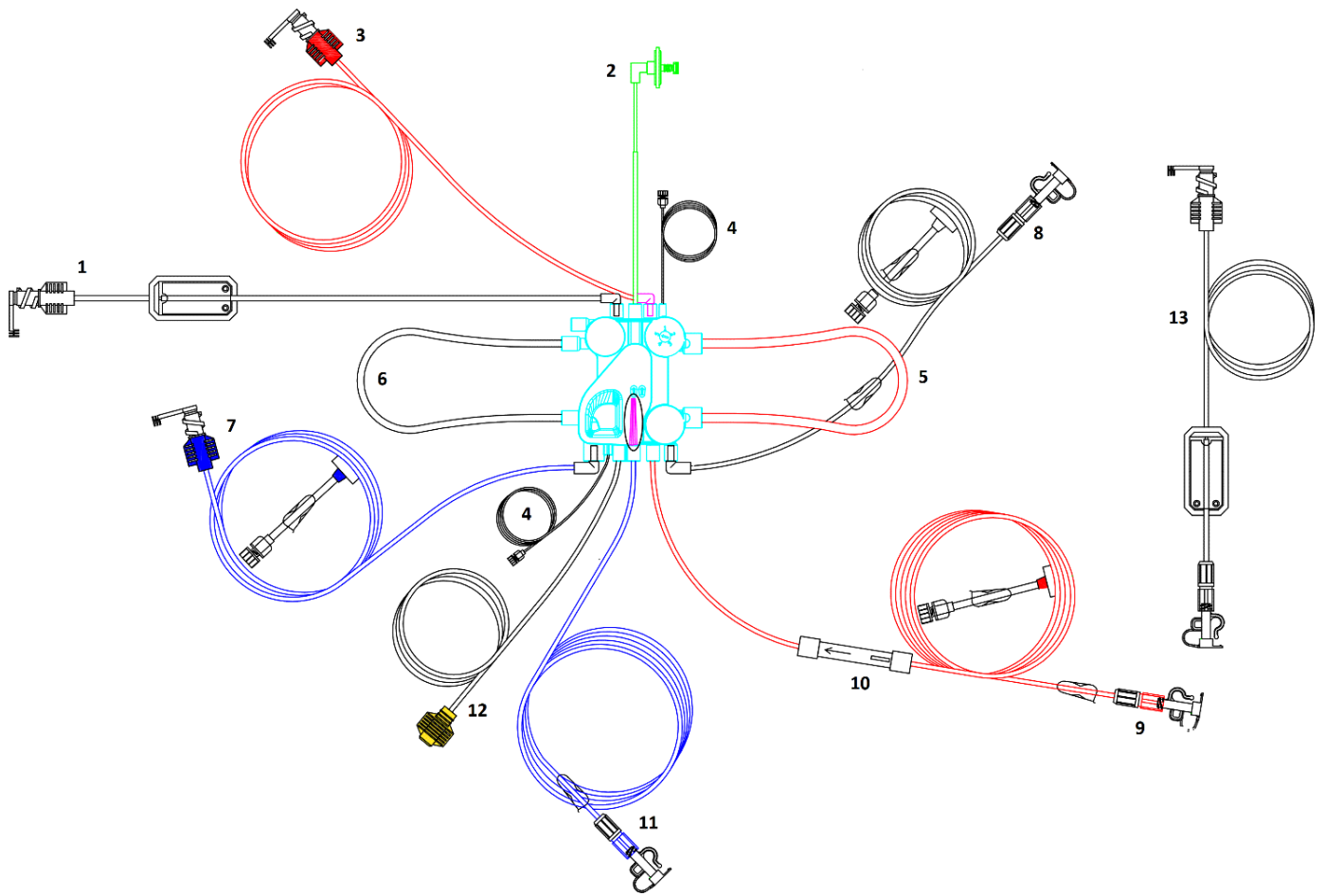
1. Superior infusion line with guardian
2. Transducer protector line
3. Arterial dialyzer line
4. Heparin line
5. Blood pump segment
6. Infusion pump segment
7. Venous dialyzer line
8. Infusion line
9. Arterial patient line
10. Venous patient line
11. Inferior infusion line
12. Free ultrafiltration line with guardian



HFR0100

Figure 8 – legend:

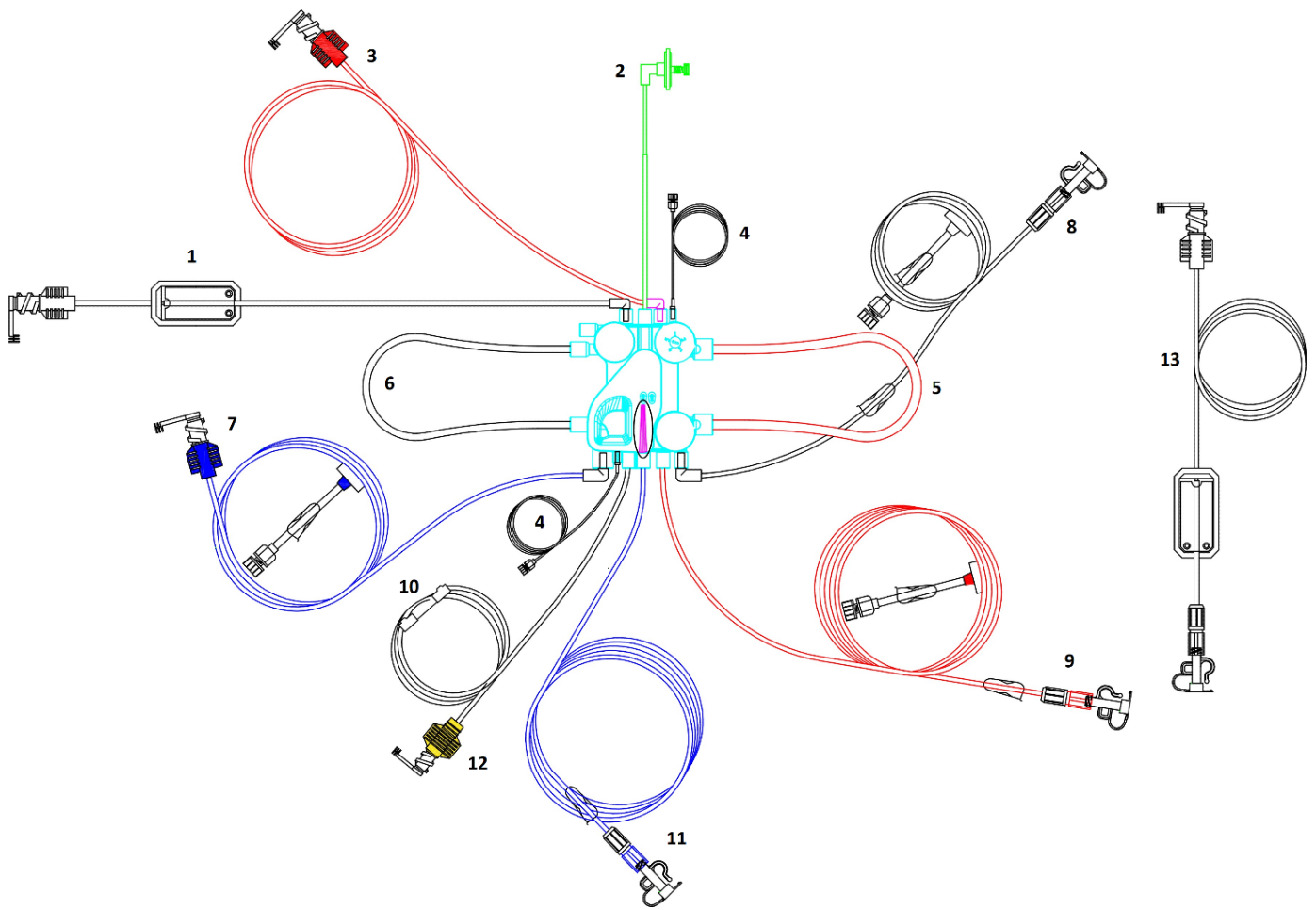
1. Superior infusion line with guardian
2. Transducer protector line
3. Arterial dialyzer line
4. Heparin line
5. Blood pump segment
6. Infusion pump segment
7. Venous dialyzer line
8. Infusion line
9. Arterial patient line
10. Natrium™ probe
11. Venous patient line
12. Inferior infusion line
13. Free ultrafiltration line with guardian



HFR1000

Figure 9 – legend:

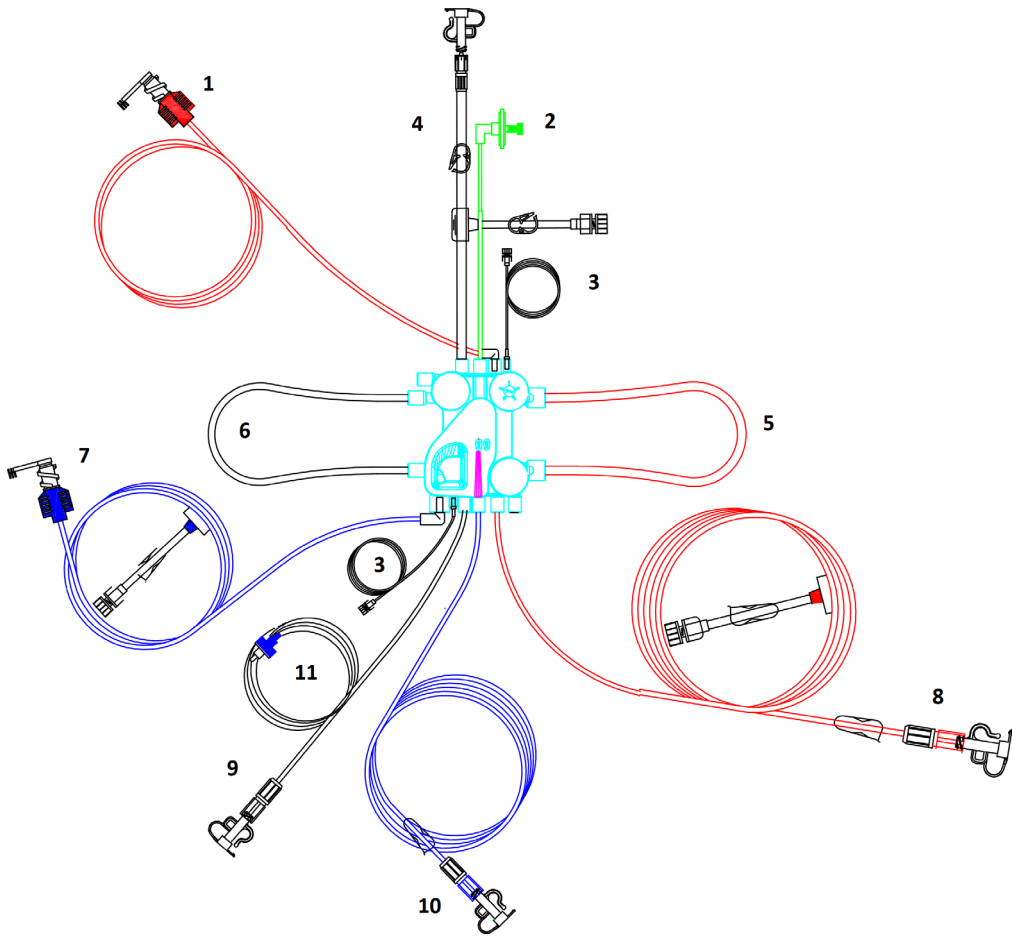
1. Superior infusion line with guardian
2. Transducer protector line
3. Arterial dialyzer line
4. Heparin line
5. Blood pump segment
6. Infusion pump segment
7. Venous dialyzer line
8. Infusion line
9. Arterial patient line
10. Hemox™ cuvette
11. Venous patient line
12. Inferior infusion line
13. Free ultrafiltration line with guardian



HFR1100

Figure 10 – legend:

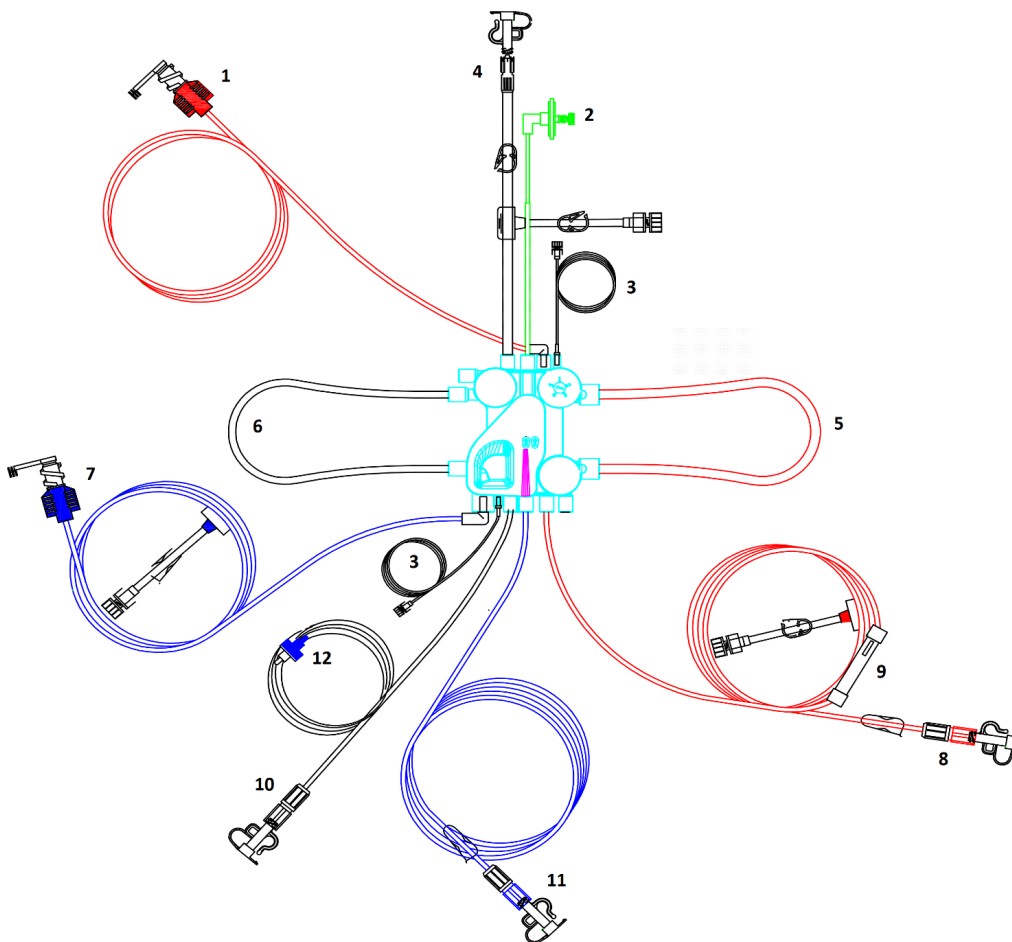
1. Superior infusion line with guardian
2. Transducer protector line
3. Arterial dialyzer line
4. Heparin line
5. Blood pump segment
6. Infusion pump segment
7. Venous dialyzer line
8. Infusion line
9. Arterial patient line
10. Hemox™ cuvette
11. Natrium™ probe
12. Venous patient line
13. Inferior infusion line
14. Free ultrafiltration line with guardian



MID0000

Figure 11 – legend:

1. Arterial dialyzer line
2. Transducer protector line
3. Heparin line
4. Infusion line
5. Blood pump segment
6. Infusion pump segment
7. Venous dialyzer line
8. Arterial patient line
9. Inferior infusion line
10. Venous patient line
11. Check valve



MID1000

Figure 12 – legend:

1. Arterial dialyzer line
2. Transducer protector line
3. Heparin line
4. Infusion line
5. Blood pump segment
6. Infusion pump segment
7. Venous dialyzer line
8. Arterial patient line
9. Hemox™ cuvette
10. Inferior infusion line
11. Venous patient line
12. Check valve

PERFORMANCE

Performance has been tested for the conditions in the chart that follows in accordance with EN ISO 8638.

Maximum arterial pressure (mmHg)	-400
Maximum prefilter pressure (mmHg)	800
Maximum QB (mL/min)	700

PACKAGING

Primary packaging ¹	Material	Weight (g)
Bag	LDPE	45.8
Pouch	PET/PE film Medical grade paper 60g/m ²	

¹The bloodline set is inserted inside the polyethylene bag which is included in the pouch

Model	Secondary packaging – Box		
	Box	Weight ² (kg)	Pcs/Box
Automatica™ BL 500	Havana colored rippled cardboard – KSFSK 36263/MB Dimensions: 57.5 × 49.5 × 32.3 cm	9.8	16

² Max box weight filled with products

STORAGE AND DISPOSAL CONDITIONS

Storage conditions: store at temperatures between 0 and +30 degrees Celsius and relative humidity < 90%.

Disposal: remove from the place of dialysis immediately after use. Disposal must be carried out in accordance with the regulations in force.

BIOCOMPATIBILITY

Biocompatibility tests of the Automatica™ BL 500 family extracorporeal circulation devices have been performed according to ISO 10993-1 and related applicable standard series.