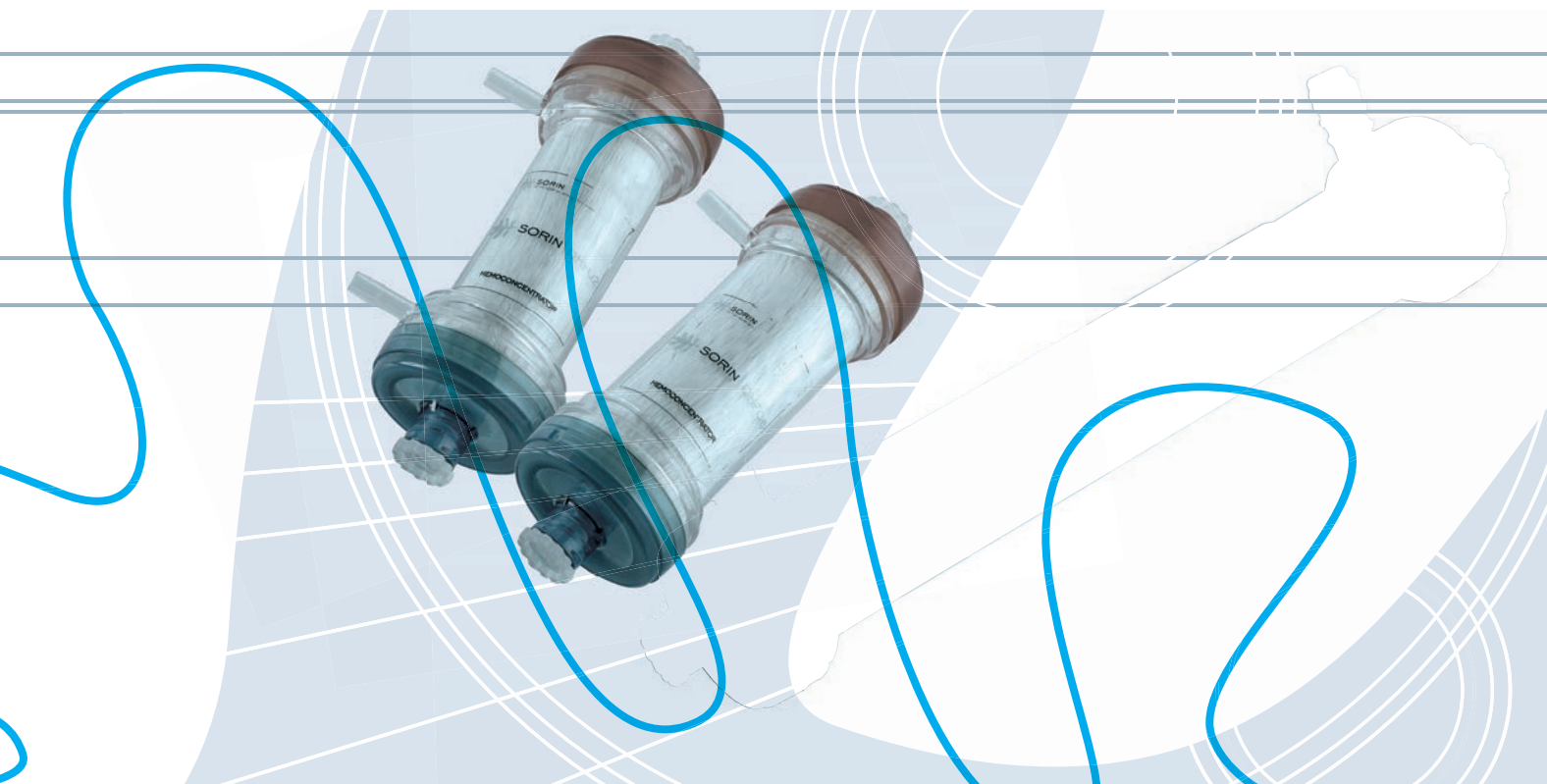
SORIN | HEMOCONCENTRATORS



Therapeutical Indications

It is widely demonstrated that low hematocrit levels during cardiopulmonary bypass lead to a worse outcome compared to higher hematocrit levels [1,2].

Hemoconcentration by ultrafiltration is recognized to be the most effective way of managing fluid in the extracorporeal Circuit in Cardiac patients [3,4] by allowing circulating Volume, hematocrit and intracellular water control.

Thanks to the ability of removing large molecules from the circulating blood, hemofiltration is also indicated for providing a better outcome to critical patients with a faster removal of blood negative elements without the coagular factor content [5];

References

[1] "Hematocrit on cardiopulmonary bypass and outcome after coronary surgery in nontransfused patients".
Ranucci M, Conti D, Castelvecchio S, Menicanti L, Frigiola A, Ballotta A, Pelissero G. Ann Thorac Surg. 2010 Jan;89(1):11-7.

[2] "Adverse effects of low hematocrit during cardiopulmonary bypass in the adult: should current practice be changed?"
Habib RH, Zacharias A, Schwann TA, Riordan CJ, Durham SJ, Shah A. J Thorac Cardiovasc Surg. 2003 Jun;125(6):1438-50.

[3] "Effects of hemofiltration on serum aprotinin levels in patients undergoing cardiopulmonary bypass."
Van Norman GA, Patel MA, Chandler W, Vocelka C. J Cardiothorac Vasc Anesth. 2000 Jun;14(3):253-6.

[4] "Hemofiltration during cardiopulmonary bypass for high risk adult cardiac surgery."
Raman JS, Hata M, Bellomo R, Kohchi K, Cheung HL, Buxton BF. The Department of Cardiac Surgery, Austin & Repatriation Medical Centre, University of Melbourne, Melbourne, Australia. Int J Artif Organs. 2003 Aug;26(8):753-7.

[5] Effects of conventional ultrafiltration on renal performance during adult cardiopulmonary bypass procedures.
Kuntz RA, Holt DW, Turner S, Stichka L, Thacker B.Coastal Extracorporeal Technology, Department of Circulation Technology, Bay Medical Center, Panama City, Florida, J Extra Corpor Technol. 2006 Jun;38(2):144-53

Using the SORIN hemoconcentrators and hemoconcentration kits:

- Provides concentrated whole blood to patient with consequent reduction of homologous blood and blood products need;
- Maintains an adequate oxygen delivery to the patient body by controlling the hematocrit level;
- Decreases the risk of post-operative bleeding as platelets and coagulation factors are preserved;
- Controls the intracellular water level by retaining plasma proteins and blood coagulation factors (albumin, immunoglobulins, ATIII), while excessive water is quickly and gently removed;
- Contributes to the elimination of the post operative renal dysfunction risk factor by minimizing the need of diuretic usage, which may not be indicated for some patients.

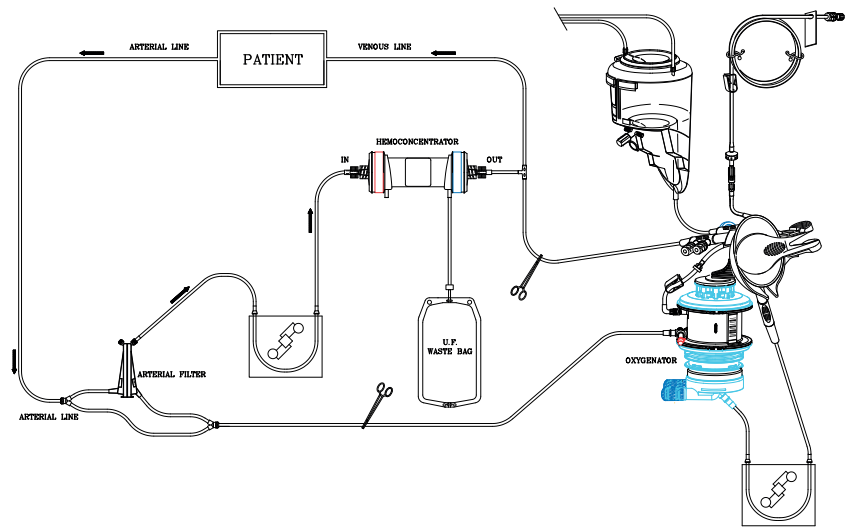
The material: polyethersulfone membrane

The high flux polyethersulfone membrane used in Sorin Group Hemoconcentrators enables a very high utltrafiltration rate with a limited priming volume. Polyethersulfone is a high biocompatible membrane as it has:

- Low contact activation
- Low TAT formation
- Very low TCC generation
- Capacity to filter out cytokines and complement factors

SORIN | HEMOCONCENTRATORS

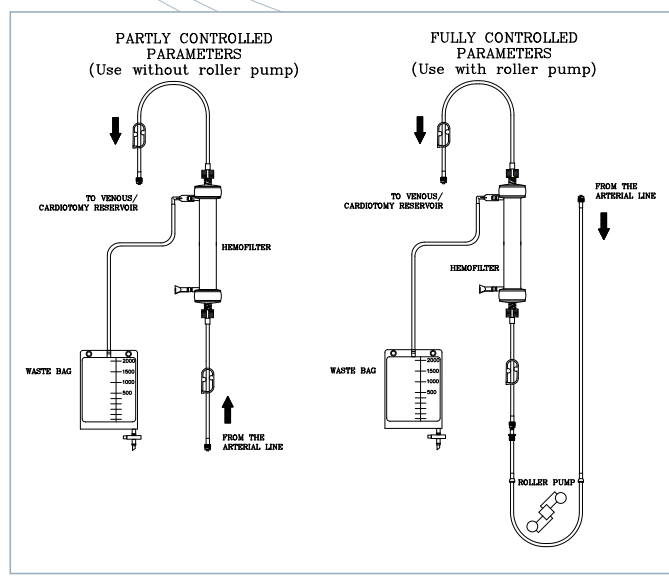
Modified Ultrafiltration (M.U.F.)



Peadiatric Application: Modified Ultrafiltration (M.U.F.)

Sorin|Hemoconcentrators are available in a kit for modified placement of the hemoconcentrator in the extracorporeal circulation during cardiopulmonary by-pass and ultrafiltration. Scope of this technique is to keep an higher colloid osmotic pressure[6,7]. The hemoconcentrator is placed with its inlet connected to the arterial line and outlet to the venous line.

The pump tubing conected to the circuit allows the use of a roller pump to precisely control the blood flow through the hemoconcentrator;



References

[6]"A prospective randomized study of a modified technique of ultrafiltration during pediatric open-heart surgery."
Naik SK, Knight A, Elliott M. - Cardiothoracic Unit, Hospital for Sick Children, London, UK. Circulation, 1991 Nov;84(5 Suppl):III422-31.
[7]"Haemodynamic changes during modified ultrafiltration immediately following the first stage of the Norwood reconstruction."
Gaynor JW, Kuypers M, van Rossem M, Wernovsky G, Marino BS, Tabbutt S, Nicolson SC, Spray TL. - Division of Cardiothoracic Surgery, The Cardiac Center at The Children's Hospital of Philadelphia, Philadelphia 19104, USA - Cardiol Young. 2005 Feb;15(1):4-7.

Conventional Ultrafiltration

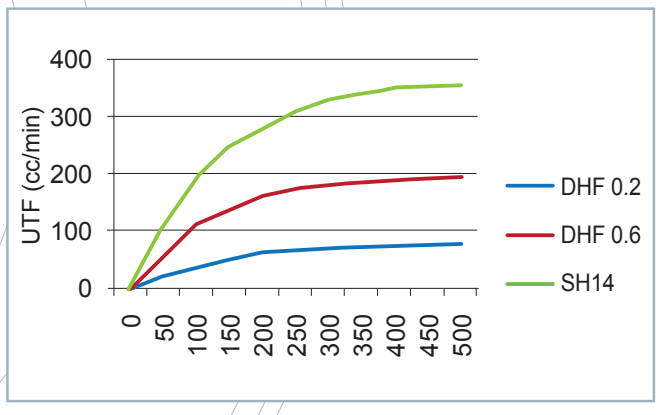
The conventional placement of the hemoconcentrator in the extracorporeal circulation system is with its inlet connected to the arterial line and outlet to the cardiotomy or to the venous reservoir.

A roller pump can be used for complete control of the working parameters (i.e. flow and pressure).

In alternative, a spontaneous flow without using a dedicated roller pump can be performed.

The Ultrafiltration Rate

Ultra filtrate extraction velocity (UTF) as result of the applied Trans-membrane pressure (TMP)**

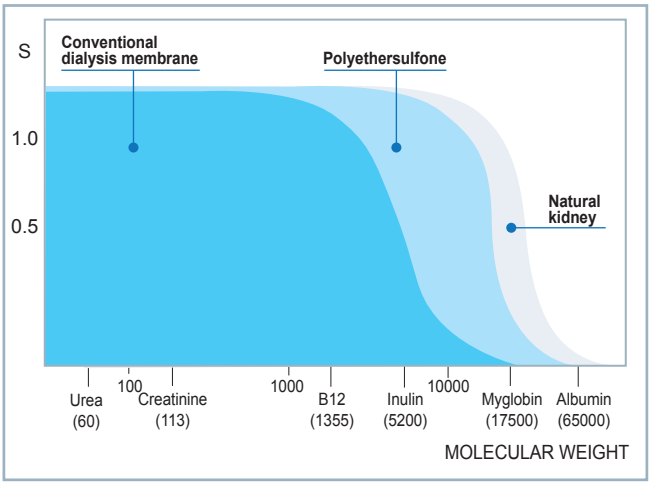


Test with Bovine Blood - HCT = 20% ±2% - Qb = 400 ml/min

$$(**TMP = \frac{p_a + p_v}{2} + p_s)$$

Where:
pa: arterial (or inlet) blood pressure into the hemoconcentrator [mmHg]
pv: venous (or outlet) blood pressure from the hemoconcentrator [mmHg]
ps: negative pressure applied to effluent side of the hemoconcentrator [mmHg]

The Sieving Coefficient



High molecular weight sieving coefficient allows removal of larger molecules without any loss of key blood proteins such as albumin.

Sieving Cut-Off* = 65.000 Daltons
(1 Dalton =1.66x 10-24 g)

*sieving Cut-Off coefficient intended as molecular weight correspondent to 99% of retention

Performance

Type	DHF02	DHF06	SH14
Urea [ml/min]	32	86	246
Creatine [ml/min]	28	78	223
Phosphates [ml/min]	26	74	213
Vitamine B12 [ml/min]	21	58	166
UFR [ml/min x mmHg of TMP*]	16	31	61

Technical Features

Type	D570 with DHF02	D575 with DHF02	D571 with DHF06	D576 with DHF06	KH14 with SH14
Surface [m2]	0,25	0,25	0,68	0,68	1,35
MAX TMP [kPa]	66	66	66	66	66
Blood port	Male pos lock	Male pos lock	Male pos lock	Male pos lock	Male pos lock
Ultrafiltrate port	¼" connector	¼" connector	¼" connector	¼" connector	Hansen connector
Filter priming [ml]	30	30	60	60	80
Circuit Priming [ml]	45	45	137	137	145

Order Guide

Identification	Description	Code	Pcs/box
D570	Conventional Kit DHF 0.2	05009	4
D575	Modified Kit DHF 0.2	05019	4
D571	Conventional Kit DHF0.6	05010	4
D576	Modified Kit DHF 0.6	05020	4
KH14	Conventional Kit SH14	050177	4
DHF 02	Stand Alone Hemoconcentrator	05326	12
DHF 06	Stand Alone Hemoconcentrator	05327	12
SH 14	Stand Alone Hemoconcentrator	050179	18
Holder	Universal Hemoconcentrator Holder	09017	1

09295-74 01/2011

CE 0123 According to Annex II (Full Quality System) of MDD 93/42/EEC as amended by directive 2007/47/EEC

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

The Sorin Group Italia Quality System complies with:
EN ISO 13485:2003/AC:2007

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