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];

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.

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[3] "Effects of hemofiltration on serum aprotinin levels in patients undergoing cardiopulmonary bypass."

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Department of Cardiac Surgery, Australia. Int J Artif Organs. 2003 Aug;26(8):753-7.

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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

Order Guide

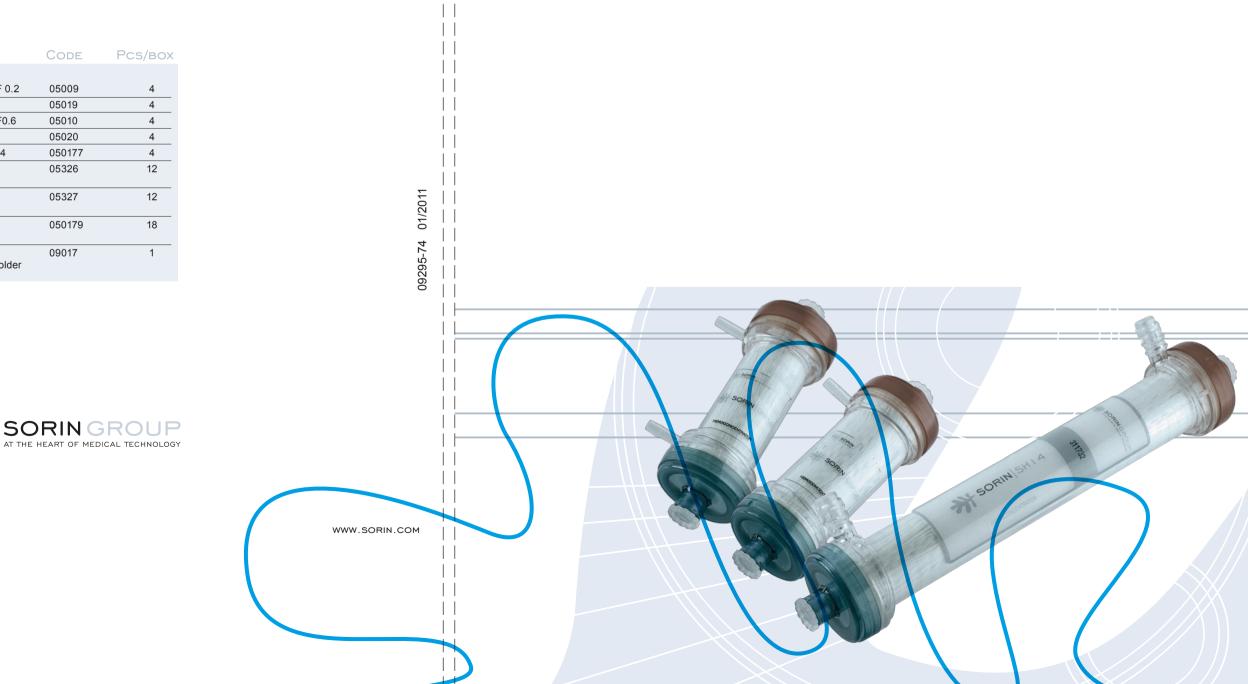
IDENTIFICATION DESCRIPTION

D570	Conventional Kit DHF 0.2	05
D575	Modified Kit DHF 0.2	05
D571	Conventional Kit DHF0.6	05
D576	Modified Kit DHF 0.6	05
KH14	Conventional Kit SH14	05
DHF 02	Stand Alone Hemoconcentrator	05
DHF 06	Stand Alone Hemoconcentrator	05
SH 14	Stand Alone Hemoconcentrator	05
Holder	Universal Hemoconcentrator Holder	09
SH 14	Stand Alone Hemoconcentrator Stand Alone Hemoconcentrator Universal	

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

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

MANUFACTURED BY: SORIN GROUP ITALIA S.R.L. VIA STATALE I 2 NORD, 86 4 I 037 MIRANDOLA MODENA ITALY TEL +39 0535 298 I I FAX +39 0535 243 I 2 INFO.SORIN-CP@SORIN.COM





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;

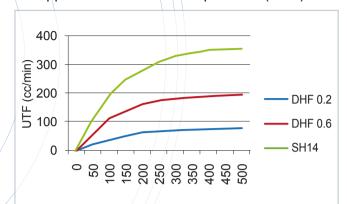
References

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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.





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



Test with Bovine Blood - HCT = $20\% \pm 2\%$ - Qb = 400 ml/min

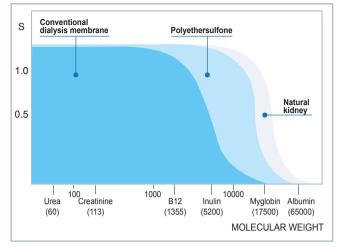
 $(**TMP = \frac{p_a + p_v}{p_s} + p_s)$

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И

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

THE SIEVING COEFFICIENT

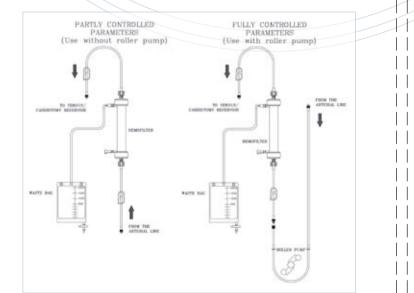


High molecular weight sieving coefficient allows removal of larger molecules without any loss of key blood proteins such as albumin.

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





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.

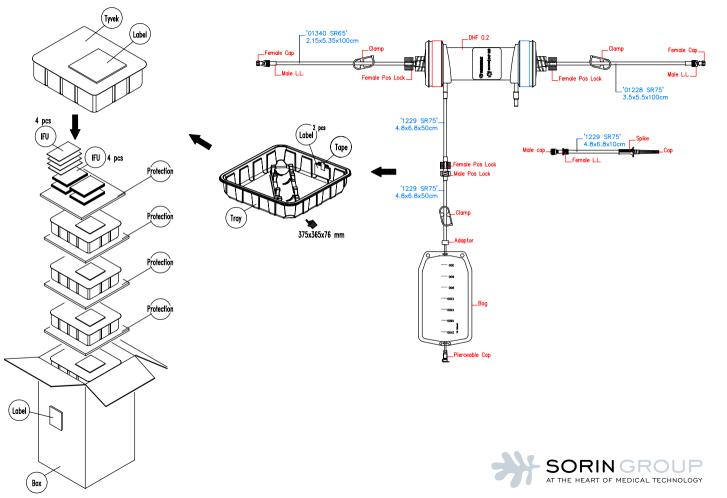
Performance

Туре	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

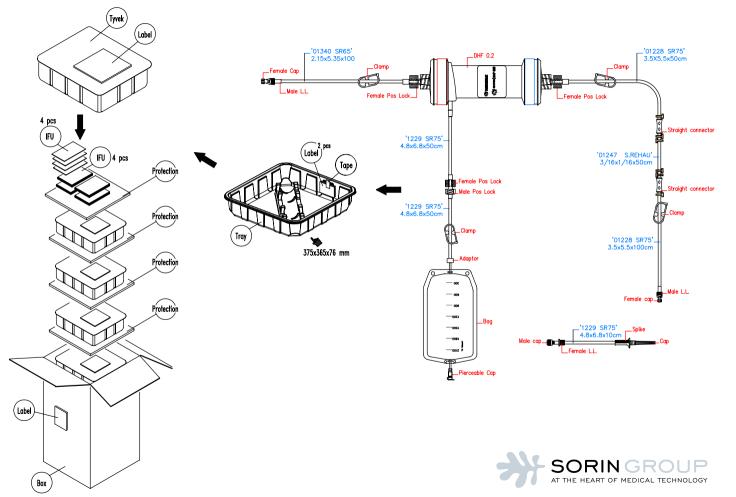
TECHNICAL FEATURES

Туре	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	¹ / ₄ " connector	1/4" connector	¹ / ₄ " connector	¹ / ₄ " connector	Hansen connector
Filter priming [ml]	30	30	60	60	80
Circuit Priming [ml]	45	45	137	137	145

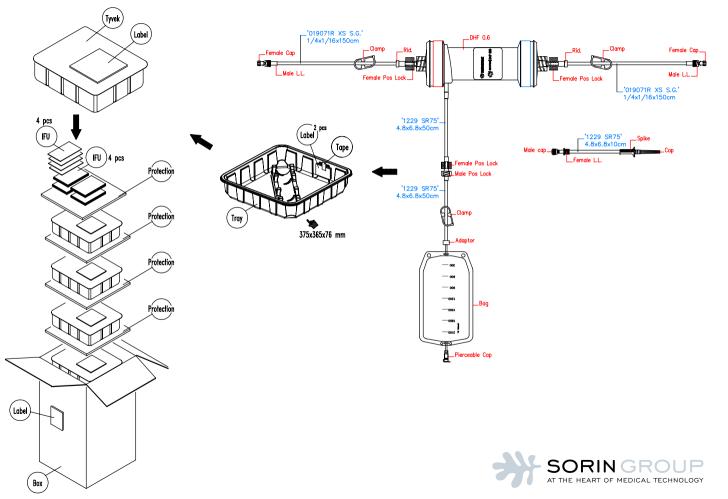
D570 CONVENTIONAL KIT DHF 0.2



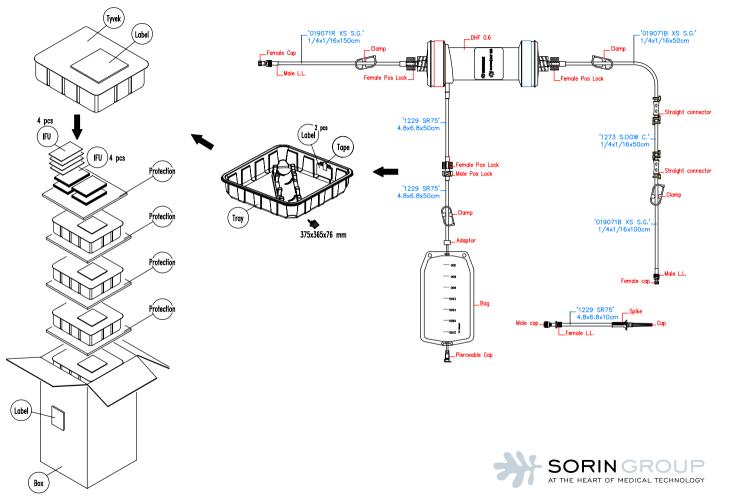
D575 MODIFIED KIT DHF 0.2



D571 CONVENTIONAL KIT DHF 0.6



D576 MODIFIED KIT DHF 0.6



KH I 4 CONVENTIONAL KIT SH I 4

