FRESENIUS KABI

CompoSelect® WB

Blood component preparation with integrated WB filter

CompoSelect® WB combines our profound expertise in leukocyte depletion filters with intelligent blood bag configurations:

- CompoSelect® WB includes a flexible leukocyte depletion filter for the whole blood filtration. It is intended for the preparation of leukocyte depleted plasma and red cell concentrates.
- CompoSelect® WB allows a safe and efficient whole blood processing with the help of components like CompoFlow closure device and RT-Needle Plus.

System Description:

- Indication: Leukocyte depletion of 1 unit of whole blood
- Single use
- Latex free
- RT-Needle Plus
- Blood Bag Material: robust PVC/DEHP foil with an internal diamond structure
- Label: tamper proof PVC material, symbol label design according to ISO norm
- RT-Needle Plus
  - Safety needle (siliconized stainless steel, 16G) with integrated, user friendly needle protector
  - High flow reduces donation times by 20%[1]
  - Tamper-proof needle cap
  - Ergonomic hub design and bevel indicator for correct needle positioning at venepuncture
- CompoFlow® bag closure device (optional)
  - Increased effectiveness by reduced preparation time and high level of automation[2]
  - Improved ergonomics[2] by automatic opening of CompoFlow® caps[3]
  - Reduced hemolytic incidents by prevention of insufficiently opened bag breakers[4]

Filter Specifications

- Filter: Bioflex WB
- Filter made by melt-blown, non woven, surface treated polyester material
- Neutral charge fiber surface
- Excellent wetting characteristic
- High biocompatibility
- Flexible, transparent housing with laser printed batch number
- Filter tested by 100% in-process control
- Performance:
  - Leukocyte depletion: consistently averaging less than 1.5 x 10^5 residual leukocytes (95% conformity to 1 X 10^6 limit with 95% confidence)[5]
  - Hemoglobin recovery: consistently averaging 92%
  - Filtration time: consistently averaging less than 18 min
  - Filter housing hold-up volume of 31 ml

1 van der Meer et al., Vox Sang. 97:21, 2009
2 Compared to standard breakers
3 Serrano et al., Transfusion 50:2240, 2010
4 Richter et al., data on file
5 EDQM 20th edition, 2020

Ordering Information

A variety of in-line blood bag systems with different sizes, additives and storage solutions are available for individual requirements. The below article codes are only exemplary.

CompoSelect® WB IN-LINE BLOOD BAG SYSTEMS

Article code	Configuration	Anticoagulant	Donation volume	Packaging	Special feature
PQ31555	Quadruple T&T	CPD/SAG-M	450 ml	20 pcs/box	
PQ41575	Quadruple T&T	CPD/PAGGS-M	500 ml	20 pcs/box	
CQ31555	Quadruple T&T	CPD/SAG-M	450 ml	20 pcs/box	CompoFlow® closure device
CQ41575	Quadruple T&T	CPD/PAGGS-M	500 ml	20 pcs/box	CompoFlow® closure device

Performance Data

- The Fresenius Kabi whole blood leukodepletion filter Bioflex WB has been tested at different actual production and storage conditions.
- The validation results represented here are from a European test center and demonstrate that the filter performance is excellent, not exceeding any given limits. In this validation 500 ml donated whole blood was processed with three different conditions: fresh whole blood, whole blood stored over night (o/n), at room temperature (RT) and at 4°C.
- The leukocyte depletion showed for all conditions median values below detection limit, not exceeding 400.000 WBC per unit at all. The median filtration time after over night (o/n) storage at 4°C was 20:15 min (mean filtration temperature: 10.2°C) and only 12:43 min after o/n storage at RT. Hemolysis rate was extremely low with a median of 0.02% with the highest result of 0.05% while the median Hb recovery was in all cases above 91.3%.

Validation Results from European Test Center

	Parameter	Fresh RT					
		Mean	StDev	Min	Max	Median	N
Filtration	Blood T (°C)	22.1	0.7	20.8	23.6	22.3	30
	Filtration time (hh:mm:ss)	0:11:49	0:02:06	0:08:25	0:15:45	0:11:43	30
WB pre-filtration	Volume (+ CPD ml)	551	10	536	572	551	30
	HCT (L/L)	0.40	0.02	0.34	0.43	0.40	30
	Hb/unit (g)	68.5	3.8	58.2	76.1	68.2	30
	10*6 WBC/unit	2947	679	1426	4644	2784	30
	10*9 PLT/unit	107.6	21.5	79.7	171.8	107.2	30
WB post-filtration	Volume (ml)	517	7	507	529	517	30
	Hb (g)	63.3	3.6	54.8	70.1	63.2	30
	WBC/unit	16/30 values < DL		< DL	105,338	< DL	30
	10*9 PLT/unit	18/30 values < DL		< DL	3	< DL	30
	Hemolysis rate Abs (%)	0.02	0.01	0.00	0.04	0.02	30
	Hb recovery (%)	92.4	1.3	89.6	95.5	92.5	30

	Parameter	o/night RT					
		Mean	StDev	Min	Max	Median	N
Filtration	Blood T (°C)	21.2	0.2	20.8	21.4	21.2	25
	Filtration time (hh:mm:ss)	0:12:58	0:02:33	0:09:10	0:20:05	0:12:43	42
WB pre-filtration	Volume (+ CPD ml)	538	13	519	557	539	42
	HCT (L/L)	0.40	0.03	0.34	0.45	0.41	42
	Hb/unit (g)	68.0	5.1	58.6	79.0	67.7	42
	10*6 WBC/unit	3477	847	2431	5667	3365	42
	10*9 PLT/unit	110.2	21.3	71.0	162.2	106.8	42
WB post-filtration	Volume (ml)	503	12	484	521	504	42
	Hb (g)	63.4	4.8	52.1	72.4	64.5	42
	WBC/unit	13/42 values < DL		< DL	387,377	< DL	42
	10*9 PLT/unit	22/42 values < DL		< DL	3	< DL	42
	Hemolysis rate Abs (%)	16/42 values < DL		< DL	0.03	< DL	42
	Hb recovery (%)	93.2	1.5	89.0	96.6	93.3	42

	Parameter	o/night 4°C					
		Mean	StDev	Min	Max	Median	N
Filtration	Blood T (°C)	10.0	1.1	7.8	12.2	10.2	30
	Filtration time (hh:mm:ss)	0:20:40	0:05:11	0:14:20	0:34:40	0:20:15	30
WB pre-filtration	Volume (+ CPD ml)	550	16	526	578	552	30
	HCT (L/L)	0.40	0.03	0.34	0.47	0.40	30
	Hb/unit (g)	69.5	5.8	55.6	82.4	69.0	30
	10*6 WBC/unit	2625	764	1511	4914	2469	30
	10*9 PLT/unit	102.8	23.2	73.7	156.1	96.7	30
WB post-filtration	Volume (ml)	513	14	491	535	516	30
	Hb (g)	63.5	4.8	53.8	75.2	63.2	30
	WBC/unit	23/30 values < DL		< DL	200,033	< DL	30
	10*9 PLT/unit	24/30 values < DL		< DL	8	< DL	30
	Hemolysis rate Abs (%)	0.02	0.01	0.01	0.05	0.02	30
	Hb recovery (%)	91.4	3.7	84.3	98.2	91.3	30

("< DL" means below detection limit)

This product contains DEHP (Bis(2-ethylhexyl) phthalate), a plasticizer suspected to be toxic for reproduction. Repeated or prolonged treatment with this or other DEHP containing products of children, pregnant or nursing women should, if possible, be avoided. Medical practitioners must assess the benefit of use against foreseeable risks.

This marking reflects compliance with the applicable CE Marking requirements for medical devices. CE 0123

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