

**Plasma From Whole Blood Treated
With INTERCEPT™ Platelet Processing Set**

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Background

INTERCEPT Blood System™ can be used for pathogen inactivation for plasma of a volume range between 385 and 650 mL (Figure 1). The INTERCEPT™ processing set for plasma has an integral flow compound adsorption device (CAD), which is capable of reducing the residual amotosalen concentration to below 2µM. Because the volume of a whole blood derived plasma unit is significantly

<385 mL pooling of 2-3 units will be required for processing using the plasma set (Table 1). Unfortunately, pooling of plasma in Belgium is not authorized. On the other hand, the volume range (255-325 mL) of the INTERCEPT small volume (SV) processing set for platelets (Figure 1) corresponds to the volume of a unit of whole blood plasma. The INTERCEPT SV set has an integral wafer CAD.

Aims

We studied the feasibility to treat whole blood plasma with the INTERCEPT platelet SV processing set. We analysed the impact of the platelet wafer CAD on coagulation proteins and the time to reduce amotosalen concentration to below 2µM.

Figure 1: INTERCEPT Blood System Processing Sets

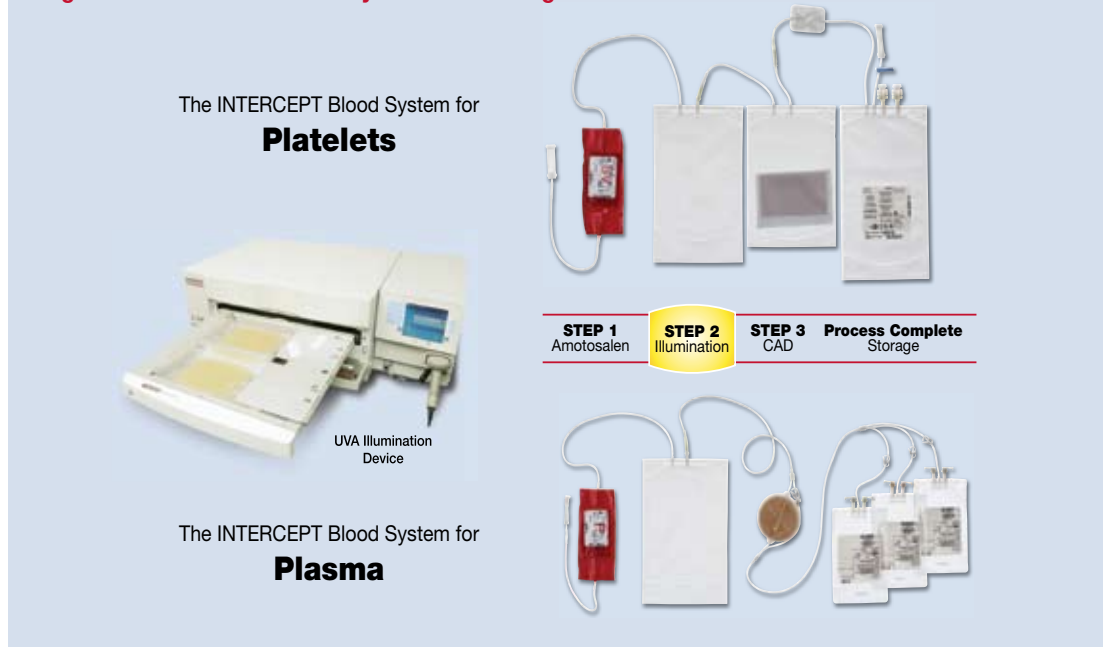


Table 1: INTERCEPT plasma and platelet (small volume) processing input requirement and whole blood derived plasma characteristics

Parameters	INTERCEPT Plasma Set	INTERCEPT Platelet SV set
Volume (mL)	385 - 650	255 - 325
RBC (x10 ⁶ /mL)	<4	<4
CAD	Flow adsorption	Wafer adsorption
Amotosalen nominal concentration (µM)	150	150
UVA (J/cm ²)	3	3

* QC data generated from this study.

Results

After photochemical treatment of whole blood plasma in the INTERCEPT platelet SV set, cellular contaminations were within the European guidelines (RBC: <6.0 x 10⁹/L, WBC: <0.1 x 10⁹/L and pIts <50 x 10⁹/L). There was an expected loss of Fibrinogen and Factor VIII after UVA illumination, respectively 15% and 29% (Table 2). The Fibrinogen concentration was stable during the entire 4 hours of incubation in the CAD, but this was not

true for Factor VIII. Indeed, the loss of this protein was 34% at 1 h, 35% at 2h, 40% at 3h and 44% at 4h compared to baseline activity. This reduction in Factor VIII activity may have been due to the prolonged storage at 22±2°C in the wafer CAD while being agitated. The amotosalen concentration range was between 1.0–3.1 µM after 4 hours on CAD (Table 3).

Table 2: Fibrinogen and Factor VIII pre- and post treatment with various CAD time

Parameters	Fibrinogen (n=10)		FVIII (n=10)	
	mg/dL	% remaining	IU/dL	% remaining
Baseline	255 ± 46	100	116 ± 33	100
Post-Illumination	218 ± 44	85 ± 5	83 ± 26	71 ± 5
CAD 1h	215 ± 43	84 ± 3	77 ± 25	66 ± 5
CAD 2h	214 ± 42	84 ± 4	75 ± 24	65 ± 5
CAD 3h	213 ± 43	83 ± 4	70 ± 23	60 ± 5
CAD 4h	212 ± 43	83 ± 4	65 ± 21	56 ± 5

Table 3: Amotosalen concentration (µM) pre- and post treatment with various CAD time

N=10	Pre-Illumination	Post-Illumination	CAD 1h	CAD 2h	CAD 3h	CAD 4h
Mean	149.9	87.7	32.1	11.1	4.2	2.0
SD	8.4	6.2	6.0	3.4	1.5	0.7
Min	132.5	73.4	23.1	5.6	2.0	1.0
Max	165.2	93.4	40.8	15.5	6.7	3.1

Methods

Whole blood (n=10) was collected in quadruple pack top and bottom system containing CPD and stored for minimum 2 hours on a cooling plate before centrifugation. The mean volume of blood collection was 463 ±21 mL and the ABO blood group was O (n=5), A (n=4) or B (n=1). After a hard spin centrifugation whole blood was separated on an automatic separator. Plasma (283 ±19 mL) was connected to an INTERCEPT platelet SV processing set, illuminated by UVA light and transferred into the container with the wafer CAD. Plasma was stored in this container for 4 hours on a flat bed shaker at room temperature. Samples were taken from each original plasma unit, before and after UVA illumination and at each hour of storage on CAD. Contamination by RBC, WBC and platelets was determined for all samples, as well as Fibrinogen, Factor VIII and amotosalen.

Conclusions

- The treatment of whole blood derived plasma with the INTERCEPT SV processing set did not maintain protein factor activity while reducing the amotosalen concentration to <2µM.
- It was necessary to incubate for a minimum of 4 hours on the wafer CAD to reduce the amotosalen concentration to approximately 2µM. The level of Factor VIII activity decreased to <70 U/dL after 4 hours on the CAD.
- Additional studies will be required to optimise a processing method for whole blood derived plasma without pooling.