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GLASGOW & WEST OF SCOTLAND
BLOOD TRANSFUSION SERVICE

REPORT TO THE SCOTTISH DIRECTORS

SOURCE PLASMA BY
AUTOMATED PLASMAPHERESIS

APRIL, 1984

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SOURCE PLASMA BY AUTOMATED PLASMAPHERESIS

By

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Following discussions and earlier proposals in 1983, two studies were commissioned by the Scottish National Blood Transfusion Directors into the production of source plasma for factor VIII, the first to compare machine and manual plasmapheresis collection systems and the second to look at the option of the optimal additive solution. It was agreed that the first project would be conducted in the West of Scotland and the second in the South East. This report outlines the progress which has been made in the West of Scotland over the past year from February 1983 until February 1984.

The design of the study has been previously indicated to Directors and modifications were made to this to take account of various comments which were made and those of Dr Harold Gunson, Director of the Manchester Blood Transfusion Centre who was attempting to carry out a similar study in his region. A Haemonetics plasmapheresis machine was kindly supplied, free of charge, by the Haemonetics Corporation for the one year of the study and the necessary bowls and harnesses were purchased from non-recurring funds.

THE AIMS OF THE STUDY

1 To investigate the motivation and reaction of donors who had not been previously plasmapheresed to an alternating system of machine and manual systems with the donors being questioned closely at preselected intervals concerning their reactions (Appendix 2). Criteria for acceptance of donors was according to the BTS memorandum with an upper age limit of 45 years.

2 Quality Assurance data on the source plasma included coagulation assays done by BTS staff in the West and also at the Protein Fractionation Centre and liver function tests and information concerning the care of the donors undertaken at the Regional Transfusion Centre in Glasgow and at the Biochemistry Department at Law Hospital, Carluke, where appropriate samples of blood and plasma were collected at each donor visit for subsequent analysis. Separate reactions observed in the donors were noted by the nursing sister at the time of the plasmapheresis sessions.

The questions to be answered by the study were:

1 Motivation of donors for manual and machine plasmapheresis: how practical are both options and how do they compare?

2 Evaluation of the safety and donor response to the machine and manual plasmapheresis.

3 Evaluation and comparison of the cost and suitability of both systems to produce source plasma.

4 Evaluation and comparison of the quality of FFP obtained by the two methods.

5 Evaluation and direct comparison of two batches of fractionated material collected by both methods from the same donor population, handled and processed identically to finished intermediate purity factor VIII concentrate.

RESULTS

1 Tables 1, 2 and 3. The tables show that 72% of the replies received from the existing donor panel produced a highly motivated cohort of donors who remained and took part in the study throughout the whole of the trial period. Reasons for deferment are shown in Table 3 and reasons given by donors for taking part are shown in Table 4.

2 The donor response to the machine was uniformly favourable and enthusiastic. Indeed as the study progressed, most of the donors were hinting that they would be bitterly disappointed if they were not able to continue with the use of the machine in the future. Only 19 out of 729 procedures were incomplete for the reasons shown in Table 5. Ninety-three percent had no difficulty in attending the sessions. Tables 6, 7, 8 and 9 show donor responses and recommendations. Table 10 shows the evaluation of the observations made by the Nursing Sister at each session. Figures 1, 2 and 3 show the procedure and anxiety ratings.

3 Table 11 shows the comparative costs of manual -v- machine for 1 litre of collected source plasma. The details of the costings are shown in Appendix 3.

4 Tables 12, 13 and 14 show the platelet count, white count, red cell count of the source plasma from both methods. These show no specific differences except that the machine showed a higher and persistent level of platelets.

5 Tables 15 and 16 show the comparison of two pools, reference NY794 and NY798 entered into process at the Fractionation Centre as source plasma and taken through to intermediate concentrate. Although only two pools have been examined, it is hoped that the PFC will be able to supply some additional pooled data from two other pools which are presently in process.

CONCLUSION

This study demonstrated that with drive and enthusiasm on the part of staff, it is possible to continue to motivate blood donors to remain enthusiastic in their willingness to supply source plasma by both manual and machine methods. The quality of the plasma is equally good and the costs of production are very comparable in terms of staffing and donor safety.

20 April 1984

TABLE 1

DESIGN OF STUDY

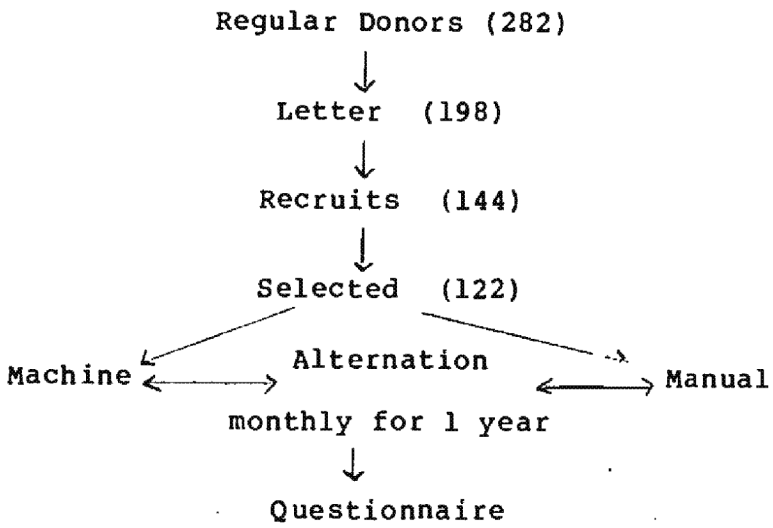

TABLE 2

RECRUITMENT

Letters sent	282	
Replies received	198	
Number unwilling or unable	29	
Number of letters returned undelivered	25	
Letters not returned	84	
Number willing to participate	144	(72%)

TABLE 3

RECRUITMENT - REJECTIONS

Unwilling/unable to participate:

Time unsuitable	15
Health reasons	4
Moved from Glasgow area	3
Feeding a baby	1
Working out of town	1
Not convenient to travel to Centre	1
No reason	4

TABLE 4

MOTIVATION (Q1)

When invited to join the programme
why did you do so?

Altruism	47	(34%)
Interest in the methods	44	(32%)
Importance of the project	37	(26%)
Egocentricity	3	(2%)
Self-need	4	(3%)
Others	4	(3%)

TABLE 5

DONOR SUBJECTIVE OPINION (Q8,9)

Out of 729 procedures only 19 dropped out

1% very difficult out of
729 procedures due to:

3 burst bags

3 tissuing

1 painful VP

1 filter collapse

TABLE 6

PROCEDURE RATING (Q2,3)

What was the part you liked least and why?

	Manual		Machine	
	No	%	No	%
No comment	399	54.5	431	58.9
Disliked needles	251	34.3	245	33.5
Felt some discomfort	35	4.8	33	4.5
Disliked sight of blood	9	1.2	7	0.9
Time involved	38	5.2	16	2.2
TOTAL	732		732	

TABLE 7

PROCEDURE RATING (Q4,5)

What was the part you liked more and was the least unpleasant?

After 12 procedures:

No comment	418	
Relaxation	78	12.6%
Involvement	66	10.6%
Atmosphere	25	4.0%
Staff	31	5.0%
TOTAL	618	

TABLE 8

IN-TRIAL VALUATION

Which procedure did you prefer and why?

	Before 3rd Procedure	Before 7th Procedure
Machine Preference:	121	123
Time factor	105	108
Less risk	3	7
Comfort of procedure	7	7
Interest	6	1
Neutral:	8	8
Manual Preference:	5	Nil
More comfortable	3	
Felt unwell on machine	1	
Preferred manual control	1	

TABLE 9

DONOR RECOMMENDATIONS (Q10)

How could the session be improved?

Number of procedures: 732

Improve atmosphere by providing TV or video, better music	19	2.6%
Improve visual display on machine	11	1.5%
Improve comfort: Arm rests - 5), Couches too hot - 8)	13	1.7%
Provide an evening session	4	0.5%
Use machine only	20	2.7%

TABLE 10

NURSE EVALUATION

Number of untoward reactions:

Out of 732, both machine and manual procedures
6 donors had untoward reactions

1st Manual - 4 [pallor, sweating, apprehension]

6th Manual - 1 [twitching]

1st Machine - 1 [pallor, sweating]

FIGURE 1

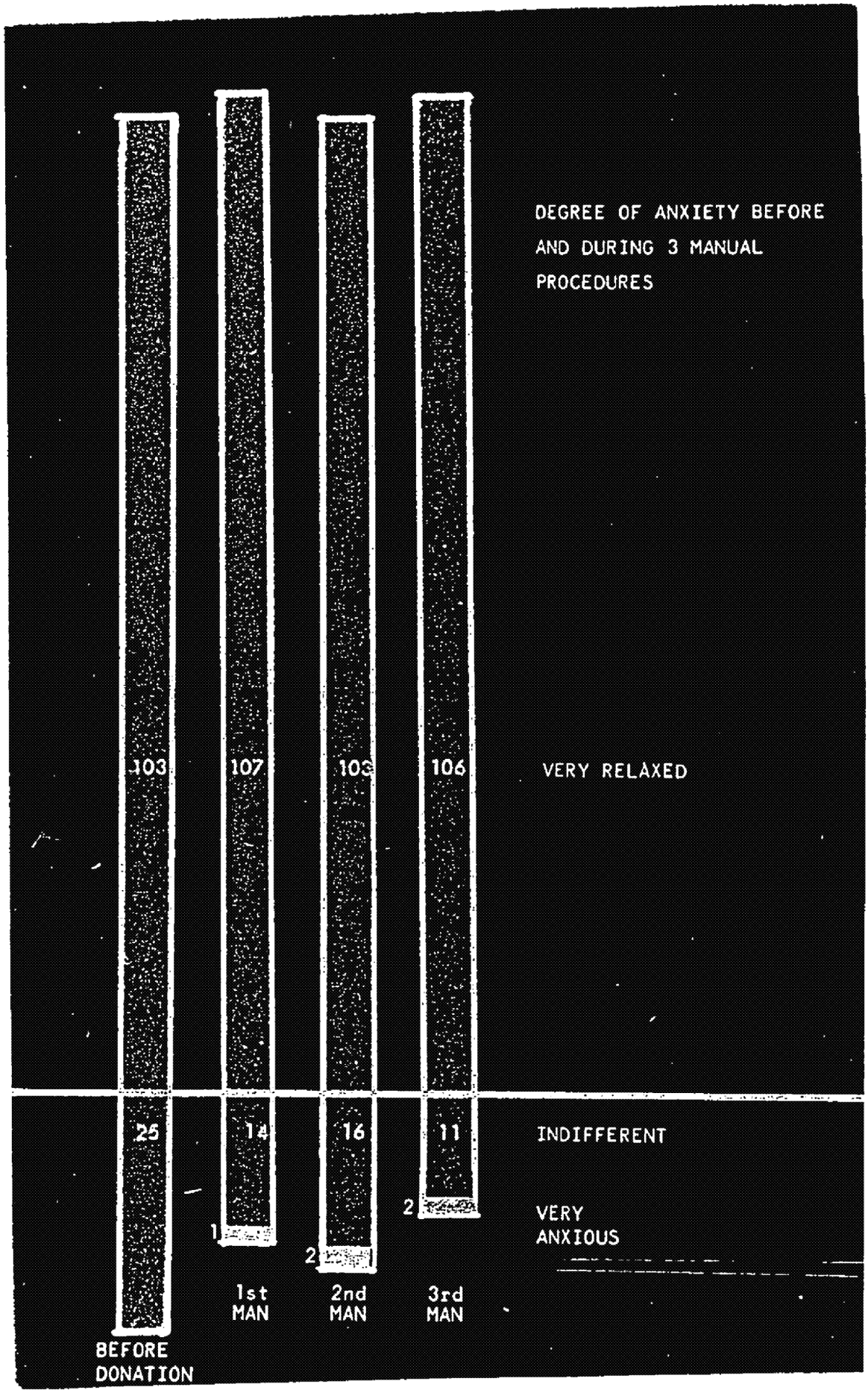

FIGURE 2

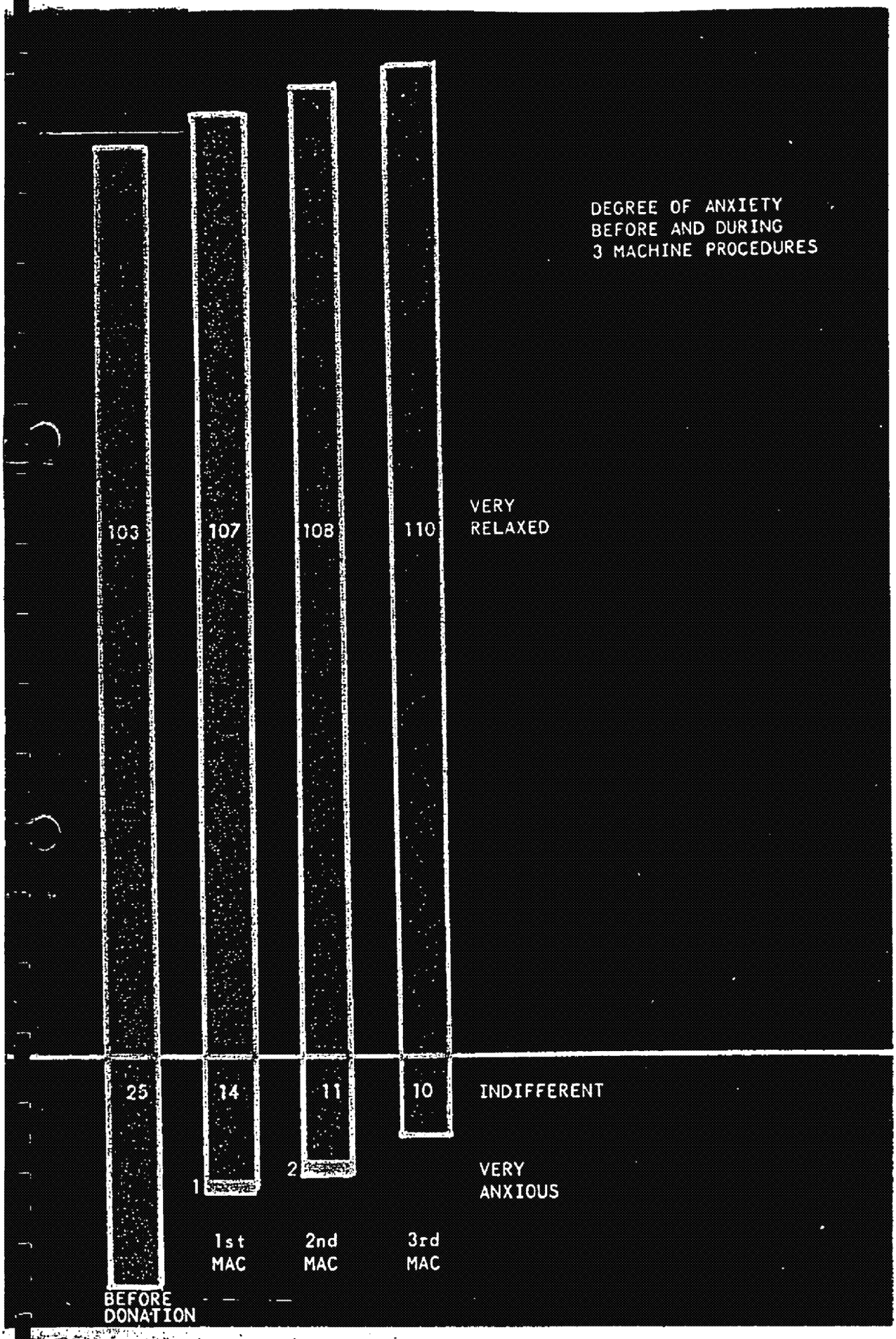

FIGURE 3

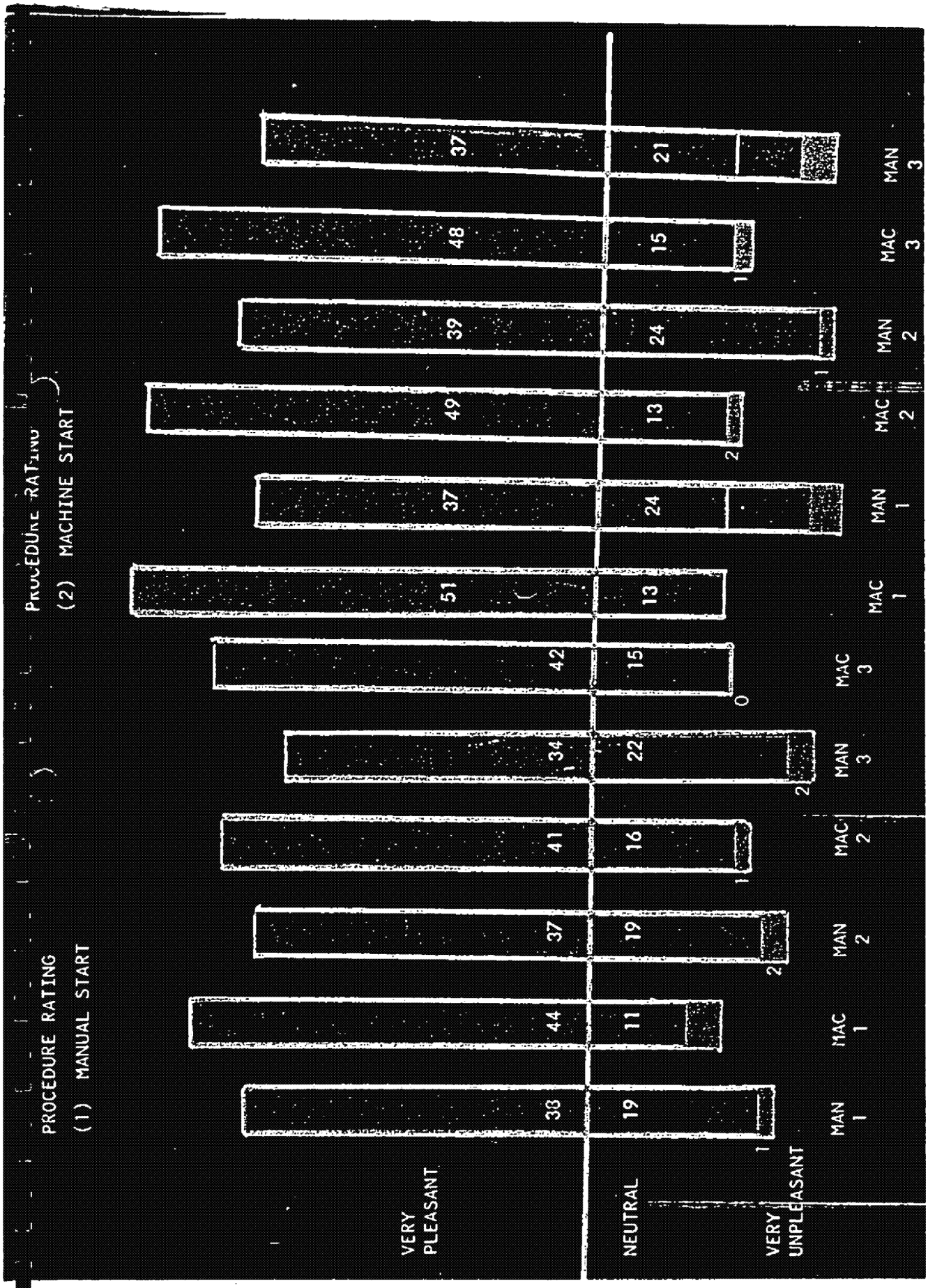

TABLE 11

COST PER LITRE OF PLASMA

Cost/ Litre	Haemonetics Model 30	Manual	Haemonetics V50
Machine	2.35	2.35	2.88
Wages	12.98	32.81	12.98
Consumables	98.80	24.66	31.60
TOTAL	114.13	59.82	47.46

TABLE 12

PLATELET CONTENT OF SOURCE PLASMA x 10^9/L

Machine (n=54)	Manual (n=90)
26 - 87	10
(65% > 50 17% < 30)	(3% > 15 < 22)

TABLE 13

WHITE CELL CONTAMINATION x 10^9/L

Machine (n=47)	Manual (n=40)
0.0 - 0.02	0.0 - 0.02
(nil in 33)	(nil in 15)

TABLE 14

RED CELL CONTAMINATION x 10^9/L

Machine (n=46)		Manual (n=44)
0.269		0.238
		0.263
3.4; 4.2	VISUAL	1.06; 2.1; 2.3

TABLE 15

COMPARISON OF PROCESSED BATCHES

	MANUAL NY 794		MACHINE NY 798	
Sample	n	FVIIIC iu/ml	n	FVIIIC iu/ml
Donor	15	0.78 ± 0.17	20	0.78 ± 0.20
Prefreezing	43	0.69 ± 0.26	51	0.72 ± 0.17
	42	0.64 ± 0.27		
	Ave	0.665		

TABLE 16

PROCESS YIELDS AT PFC

Stage	Process Yield iu/ml NY 794, 120 Kg	Process Yield iu/ml NY 798, 160 Kg
Cryoprecipitate	340.3 (51% recovery)	558.5 (72.4% recovery)
Final Product	258.7 (76% of cryo recov)	260.7 (46% of cryo recov)
Overall Recovery	38.0%	33.8%
Spec Activity iu/mg Protein	0.34	0.23
Fibrinogen	61%	61%
Solubility	7 minutes	26 minutes