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16. Abstract

Penetration characteristics of 20 gauge IM needles with constant side bevel length (45%) and varied side bevel rotation angle, and needles with constant side bevel rotation angle (42°) and varied side bevel lengths were studied. Measurements were made, as previously described using a NOVA 1220 computer system, and analyzed using algorithms developed by HSRI personnel. Side bevel length and rotation angles other than those in present use on the BD42 needle (45%, 42°) give lowered needle parameters. This may not be advantageous as double peaked force curves are also often generated. Of needle variations tested 50 and 60% side bevel rotation angle (21° and 25° respectively) give the lowest mean parameter values.

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THE EFFECT OF POINT GEOMETRY ON NEEDLE PENETRATION PARAMETERS

July 31, 1980

Submitted to:

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INTRODUCTION AND PROCEDURES

On May 6th and 7th, 1980, penetration tests were performed using B-D dry 20G 1-1/2 inch IM needles with differing tip geometry. The purpose of this study was to determine a point geometry which gives optimal performance as judged by needle penetration parameters.

Testing was carried out on a 71 year old unembalmed female cadaver, ten days post mortem. The HSRI computer controlled injector (described previously) was used to perform the penetration tests. Force and displacement signals were digitized on-line and stored on magnetic tape for later analysis. The needles were divided into two groups. The first group consisted of control needles and needles with differing side bevel rotation angles. These needles were injected into the left buttock on the first day of testing. The second group of needles consisted of control needles and needles with differing side bevel lengths. This group was injected into the right buttock on the second day of testing. Controls were injected on both days to provide an estimate of variation in time and tissue site.

Table 1 lists the needle descriptions and codes used for this study. Test conditions were as follows:

Penetration velocity	3 ips
Retraction velocity	2 ips
Dwell	0.5 sec
Penetration angle	90°

Penetration depth was 1.25 inches for all needles, except the 200% rotation angle which was injected to a depth of one inch.

Table 2 presents the description and units of the parameters calculated from the needle penetration data. Figure 1 is a graphic illustration of these parameters and their meaning.

TABLE 1

NEEDLE DESCRIPTIONS AND CODES

	NEEDLE CODE	DESCRIPTION
GROUP I	20 R	20% Rotation Angle
First Day	30 R	30% Rotation Angle
	40 R	40% Rotation Angle
	50 R	50% Rotation Angle
	60 R	60% Rotation Angle
	*BD42	BD 42 (Control-100% Rotation Angle)
	BB	BD Back Bevel (Control)
	00	Primary Bevel (0% Side Bevels, 0% Rotation Angle)
GROUP II	10 SB	10% Side Bevels
Second Day	15 SB	15% Side Bevels
	20 SB	20% Side Bevels
	25 SB	25% Side Bevels
	30 SB	30% Side Bevels
	*BD42	BD 42 (Control-45% Side Bevels)
	65 SB	65% Side Bevels
	**200 R	200% Rotation Angle
	BB	BD Back Bevel (Control)
	00	Primary Bevel (0% Side Bevels, 0% Rotation Angle)

* BD42 needles are referred to by their appropriate percent rotation angle or side bevel length in this report.

** Although this needle belongs with the Rotation Angle group, time did not permit it to be tested on the first day.

TABLE 2

DESCRIPTION AND UNITS OF
NEEDLE PENETRATION PARAMETERS

Parameter	Description	Units
F2*	peak force	grams
D2	needle displacement at F2	centimeters
F12	first force peak on double peaked curves	grams
D12	needle displacement at F12	centimeters
F3	minimum force after penetration	grams
D3	needle displacement at F3	centimeters
F3/F2	ratio of minimum to peak force	——
F4	force at maximum displacement	grams
D4	maximum needle displacement	centimeters
PW	penetration work (area under the force-needle displacement curve from skin contact to D2)	gram-centimeters
DW	drag work (area under the force-needle displacement curve from D2 to D4)	gram-centimeters
TW	total work (PW + DW)	gram-centimeters

* Due to the double peaked nature of force curves for some tests (10%, 15%, 20% and 25% side bevels; back bevel; 200% rotation angle) difficulty was encountered in selecting the proper F2. The standard HSRI program was modified slightly or hand calculations were done so that the second peak was always selected as F2.

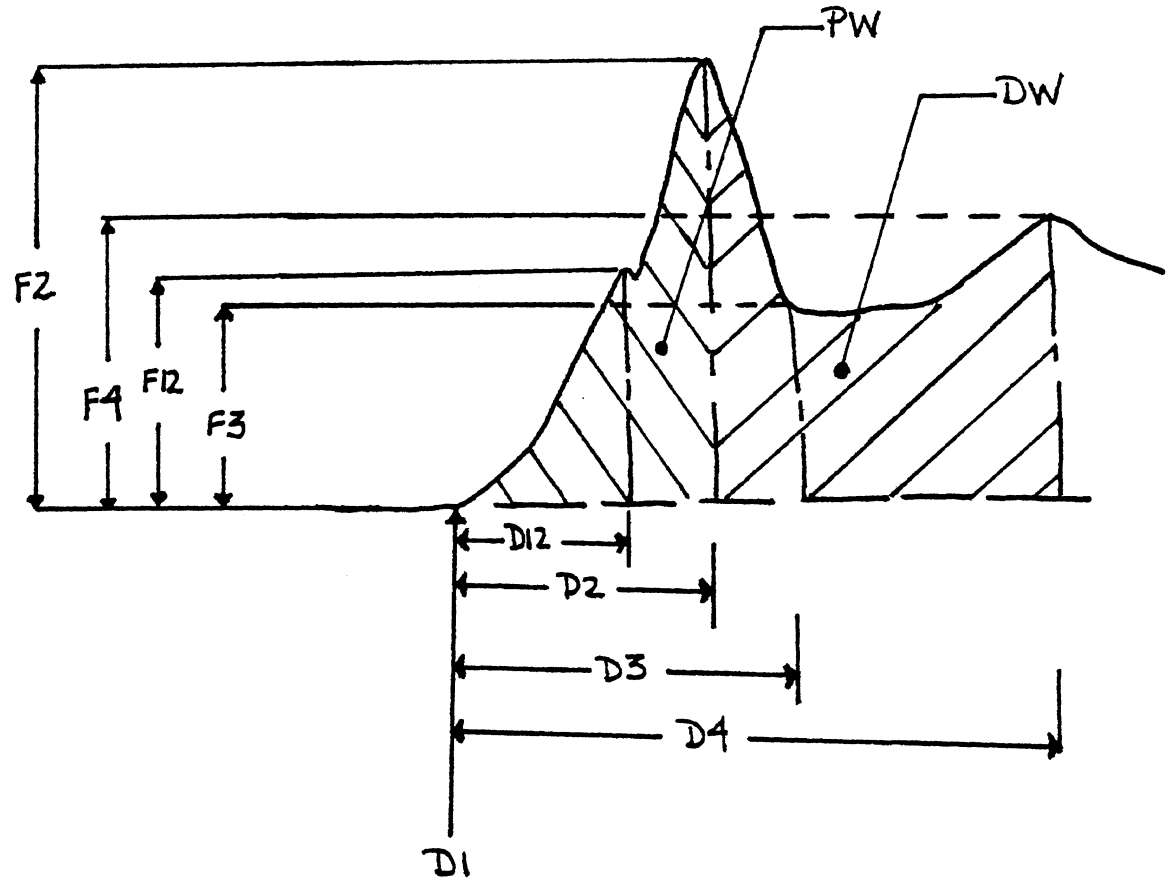

Figure 1. Schematic of force curve indicating needle parameters. Refer to Table 2 for descriptions.

RESULTS

Means and estimated population standard deviations of penetration parameters for each needle group are presented in Tables 3 and 4 and Figures 2 through 11 of Appendix A. Copies of characteristic force curve chart recordings are included in Appendix B. Complete copies of chart recordings were sent to B-D on May 15.

Side Bevels

The chart recordings show consistent graphs for each needle type. One can almost guess the needle type from the chart recording. The most prominent feature of the recordings is the double peaking for 10, 15, 20, 25% and back bevel needles, also the multiple peaking for the 0%0% needles. The 45 and 65% side bevel needles had no double peaking and only a few of the 30% group showed any double peaking. The first peak often becomes only a shoulder as the side bevel is lengthened.

Figure 2 illustrates mean peak penetration force (F2) for the side bevel needle groups. Also plotted on this figure are the mean force values for F12, the first peak of double peaked force curves. There appears to be a broad minimum in mean peak force (F2) between 10% and 45% side bevel length. The 0%0% and 65% side bevel needles have the highest mean F2 values. The standard deviations for F2 are fairly large (16-23% of the mean value). Except for the 0%0% needle group, each needle group's mean F12 is lower than its mean F2. The mean F12 values show a downward trend from 0%0% to 25% side bevel length. The 25% side bevel needle group gives both the lowest mean F12 and F2 value. Since the 30%, 45% and 65% needles do not give double peaks, there is no F12 value for these needles. Mean peak force and F12 for the back bevel group fall within the range of the 10% to 45% side bevel groups.

The mean values of needle displacement at peak force (D2) and at first peak (D12), plotted in Figure 3, show little variation. The mean needle displacement for the second peak of double peaked force curves is

similar to the mean needle displacement values at F2 in single peaked force curves.

Recovery force means (F3) are shown in Figure 4. There seems to be no clear trend. The 65% needle gives the highest mean F3 value. Penetration work (PW) is shown in Figure 5. Only tests for which the program took the second peak as F2 (see sample size "n" values in Table 3) were used in calculating means for F3, PW, and DW. Again, no clear trend seems to exist.

Mean drag work, also plotted on Figure 5, shows increasing values as the side bevels are lengthened. Mean total work (TW), illustrated in Figure 6, has maximum values for the 0%0% and 65% side bevel needles.

No one needle group exhibited lowest mean values for all parameters measured. Side bevel lengths shorter than BD42 (45%) gave lowered mean values for F3, DW and TW. Shortening the side bevel had little effect on F2, and increased D2 and PW slightly. Side bevel length greater than 45% increases all mean parameter values except D2.

Rotation Angle

As with the side bevel needle groups, the chart recordings for the rotation angle needle types show characteristic curves for each needle type. Multiple peaks occur for the 0%0% needle. Double peaking is most pronounced for the 20% rotation angle. Thirty, 40, 50 and 60% needles also all gave double peaks. The 100% (BD42) gave no double peaks and there was double peaking in less than half of the 200% needles.

Figure 7 illustrates mean peak penetration force for the rotation angle. needle groups. Fifty percent and 60% rotation give minimum mean F2 values with maximum mean values for 0%0% and 200% rotation. Back bevel needles give mean values similar to 20% and 100% rotation. Standard deviations are large (13-33% of the mean values) with the largest occurring for the 100% rotation (BD42) needle.

F12, the force in grams of the first peak in double peaked curves, in also illustrated in Figure 7. Mean F12 values follow the same trend as mean F2 values, giving a minima at 50% and 60% and maxima at 0%0% and 200%. For the 0%0%, 20% and 200% needles mean F12 is greater than F2; for the other needle groups, F2 is greater.

Needle displacement at peak force (D2) and first peak (D12) are depicted in Figure 8. The mean D2 value varies little between rotation angle needle groups. All means fall within the standard deviations of other groups. The mean D12 value exhibits a slight decreasing trend as rotation angle increases.

The mean values for recovery force (F3, Figure 9) show a trend similar to that for F2; minima at 50-60%, maxima at 0%0% and 200%.

Penetration work (PW) and drag work (DW) are shown in Figure 10. Disregarding the DW value for 20% needle, since it only has an n of 3, we observe minimum values at 40%, 50%, 60% rising to maximal values for 0%0% and 100%. Total work mean values show a similar curve (Figure 11). Fifty and 60% rotation angles give the lowest mean values for all parameters measured.

Regardless of the differences in dates of injection and injection site, the control groups; 0%0%, back bevel and BD42, produced similar chart recordings and parameter values.

The mean values of F2, F3, and PW in this study are on the average approximately 20% lower than those found by B-D. This is probably due to cadaver differences. The general trend for both side bevel length and rotation angle parameters values is similar in both studies. This gives further validation to the usefulness and consistency of the cadaver model.

DISCUSSION

B-D's initial data on point geometry suggested a range of side bevel lengths and rotation angles which might encompass optimum needle performance as judged by force and work parameters. Our tests show that point geometry does affect the force curve and needle parameter values. The relationships are not simple, however. All needles tested have the same primary bevel angle and shaft dimensions and lubricant. Variations in needle parameter values can, therefore, be attributed to changes in the point geometry and interactions of the tip with the skin.

Both side bevel length and rotation angle have significant effects on parameters in the force curves. Adding a side bevel to the needle lowers the mean value of all parameters measured, but no side bevel length needle group stands out as giving optimum performance.

Rotation of the side bevels to angles less than the standard (42°, 100%) BD42 needle also lowers all the needle parameter values measured. Needles with 50% and 60% (21° and 25° respectively) rotation of side bevels give the lowest mean values for all needle parameters.

Although tip geometries other than the standard BD42 give lower mean parameter values, the double peaking which occurs in the force curves may not be desirable. The 0%0% needles give a curve with muliple peaking. When a short side bevel is added, force curves become double peaked. As the side bevel is lengthened the first peak becomes progressively smaller until it is only a shoulder and finally with the 30% and higher side bevel length needles, there is a single peak force. Among the rotation angle groups, only the BD42 (100%) needle did not give double peaked force curves.

Subjective nurse-user evaluation of needles which produce double peaking would be useful. It would be expected that the double peaking would lead to an uneven "feeling" on penetration. This may be undesirable from a user standpoint, even though peak force and other parameter values are lower than those of needles giving a single peak.

The source of double peaking in the force curves is not clear. Two hypothesis can be given:

1) The peaks are a product of the same needle structure coming into contact with discontinuities in the tissue.

2) The peaks are a product of different needle structures coming into contact with the same tissue structure or interface.

The first hypothesis assumes that all needles are subjected to the same skin discontinuities. The double peaking only occurs for some needle groups. This would indicate that cutting ability differs between needle groups, causing a discontinuity in the force curve to manifest itself only with certain tip geometries.

The second hypothesis is based on the discontinuities of the needle point itself. Peaks may be caused by tip, end of side bevel or of primary bevel as they penetrate the skin. For the rotation angle needle groups all side bevel lengths are 45%, i.e. needle discontinuities are the same distance from each other on all needles. If either hypothesis is correct the penetration depth at F12 and F2 should be constant for all needles and between groups.

Neither hypothesis can be proven with the data we now have. Comparison of D12 and D2 values only indicate where the needle is, not its penetration depth. These measurements cannot be used alone to determine what part(s) of the needle is causing force peaks. Excised skin studies, high speed cinematography and penetration depth data obtained with the aid of blunt needle injections* might answer the question of where and how the double peaking is generated.

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* See discussion in letter of July 21, 1980 to Howard Berger.

CONCLUSIONS

Point geometry is an important factor in determining needle parameters. This can be seen in the difference between parameter values for the 10% side bevel length needles and the 0%0% needles. Changing the rotation angle of the side bevels produces more dramatic changes than altering the side bevel length. Combining side bevel lengths and rotation angles might well produce a needle with high cutting ability, generating low forces and exhibiting little or no double peaking. Further insight into the issue of point geometry penetration parameters could be obtained by:

1. Using high speed cinematography.
2. Using slow speed injection and event marking.
3. Testing of other combinations of side bevel length and rotation angles.
4. Testing in excised skin as well as cadavers.
5. Obtaining subjective data from consumer/user testing.
6. Using the blunt needle injection procedure to determine needle penetration depth.

APPENDIX A

Tables 3 and 4
Figures 2 through 11

MEANS AND ESTIMATED POPULATION STANDARD DEVIATIONS OF PENETRATION PARAMETERS

TABLE 3

SUMMARY OF COMPUTED PENETRATION PARAMETERS
FOR SIDE BEVEL LENGTH NEEDLE GROUPS

Side Bevel Length		F12 gm.	D12 cm.	F2 gm.	D2 cm.	F4 gm.	TW gm.cm.	n	F3 gm.	PW gm.cm.	DW gm.cm.	n
0%0%	Mean	290	.93	278	1.30	240	448	10	187	160	265	3
	S.D.	74	.08	56	.12	35	52		22	21	21	
10%	Mean	170	.75	231	1.25	218	374	20	155	135	243	17
	S.D.	29	.10	38	.11	.9	38		20	26	29	
15%	Mean	198	.79	255	1.22	241	421	20	183	146	278	19
	S.D.	42	.08	49	.08	33	66		35	31	42	
20%	Mean	171	.77	224	1.14	229	385	20	162	117	265	17
	S.D.	26	.09	35	.09	18	33		19	15	28	
25%	Mean	157	.77	220	1.16	230	383	20	164	117	269	19
	S.D.	29	.09	39	.08	25	47		23	20	36	
30%	Mean	-	-	248	1.16	256	424	20	182	126	298	20
	S.D.	-	-	50	.08	41	61		28	24	48	
45%	Mean	-	-	235	1.14	268	432	11	194	114	318	11
(BD42)	S.D.	-	-	52	.11	38	70		38	27	51	
65%	Mean	-	-	309	1.13	290	483	20	205	137	346	20
	S.D.	-	-	71	.13	52	91		46	41	67	
Back Bevel	Mean	227	.86	234	1.17	217	394	11	168	142	270	8
	S.D.	49	.11	53	.08	29	65		31	32	37	

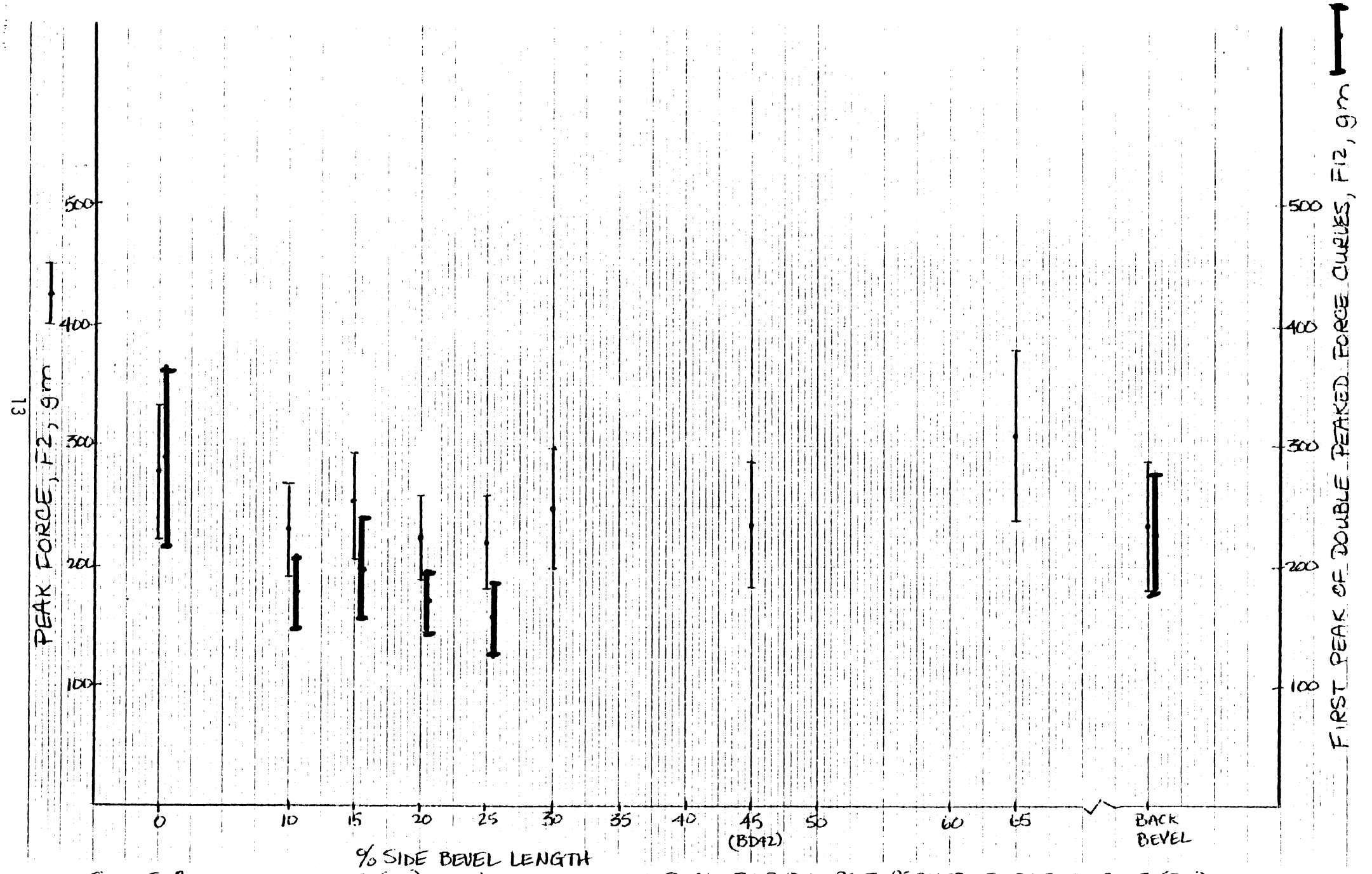


FIGURE 2 . PEAK FORCE (F2), and FIRST FORCE PEAK FOR DOUBLE PEAKED FORCE CURVES (F12) FOR THE SIDE BEVEL LENGTH NEEDLE GROUP

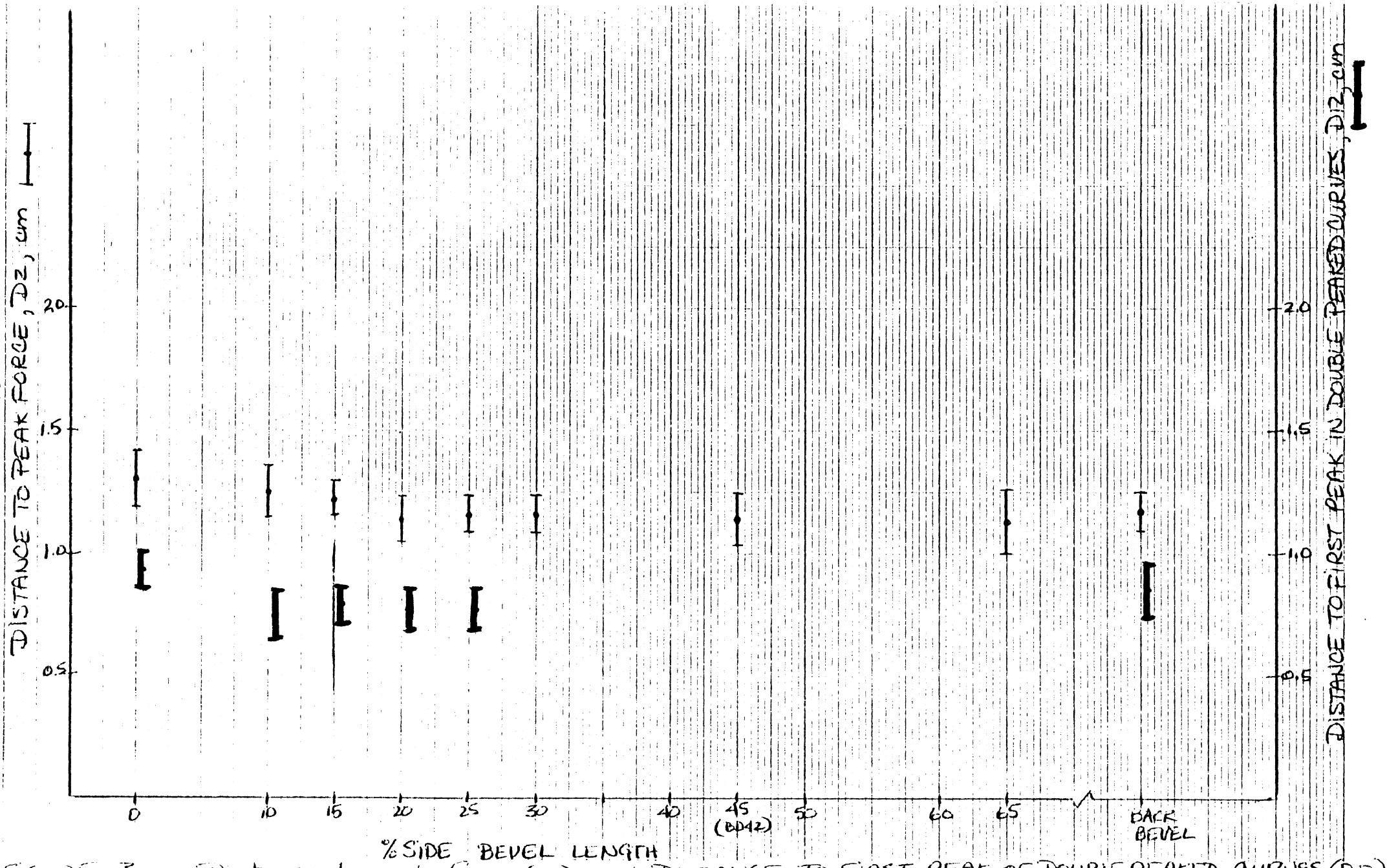


FIGURE 3. Distance to peak force (D2) and DISTANCE TO FIRST PEAK OF DOUBLE PEAKED CURVES (D12) FOR SIDE BEVEL LENGTH ANGLE GROUPS

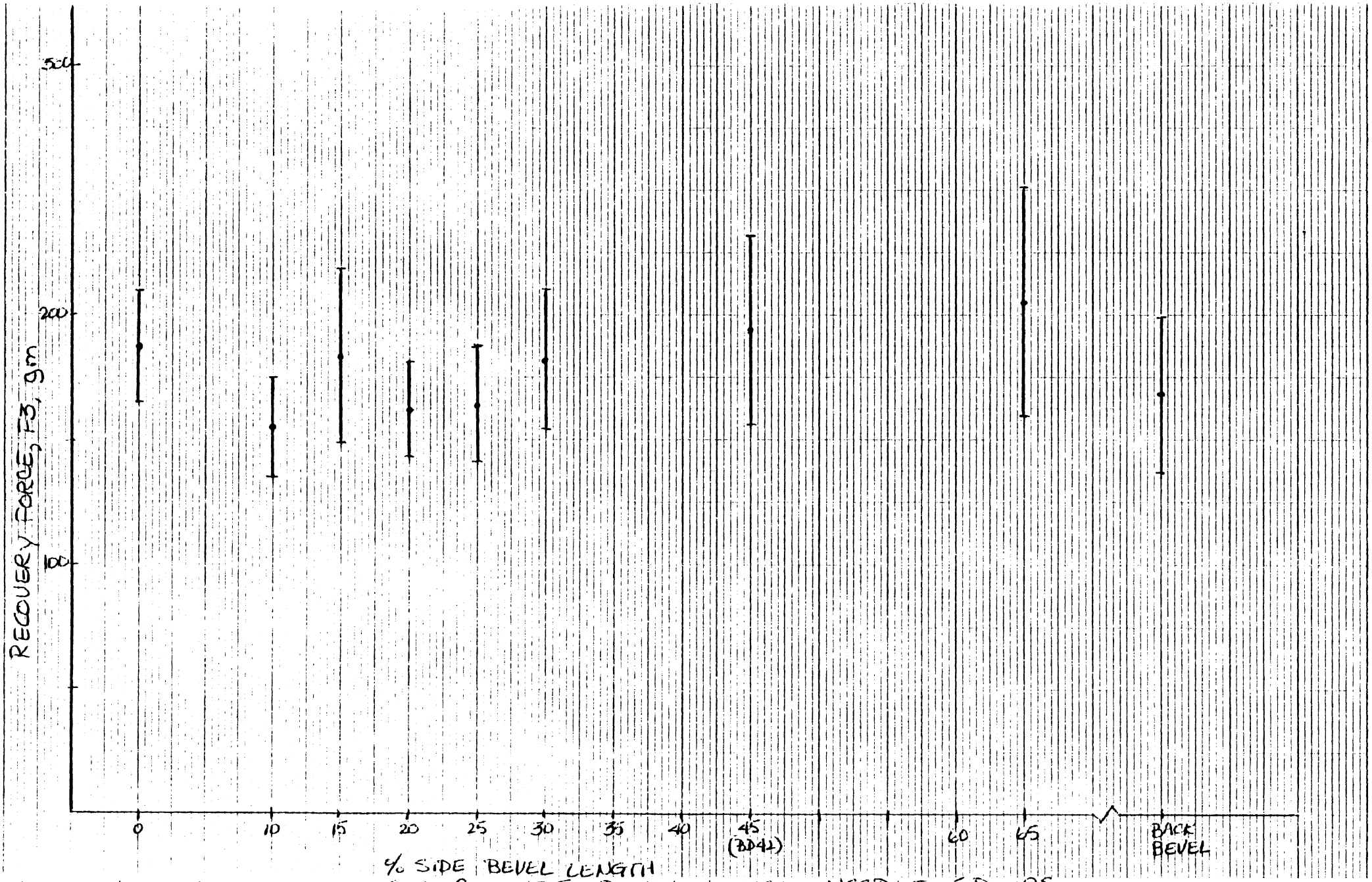


FIGURE 4. RECOVERY FORCE (F3) for SIDE BEVEL LENGTH NEEDLE GROUPS

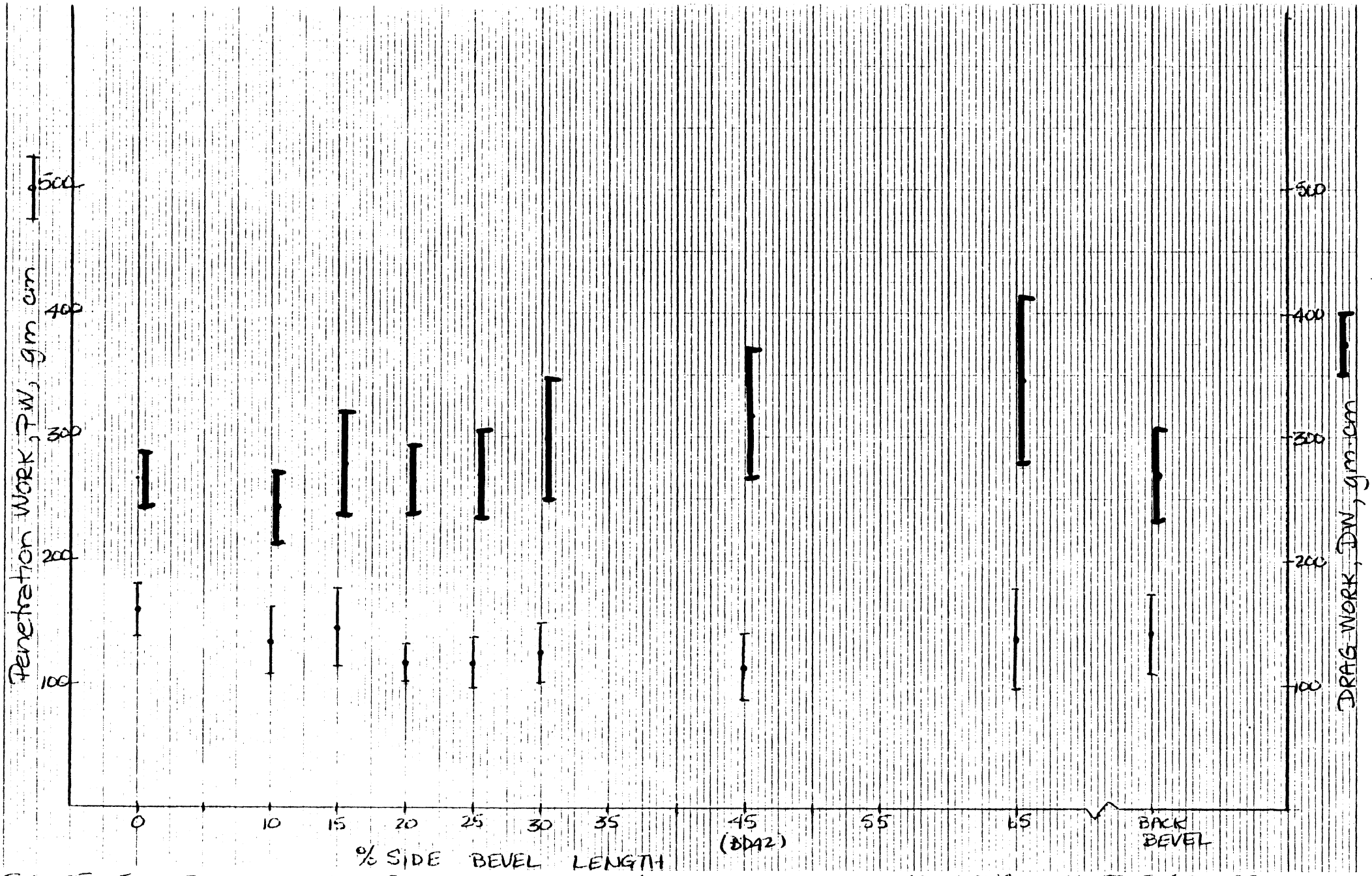


FIGURE 5 PENETRATION WORK AND DRAG WORK FOR THE SIDE BEVEL LENGTH NEEDE GROUPS

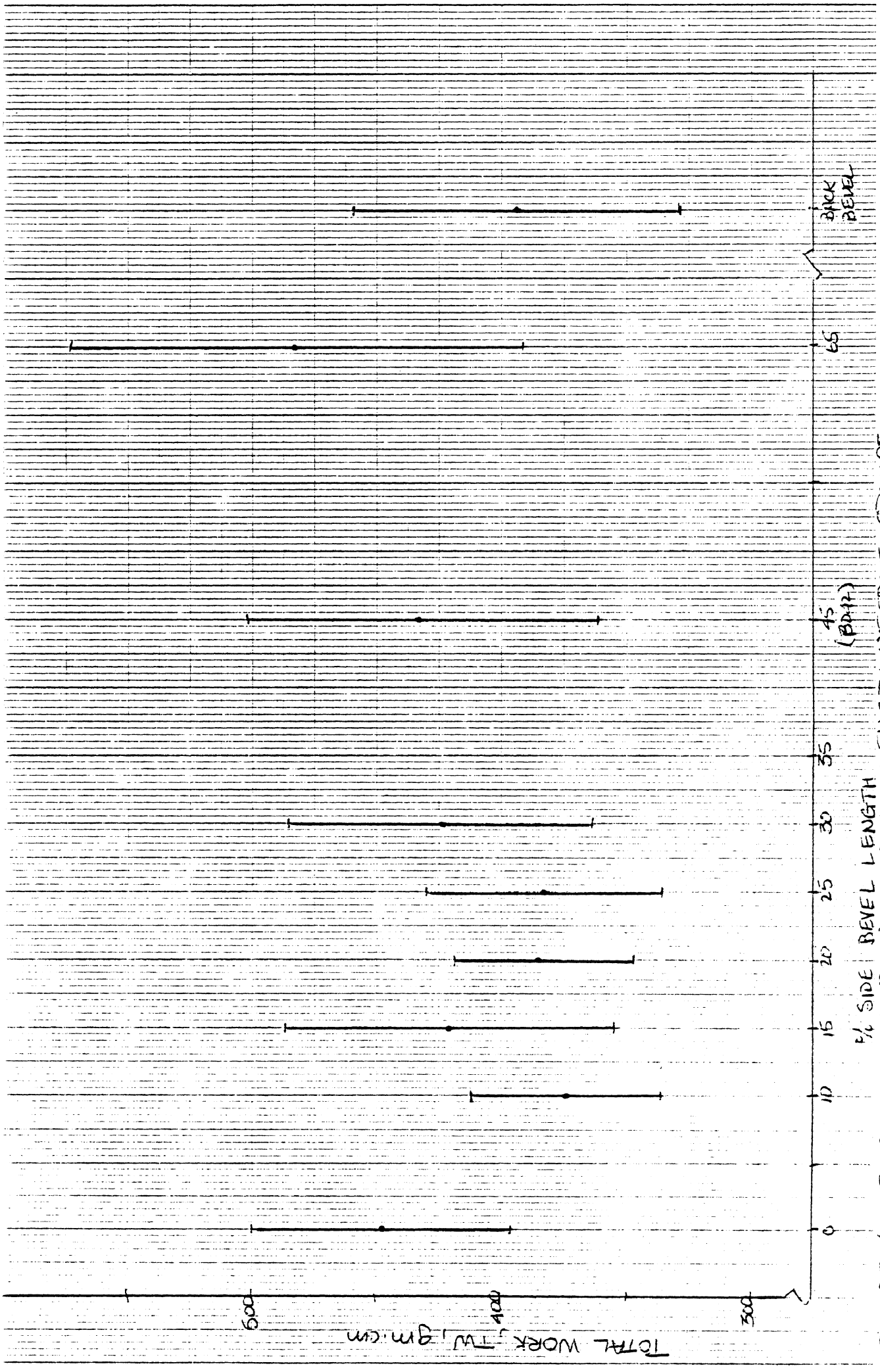


FIGURE 6. TOTAL WORK FOR SIDE

TABLE 4

SUMMARY OF COMPUTED PENETRATION PARAMETERS
FOR ROTATION ANGLE NEEDLE GROUPS

Rotation Angle	F12 gm.	D12 cm.	F2 gm.	D2 cm.	F4 gm.	TW gm.cm.	n	F3 gm.	PW gm.cm.	DW gm.cm.	n
0%0% Mean	283	.88	245	1.23	240	448	13	174	173	293	5
S.D.	±85	.16	63	.15	35	52		25	30	33	
20% Mean	232	.83	191	1.12	176	306	18	141	163	201	3
S.D.	76	.13	40	.17	48	87		20	78	25	
30% Mean	130	.71	182	1.09	199	320	18	128	95	228	15
S.D.	21	.08	49	.09	29	52		28	22	36	
40% Mean	116	.68	183	1.08	180	304	19	120	88	216	19
S.D.	17	.13	43	.13	28	53		29	18	46	
50% Mean	108	.70	158	1.08	184	298	19	125	80	222	17
S.D.	29	.13	37	.13	30	51		29	23	40	
60% Mean	112	.70	156	1.04	188	307	19	121	79	228	19
S.D.	18	.13	32	.12	23	47		17	14	41	
100% Mean	-	-	222	1.09	253	416	10	180	108	308	10
(BD42) S.D.	-	-	73	.11	57	113		52	35	82	
200% Mean	360	1.02	342	1.19	207	-*	21	228	213	-*	3
S.D.	67	.05	64	.07	22	-		11	39	-	
Back Mean	209	.80	234	1.09	194	366	13	151	124	253	7
Bevel S.D.	26	.08	35	.10	19	47		18	16	26	

* Because 200% rotation angle needle was shorter, changes were made in calculations. Therefore, DW and TW cannot be compared to those of other needles.

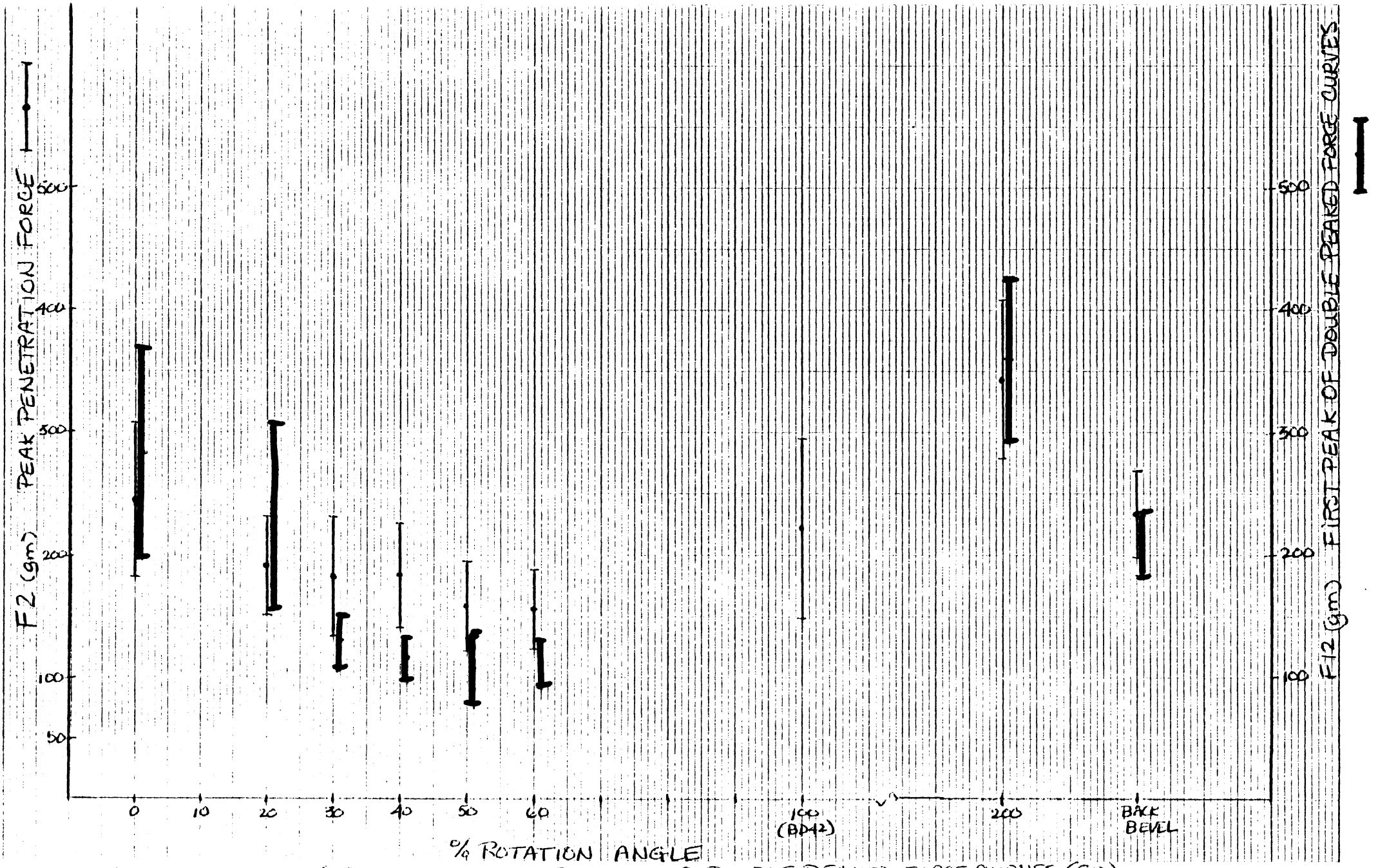


FIGURE 7. PEAK FORCE (F2), AND FIRST FORCE PEAK FOR DOUBLE PEAKED FORCE CURVES (F12) FOR FIVE SIDE BEVEL ROTATION ANGLES AND

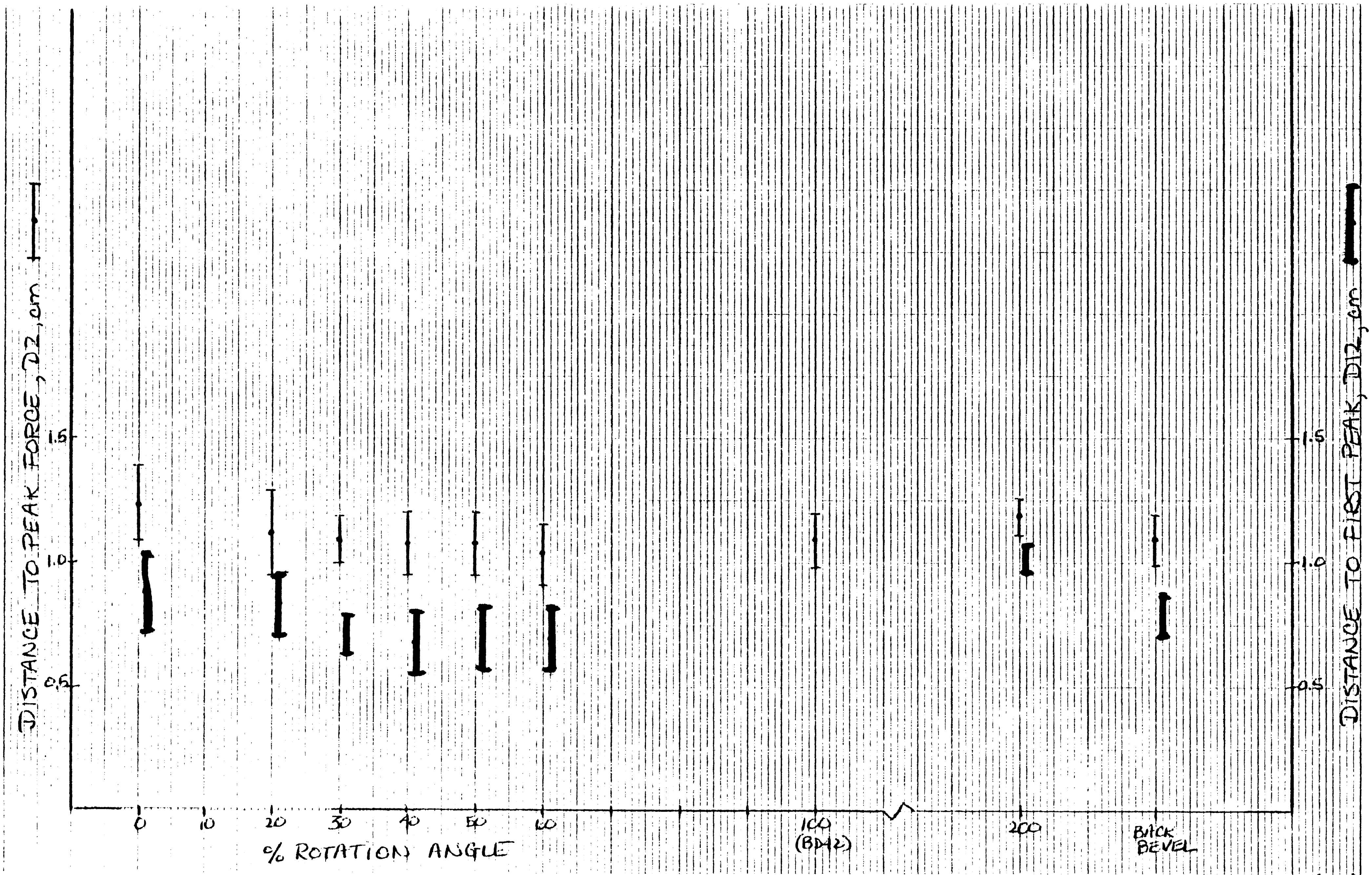


FIGURE 8. DISTANCE TO PEAK FORCE (D2) AND DISTANCE TO FIRST PEAK OF DOUBLE PEAKED CURVES (D12) FOR SIDE BEVEL ROTATION ANGLE NEEDLE GROUPS

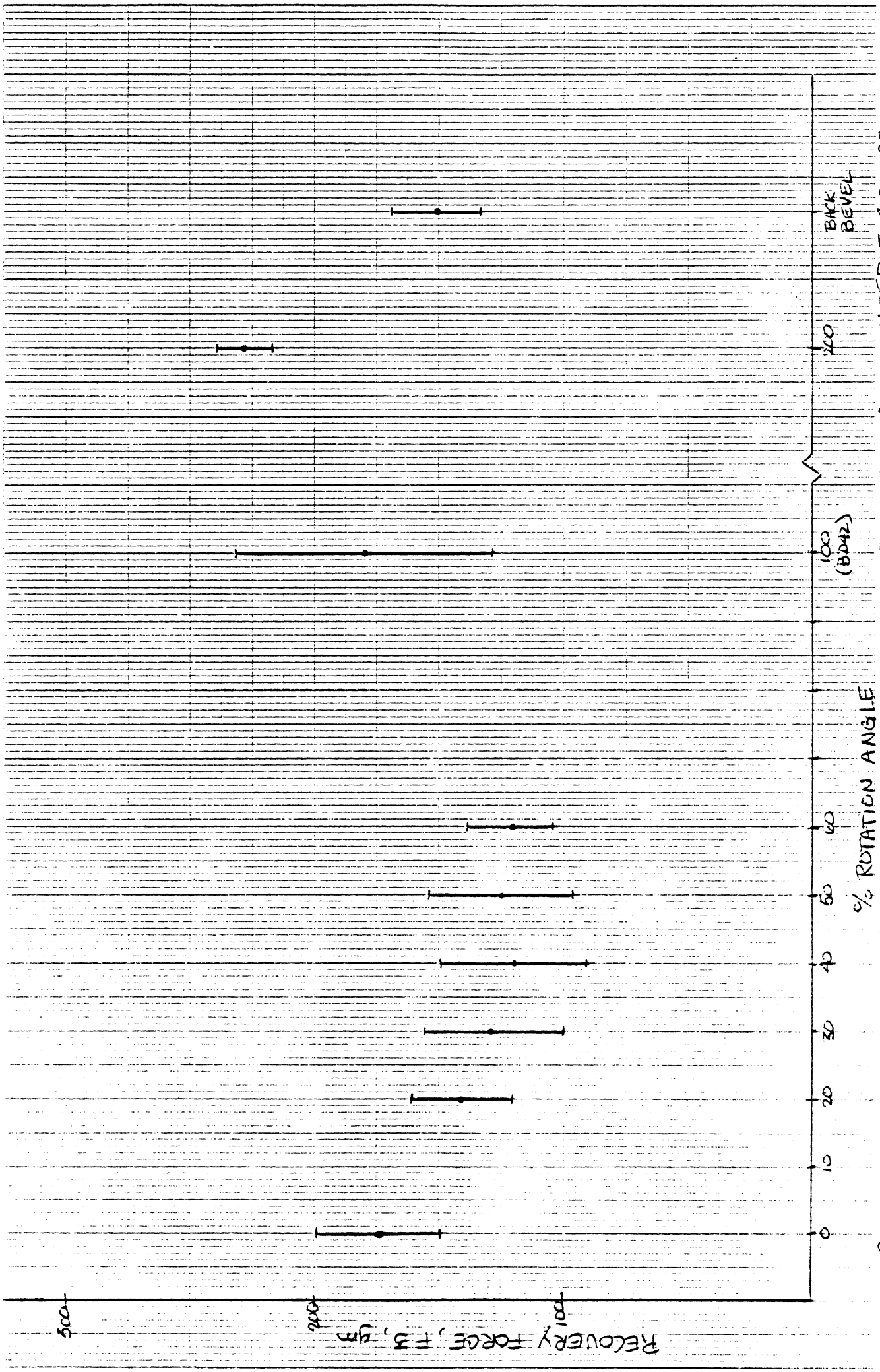


FIGURE 9. RECOVERY FORCE (F3) FOR THE SIDE BEVEL ROTATION ANGLE NEEDLE GROUPS

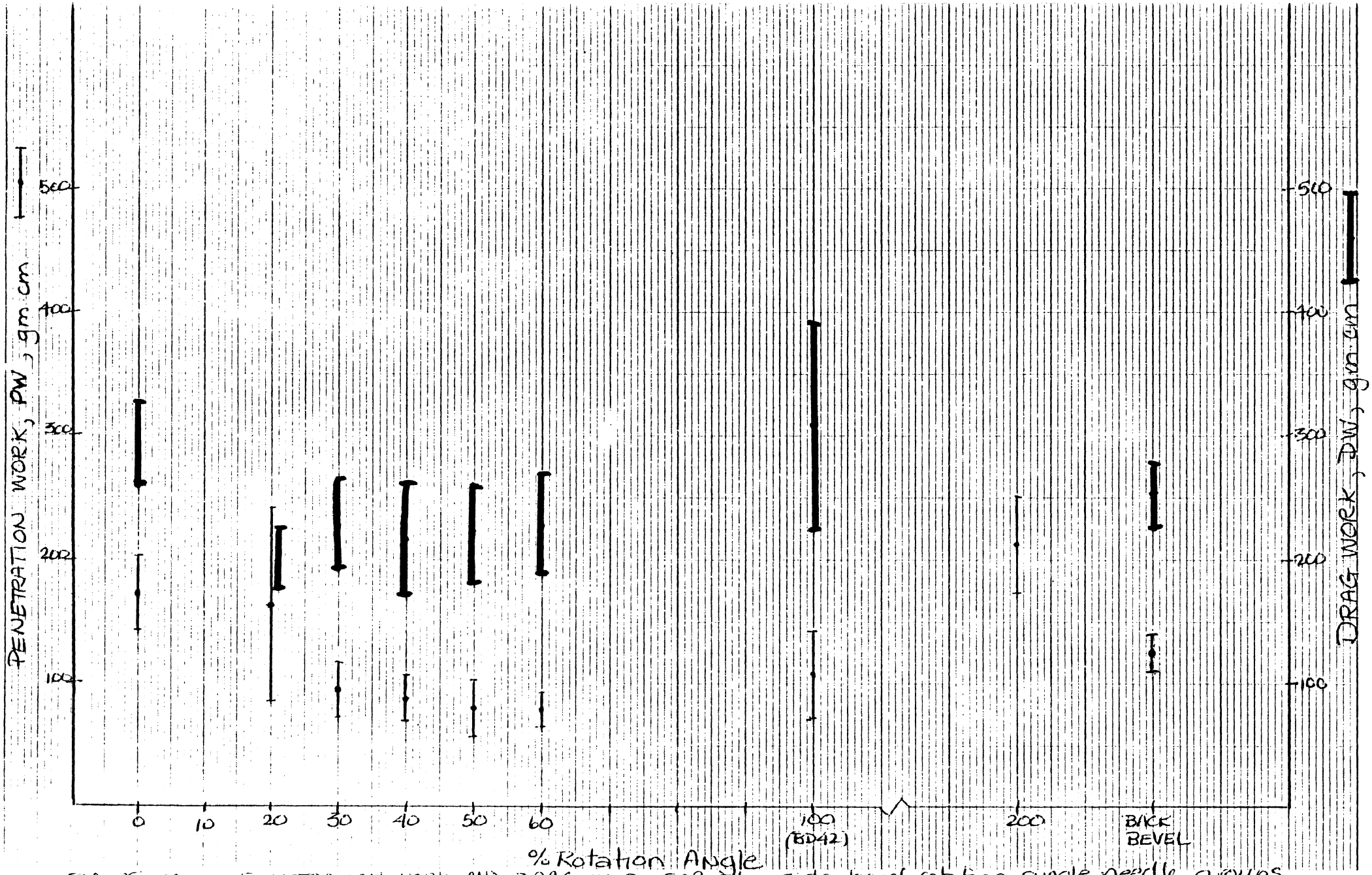


FIGURE 10 PENETRATION WORK AND DRAG WORK FOR the side bevel rotation angle needle groups

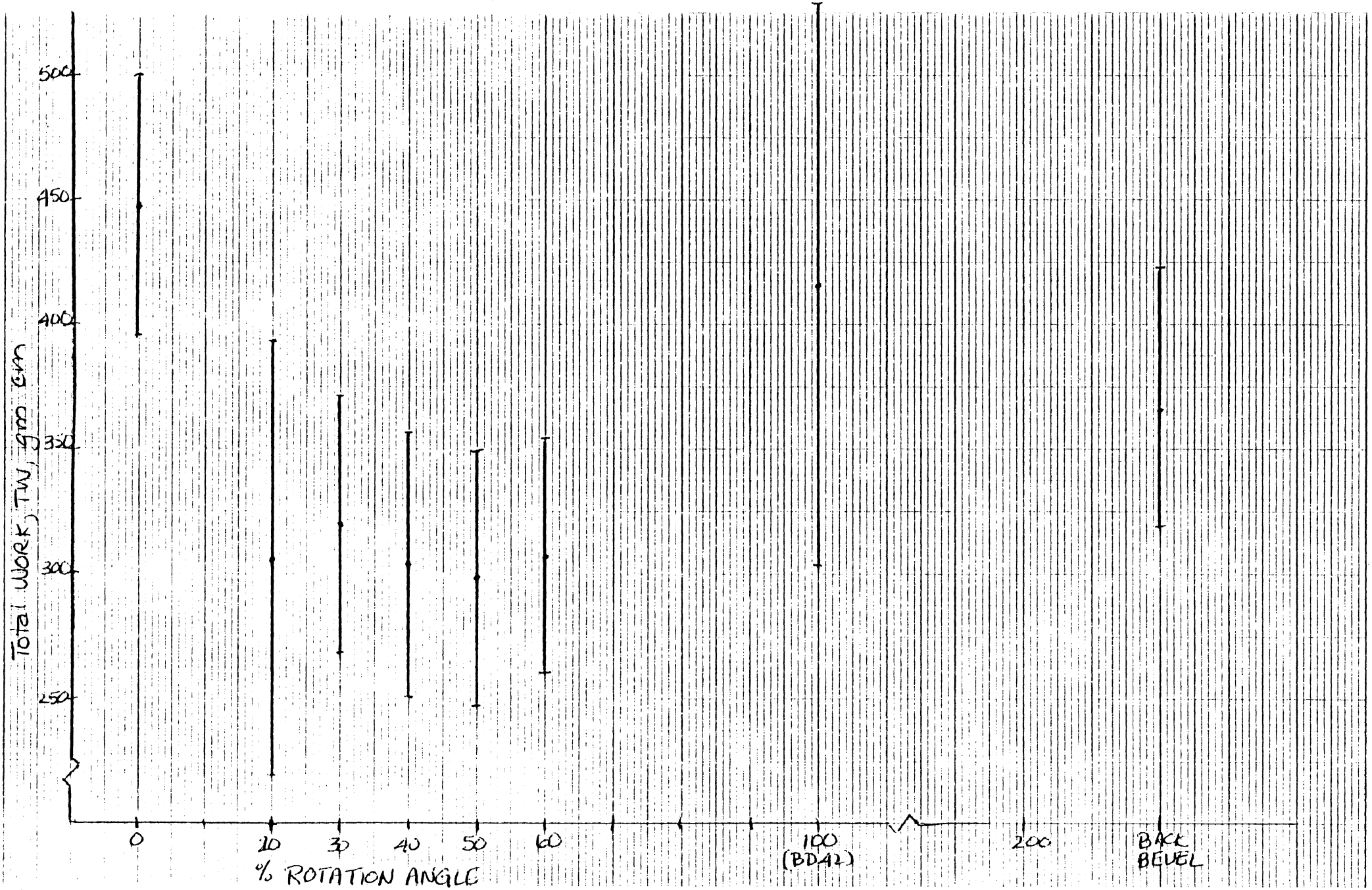


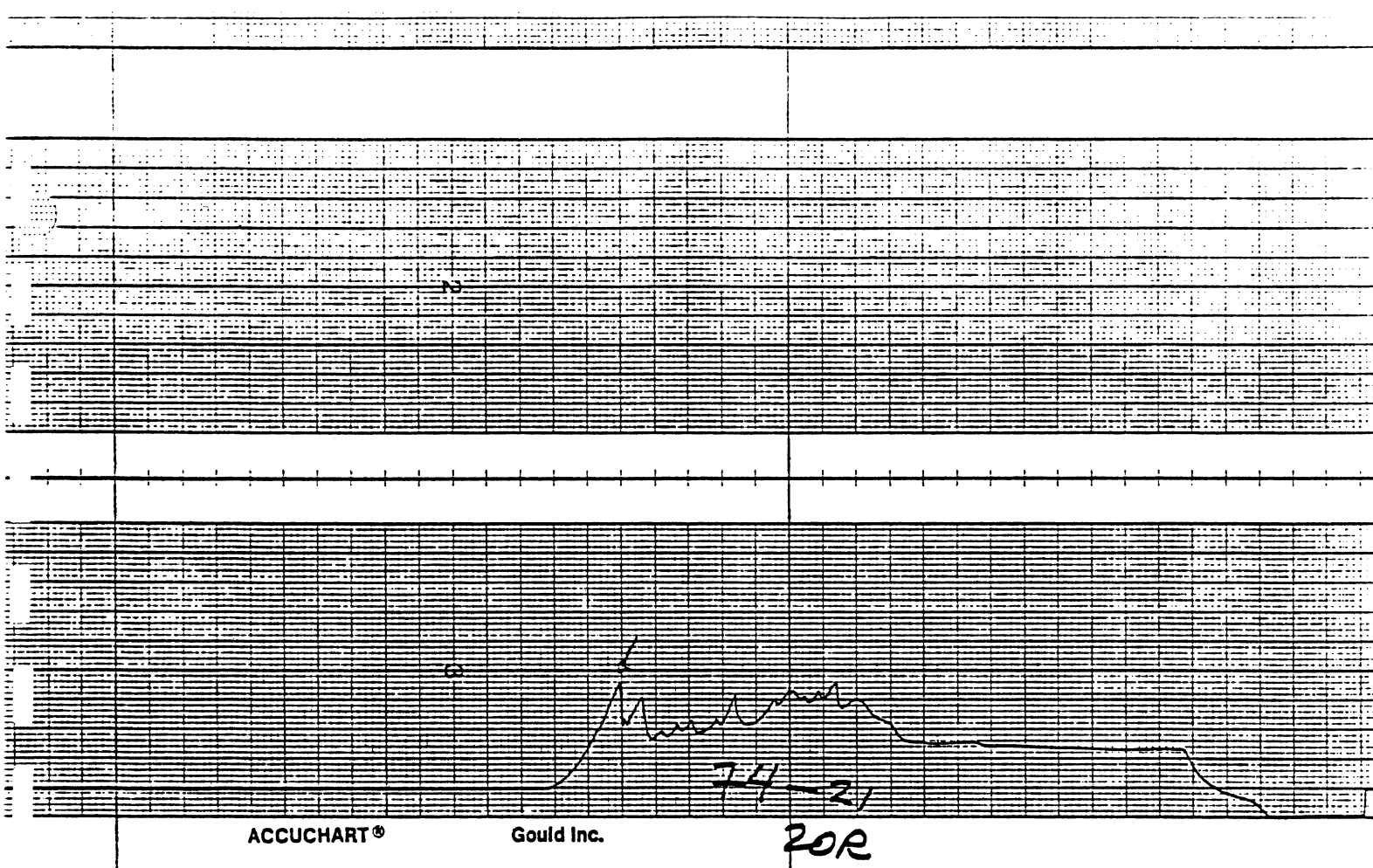
FIGURE 11. TOTAL WORK FOR SIDE BEVEL ROTATION ANGLE NEEDLE GROUPS

APPENDIX B

CHARACTERISTIC FORCE CURVE CHART RECORDINGS FOR EACH NEEDLE TYPE STUDIED

Chart Speed: 100mm/sec

Sensitivity: 50 gram/large division



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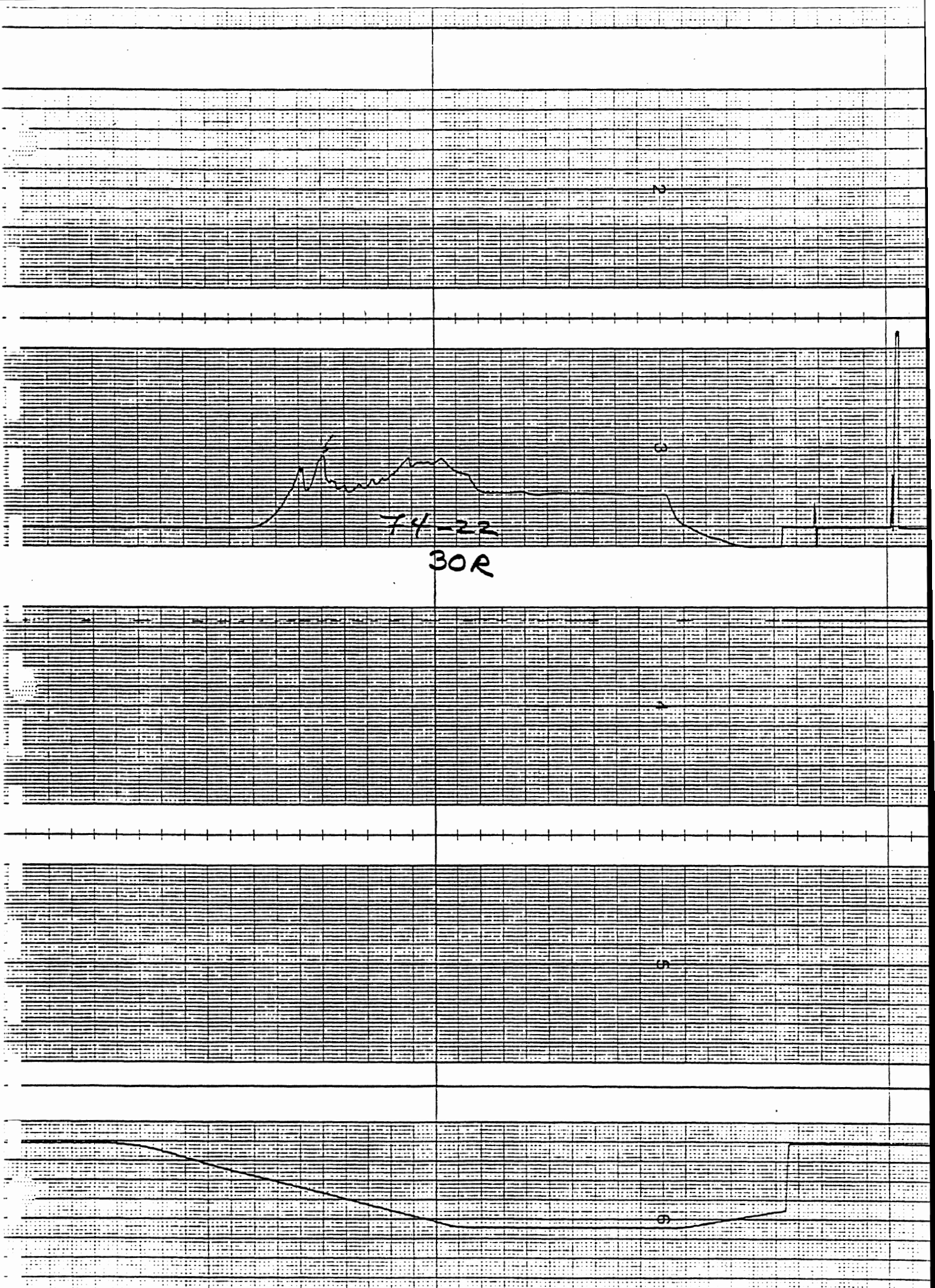
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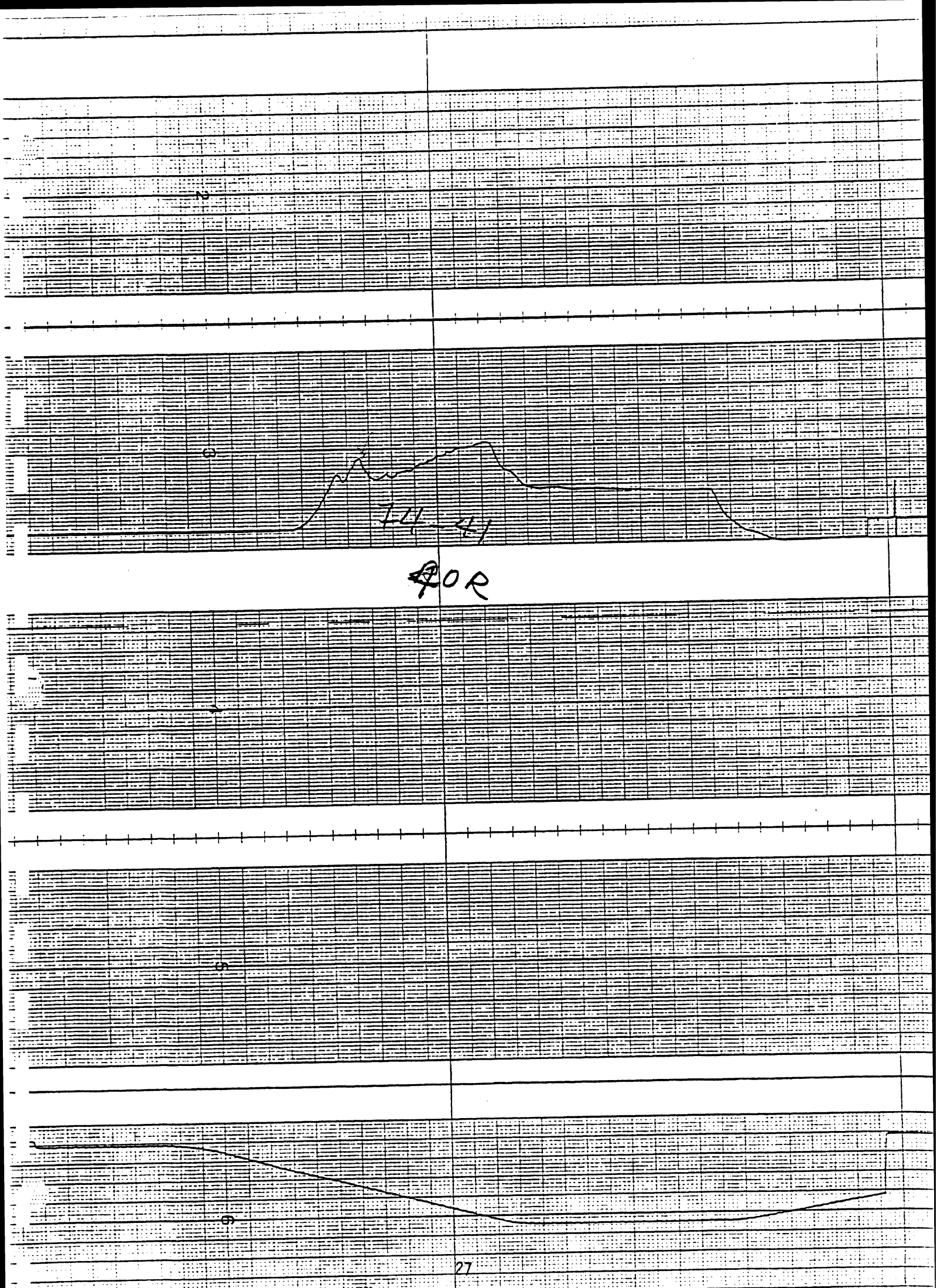
30R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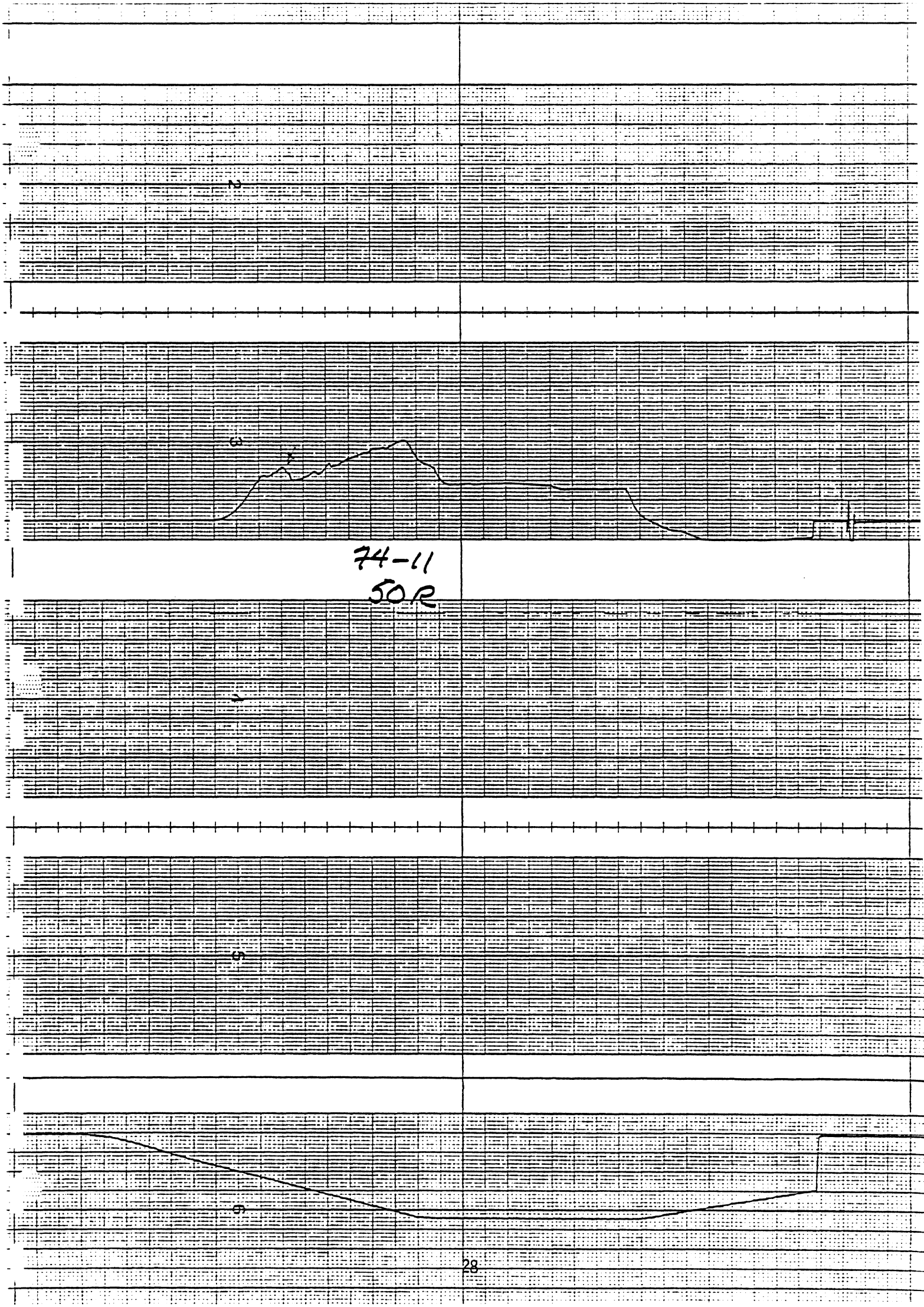
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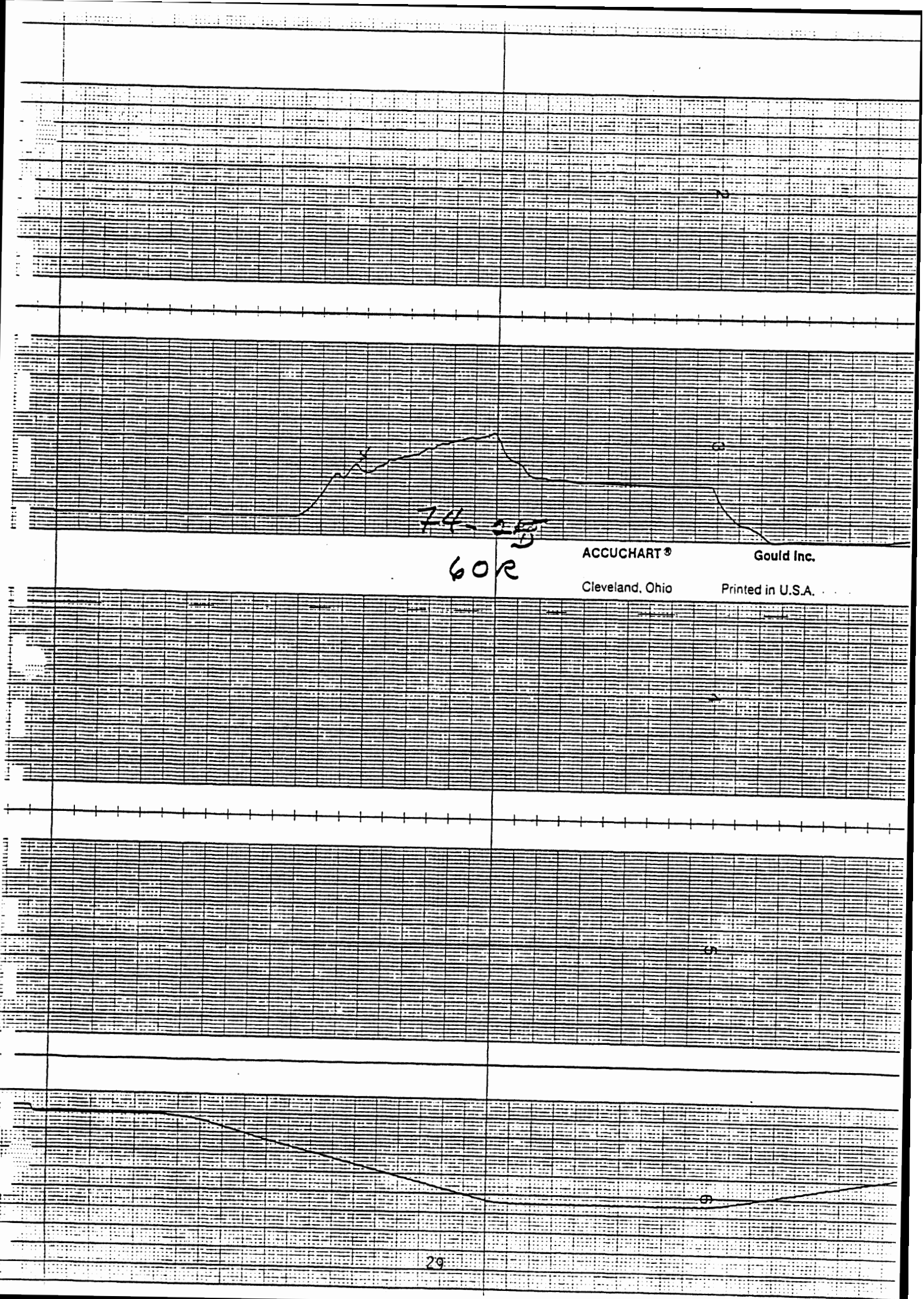
50R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60R
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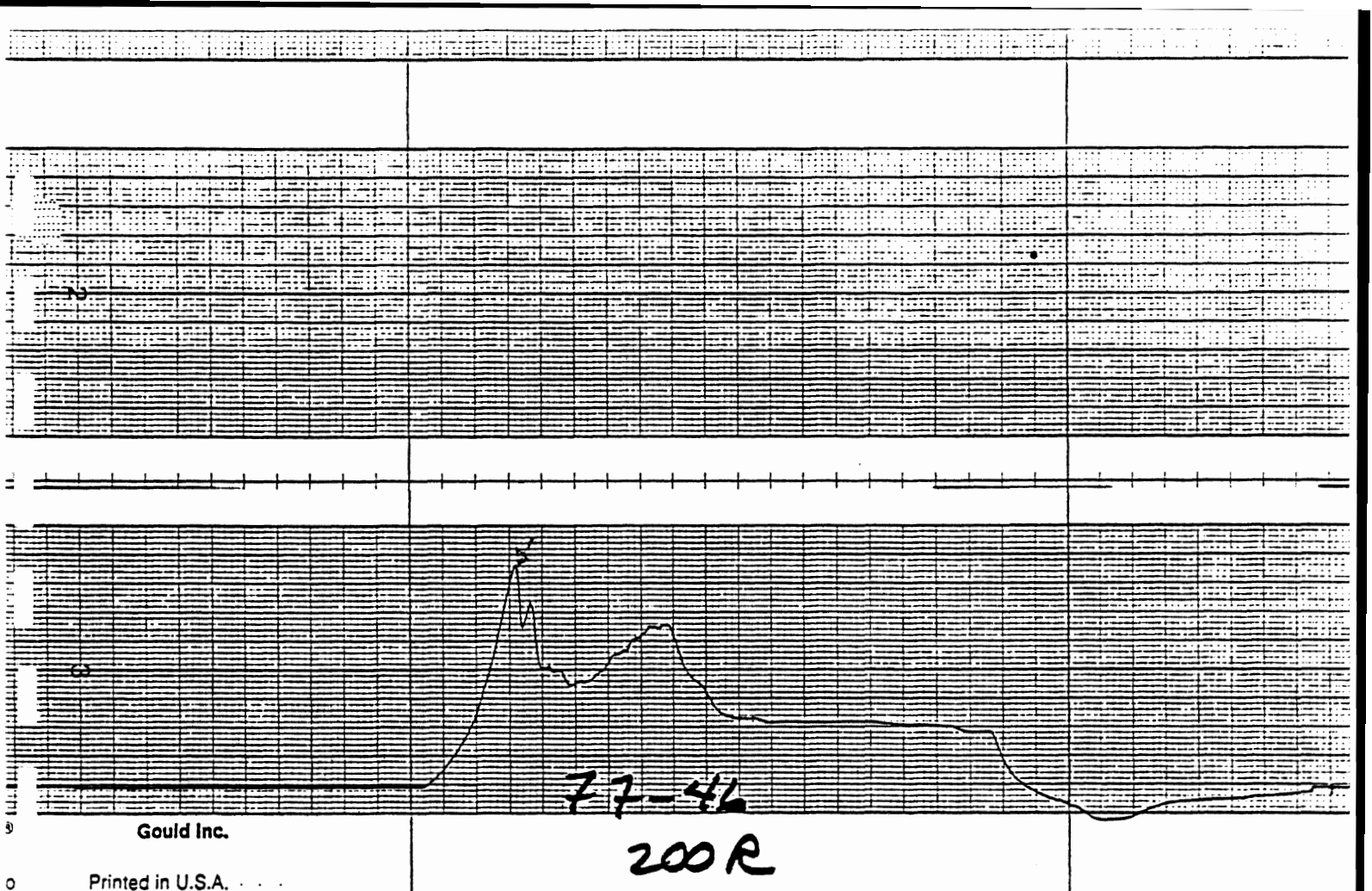

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200 R

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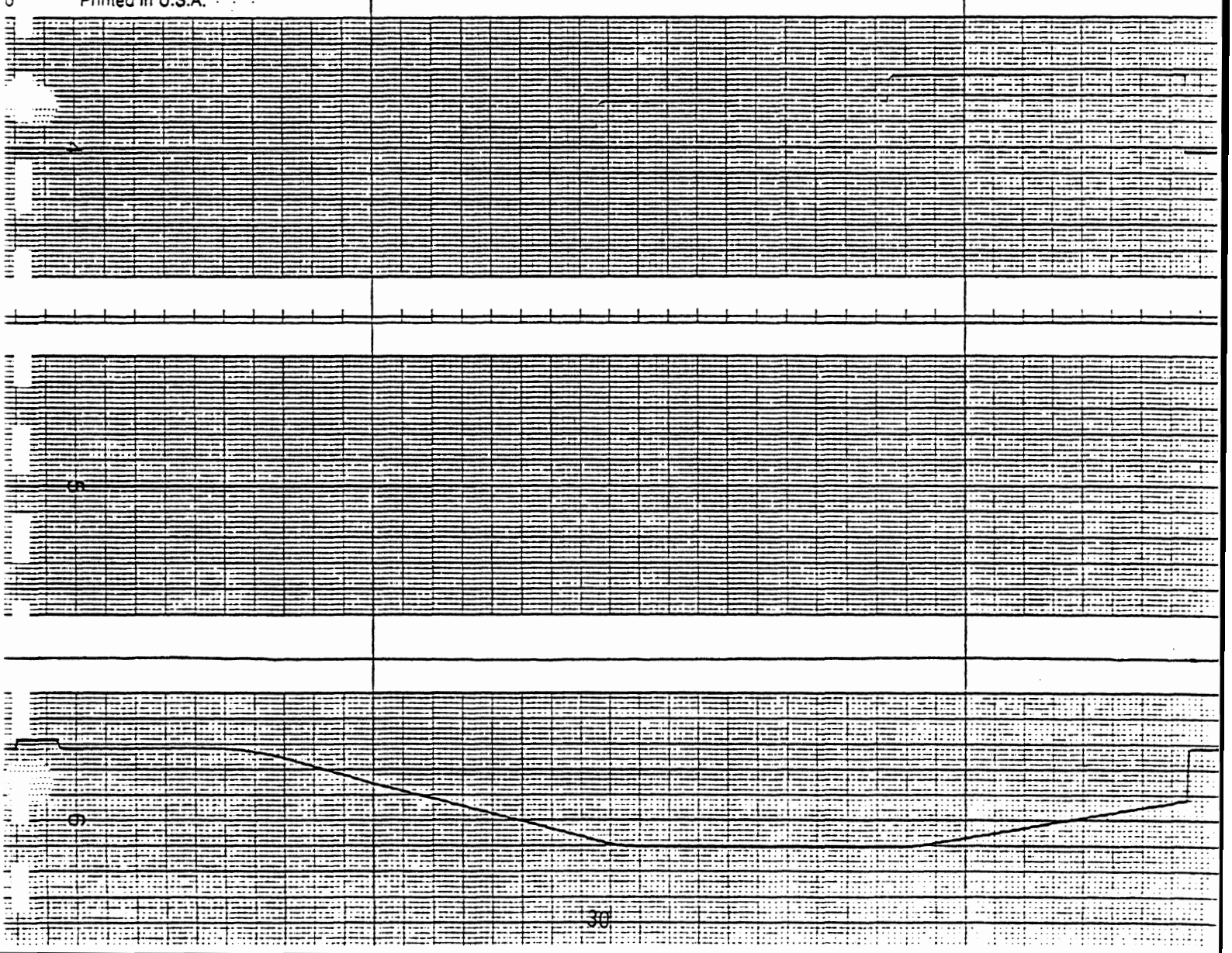

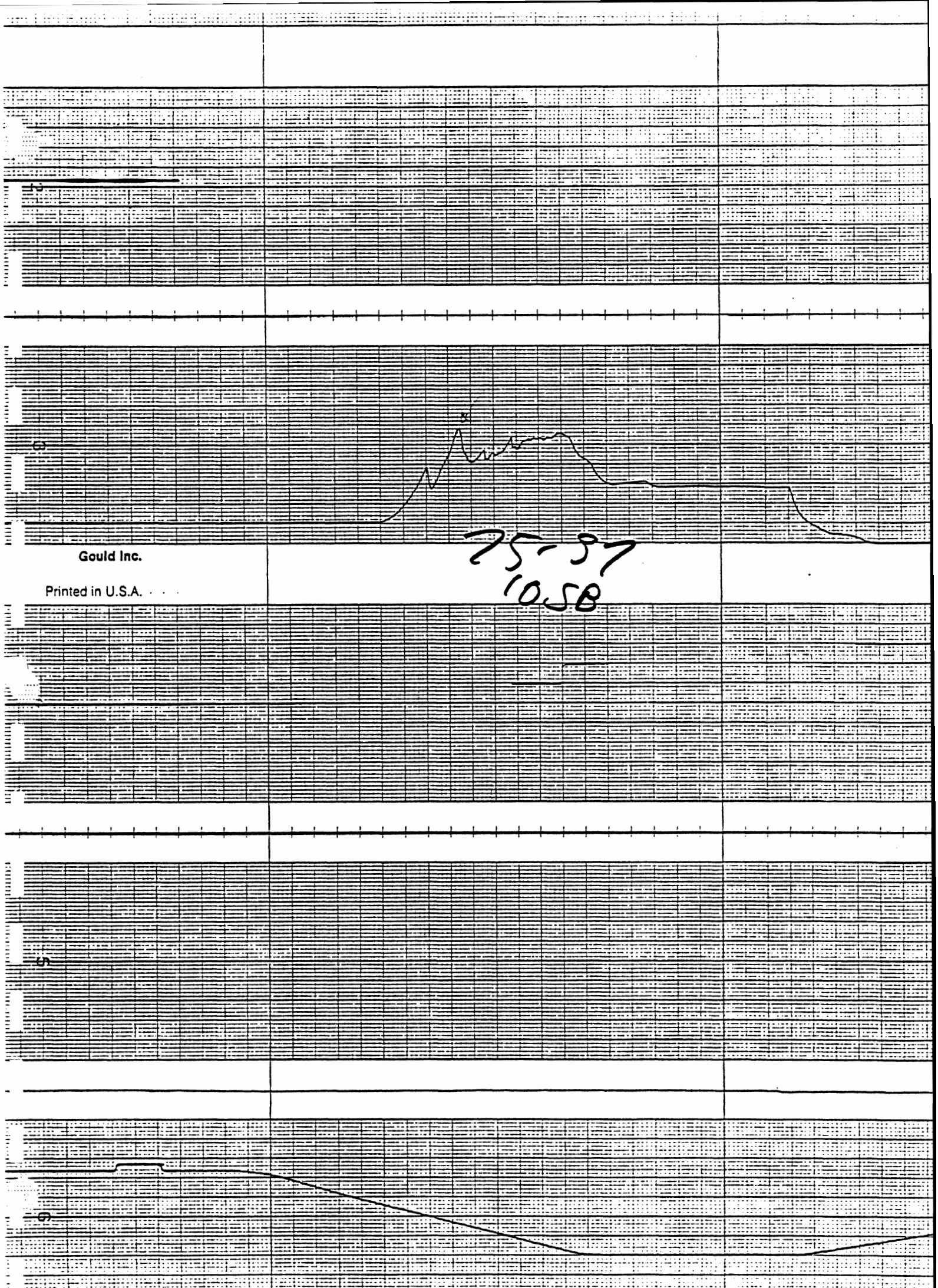
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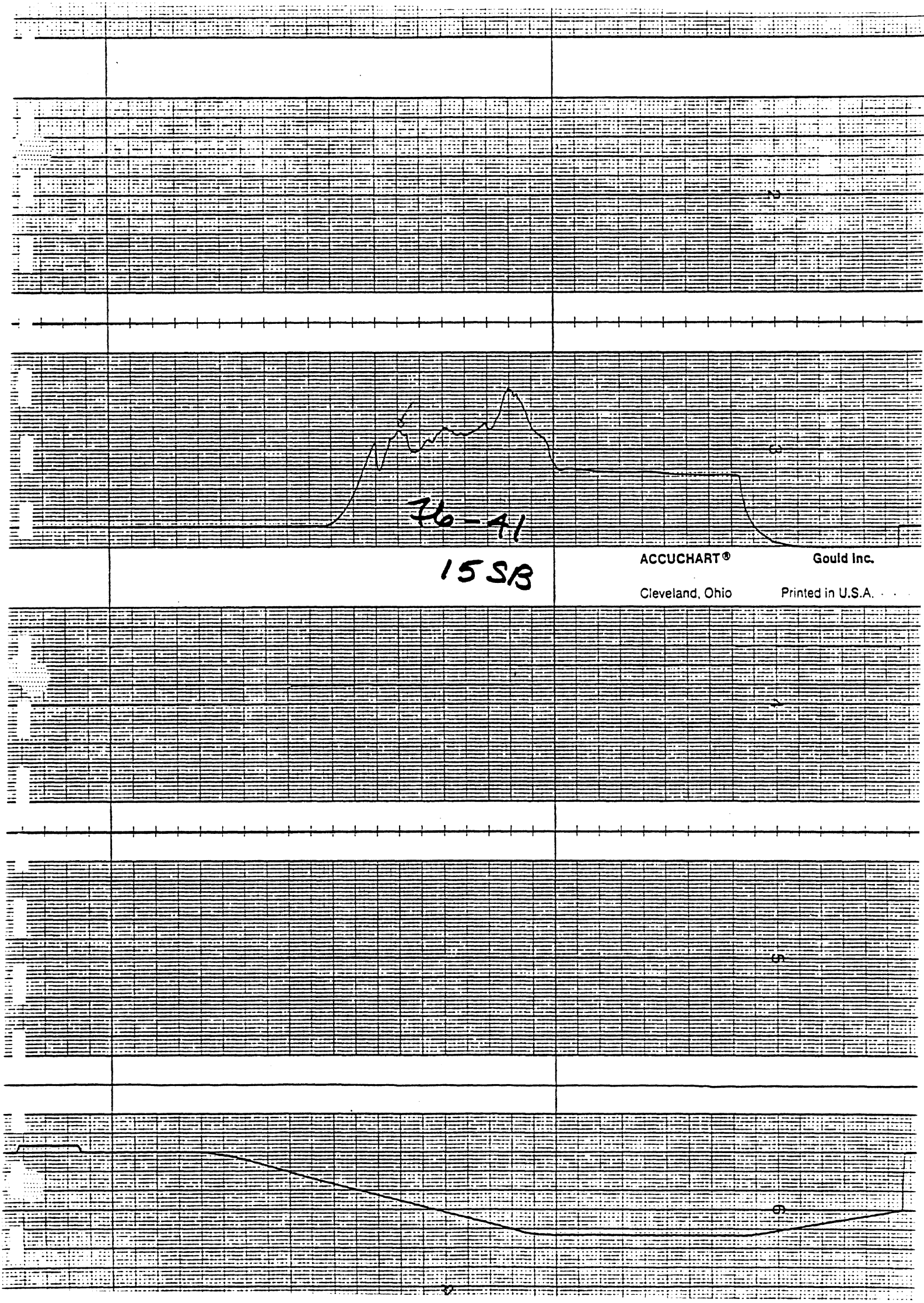
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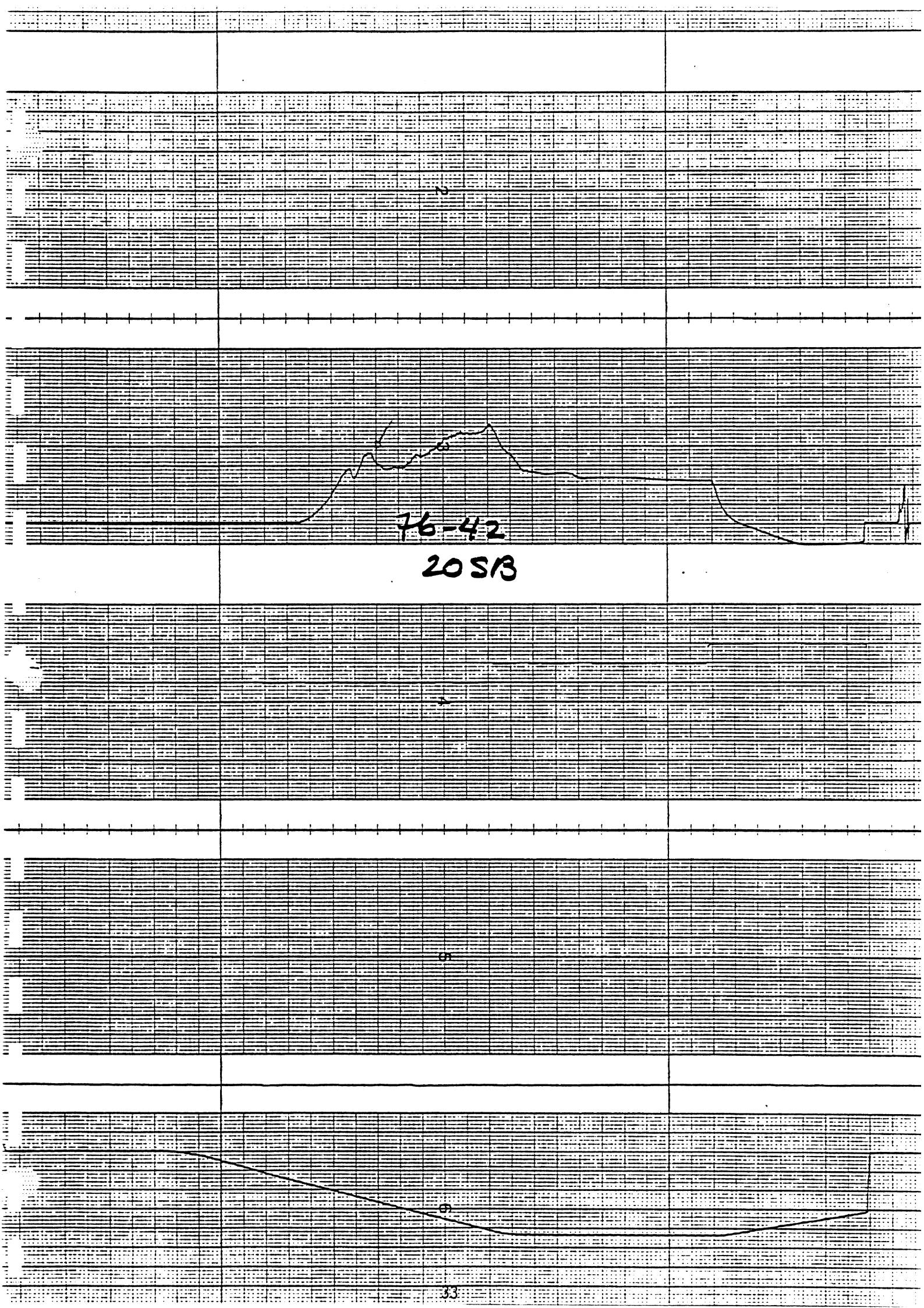
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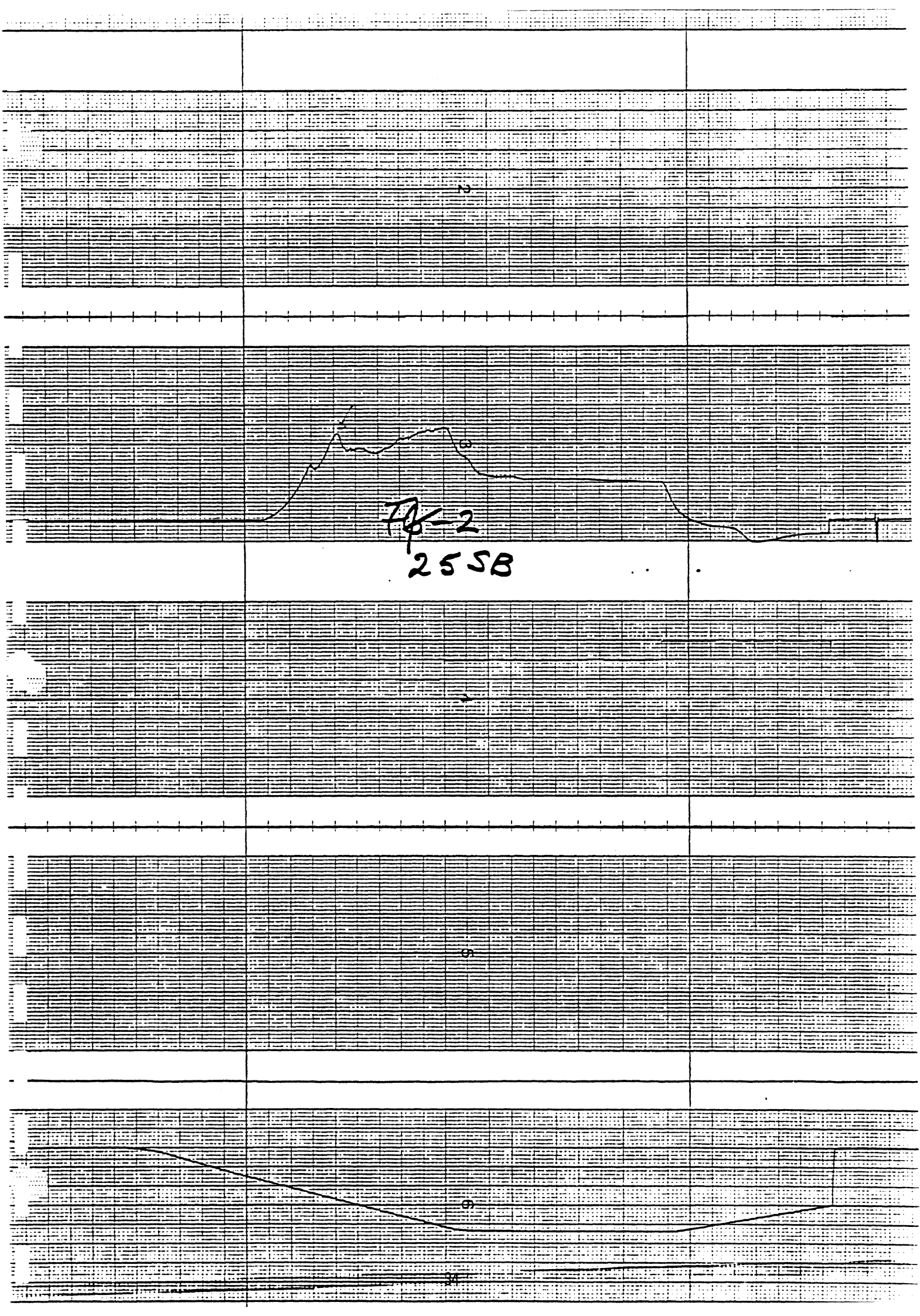
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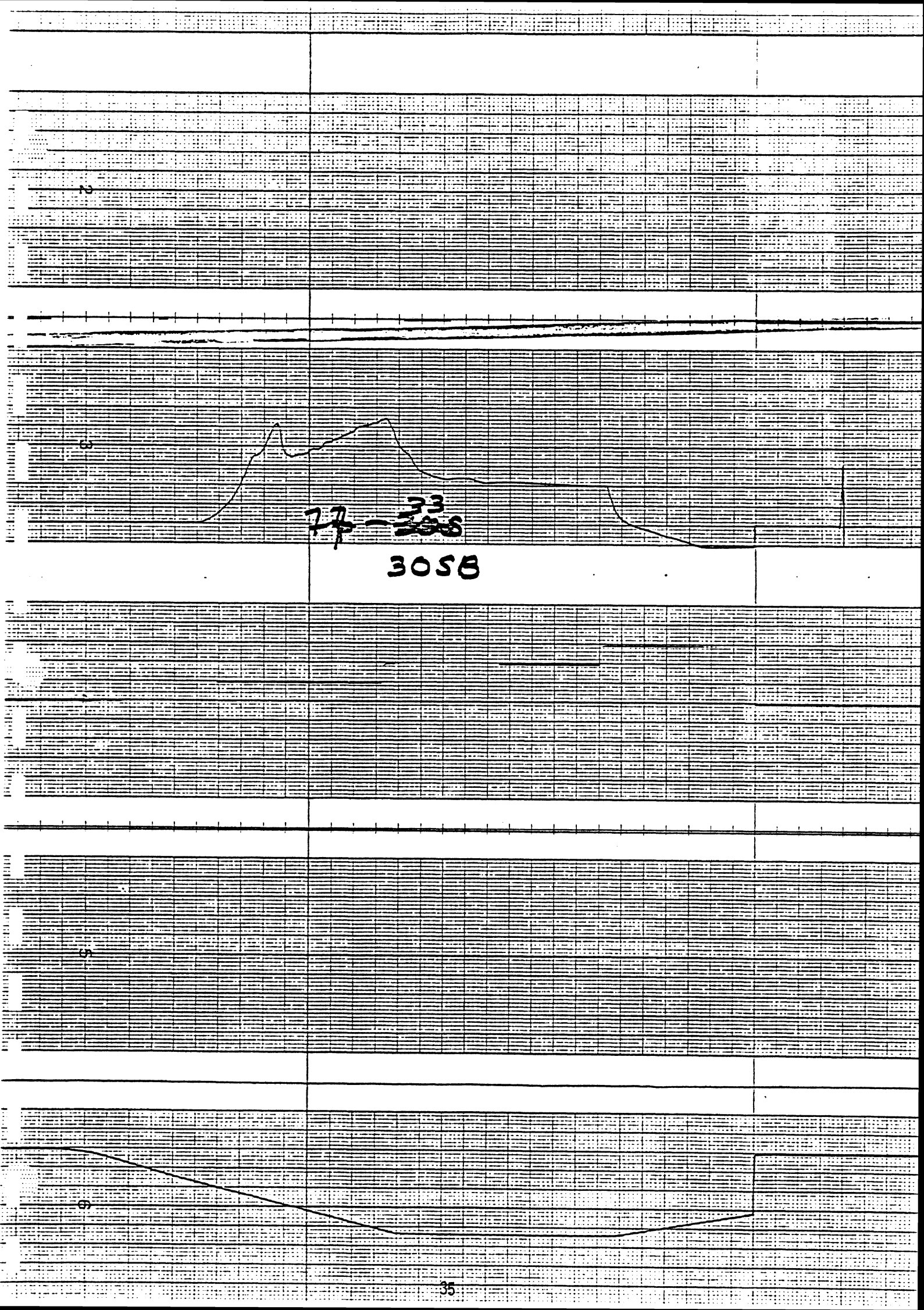
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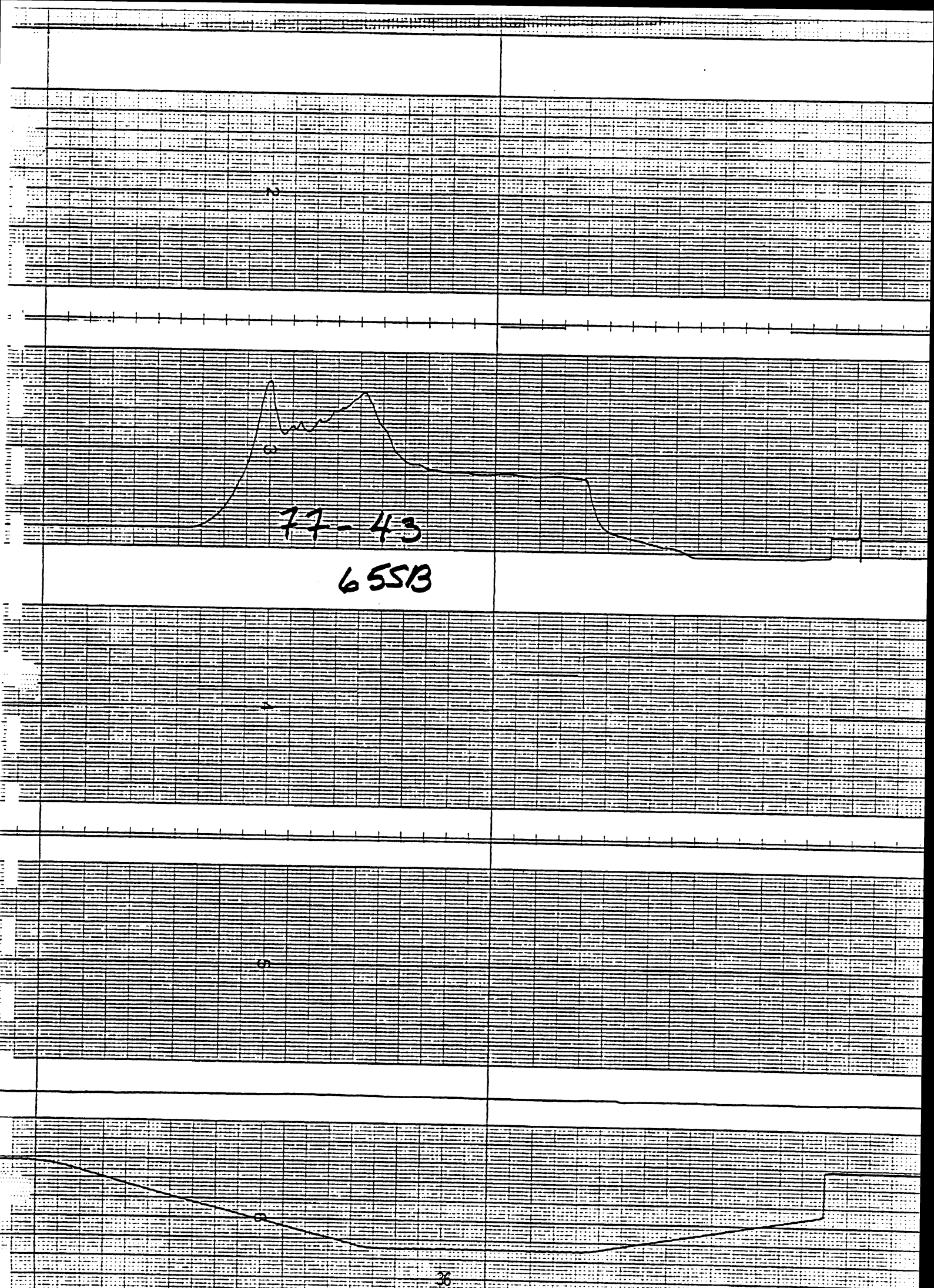
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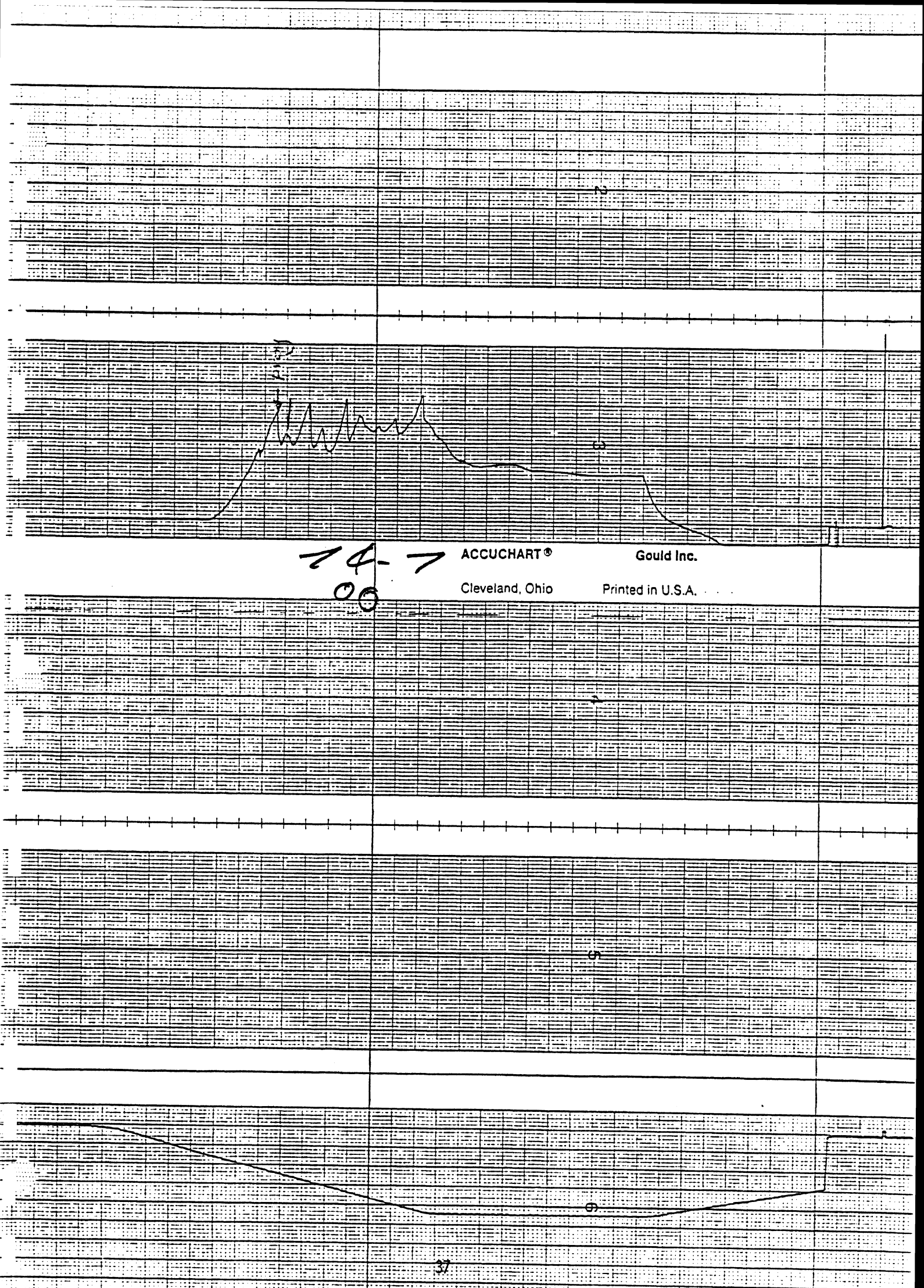
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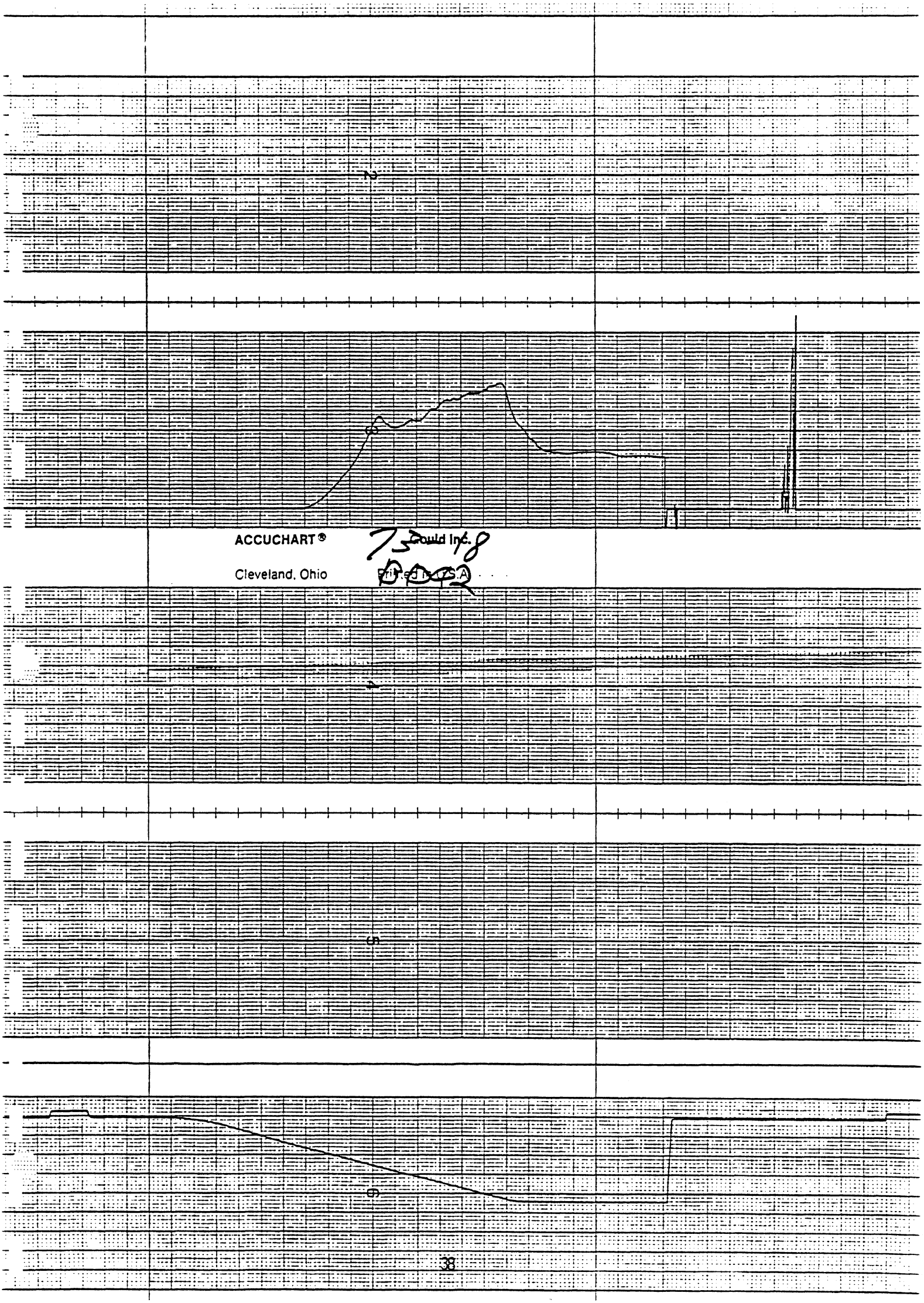
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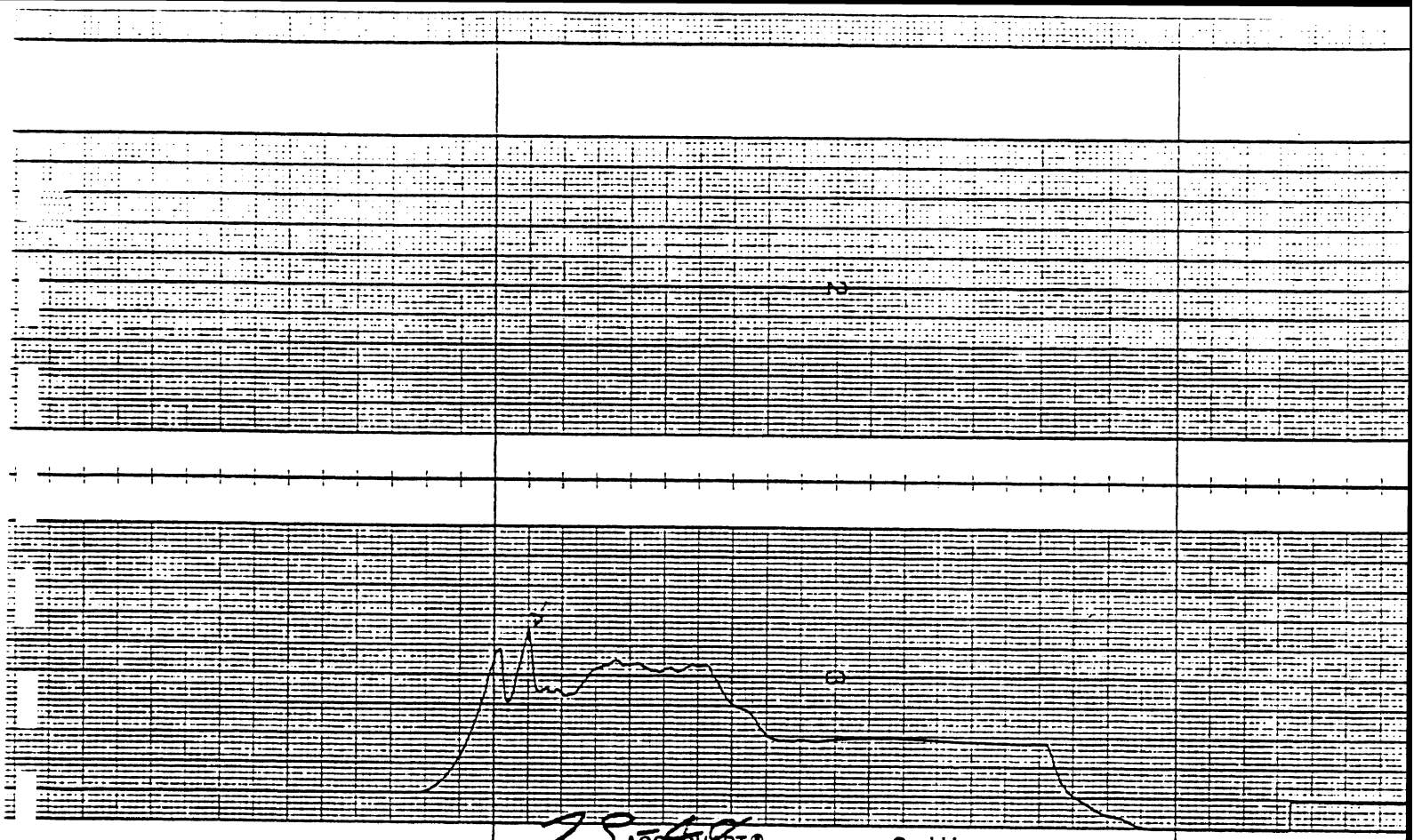
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