



## Certificate of Conformance

Certificate Number: EXMXJ3459X80

Dated Issued: 05/11/2021

The blades were produced in accordance with Exsurco current design specification using only approved manufacturing processes and conforms to all established quality inspection and test criteria.<sup>1</sup>

<b>Product Item Number:</b>	X100593
<b>Item Description:</b>	Pack, Amalgatome SK Head, 5 PC
<b>Item Lot Number:</b>	X-0000000000080
<b>Expiration Date:</b>	2023-04

The blades were manufactured using a validated sterilization process:

<b>STERIS Gamma Process Run ID:</b>	1073-3685A		
<b>Processing Run Date:</b>	10-May-21		
<b>Minimum Specified Dose (kGy):</b>	25.0	<b>Minimum Delivered Dose (kGy):</b>	27.2
<b>Maximum Specified Dose (kGy):</b>	45.0	<b>Maximum Delivered Dose (kGy):</b>	39.8

Exsurco Medical is an ISO 13485:2016 certified and an FDA registered company. Exsurco Medical is committed to a policy of **QUALITY WITHOUT COMPROMISE**.

  
Quality Department

  
Quality Manager

05/13/2021  
Date

05/11/2021  
Date

<sup>1</sup> Manufacturing data filed within the Quality Management System and available onsite.

JOB:	XJ3459	LOT:	X-00000000000080	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

**OPERATION 0002 PULL PARTS/PRINT LABEL**

INITIAL LINE CLEARANCE		CLOCK ID	DATE
		1821	4.26.21

**BOM**

ITEM	MATERIAL DESCRIPTION	QTY.	U/M	SERIAL(S)	LOT(S)	QTY PICKED	DELIVERY LOCATION
X100055	FRAME, MOLDED, AMAL SK	5	PC	N/A	X-45	512	WASH/ASSEMBLY
X100046	PINION ASSEMBLY, AMALGATOME SK	5	PC	N/A	X-27	511	WASH/ASSEMBLY
X100048	RETAINER, PINION, AMAL SK	5	PC	N/A	X-26	530	WASH/ASSEMBLY
X100050	CLIP SPRING	5	PC	N/A	X-27	500	WASH/ASSEMBLY
X100051	RING, BLADE RETAINING, AMAL SK	5	PC	N/A	X-28	575	WASH/ASSEMBLY
X100596	TRAY, STERILIZATION	5	PC	N/A	X-14	500	ASSEMBLY
X100612	POUCH, STERILIZATION, AMAL SK	5	PC	N/A	X-15	571 +12	ASSEMBLY
X100608	BOX, 5 PC AMALGATOME SK HEADS	1	PC	N/A	X-07	100	ASSEMBLY
X100613	LABEL, 5 PC BOX, AMAL SK	1	PC	N/A	X-09	100	ASSEMBLY
X100303 *	LABEL, LOT CONTROL	6	PC	N/A	N/A	SEE PAGE 2	ASSEMBLY
X100391	LABEL, 2" X 1"	1	PC	N/A	X-17	AS NEEDED	ASSEMBLY
X101312	INK, ZEBRA PREMIUM 51000 RESIN, BLACK	0.0001	PC	N/A	X-11	AS NEEDED	ASSEMBLY
X100595	Blade, Stainless Steel, Amalgatome SK	5	PC	N/A	X-52/X-57/X-58/X-59	142/31/09/229	WASH/ASSEMBLY
X100787	Mineral Oil, Sterile	0.0001	ML	N/A	X-05	AS NEEDED	ASSEMBLY

JK  
05-03-21

\* DENOTES PHANTOM BUILD

CLOCK ID	DATE
1817	04-30-21

JOB:	X13459	LOT:	X-00000000000080	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

**OPERATION 0002 PULL PARTS/PRINT LABEL**

OPERATION	WORK STATION	ITEM NUMBER	REVISION	DESCRIPTION	CLOCK ID	DATE
0002	WAREHOUSE	X100303	F	LABEL, LOT CONTROL	1831	4.26.21

NOTE: EXPIRATION DATE IS TWO (2) YEARS FROM JOB ISSUE DATE.

ITEM #: X100593  
**LOT** X-000000000000080  
 2023-04  
 STERILE R  
 EXSURCO LOT CONTROL LABEL

FIRST

ITEM #: X100593  
**LOT** X-000000000000080  
 2023-04  
 STERILE R  
 EXSURCO LOT CONTROL LABEL

LAST

**OPERATION 0002 QC VERIFICATION**

OPERATION	WORK STATION	DOCUMENT/GAGE	REVISION	DESCRIPTION	FREQUENCY	GAGE USED	PASS/FAIL	CLOCK ID	DATE
0002	WAREHOUSE	SOP-4_00026_WI-G13	02	E-0013 VISUAL INSPECTION GUIDELINES	FIRST/LAST	E-0013	(PASS) / FAIL	1940	04/26/21

QTY. ACCEPTED	600
QTY. REJECTED	0
MRR#	N/A

FINAL LINE CLEARANCE	CLOCK ID	DATE
	1847	04-30-21



JOB:	X13459	LOT:	X-00000000000080	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

**OPERATION 0010 WASH**

INITIAL LINE CLEARANCE	CLOCK ID	DATE
	1831	4-27-21

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
0010	WASH	SOP-4_00026_WI-SK03	01	X100593-AMALGATOME SK ULTRASONIC WASH	1031	4-27-21

**BATCH RESULTS TANK #1: Conductivity (µS)**

1	961.2	4	939.9	7	934.1	10	934.1	13	933.7	16	940.8	19	940.3	22	28
2	959.3	5	937.3	8	933.8	11	932.1	14	947.9	17	936.6	20	932.3	23	29
3	944.7	6	945.7	9	929.5	12	936.2	15	936.3	18	943.0	21	936.2	24	30

**BATCH RESULTS TANK #2: Resistivity (Ω)**

1	1.0M	4	192.3k	7	272.4k	10	239.8k	13	200.1k	16	235.9k	19	229.2k	22	28
2	324.4k	5	218.5k	8	206.4k	11	207.4k	14	301.1k	17	215.7k	20	305.8k	23	29
3	209.8k	6	205.6k	9	229.5k	12	269.1k	15	252.2k	18	216.3k	21	251.0k	24	30

**BATCH RESULTS TANK #3: Resistivity (Ω)**

1	3.2M	4	3.3M	7	3.6M	10	3.3M	13	3.4M	16	3.1M	19	3.2M	22	28
2	3.3M	5	4.0M	8	3.7M	11	3.1M	14	3.1M	17	3.2M	20	3.3M	23	29
3	3.0M	6	3.4M	9	3.8M	12	3.1M	15	3.0M	18	3.3M	21	3.3M	24	30

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR#	NA

FINAL LINE CLEARANCE	CLOCK ID	DATE
	1847	04-27-21

JOB:	XJ3459	LOT:	X-000000000000880	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

**OPERATION 0020 ASSEMBLE**

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
0020	ASSEMBLY	SOP-4_00026_WI-SK15	01	X100593-PACK, AMALGATOME SK HEAD, 5 PC ASSEMBLY	1831	4.28.21

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR#	NA

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
					1831	4.29.21

JOB:	X13459	LOT:	X-00000000000080	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

**OPERATION 0025 ASSEMBLE**

INITIAL LINE CLEARANCE		CLOCK ID	DATE
		1831	4.27.21

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
0025	CLEANROOM	SOP-4_00026_WI-SK16	02	X100593-PACK, AMALGATOME SK HEAD, 5 PC RUN TEST	1831	4.27.21

FINAL LINE CLEARANCE		CLOCK ID	DATE
		1831	4.30.21

QTY. ACCEPTED	100
QTY. REJECTED	NA
MRR#	

JOB:	X13459	LOT:	X-00000000000080	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

**OPERATION 0030 PACK**

INITIAL LINE CLEARANCE	CLOCK ID	DATE
	1847	04-29-21

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
0030	CLEANROOM	SOP-4_00026_WI-SK04	04	X100593-AMALGATOME SK STERILE PACKAGING	1847	04-29-21

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR #	NA

FINAL LINE CLEARANCE	CLOCK ID	DATE
	1847	04-30-21

JOB:	X13459	LOT:	X-0000000000080	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

**OPERATION 0030 IN PROCESS INSPECTION**

INITIAL LINE CLEARANCE			CLOCK ID	DATE
			1940	04/29/2021

OPERATION	WORK STATION	DOCUMENT/GAGE	REVISION	DESCRIPTION	FREQUENCY	GAGE USED	PASS/FAIL	CLOCK ID	DATE
0030	QUALITY	SOP-4_00026_WI-G13	02	E-0013 VISUAL INSPECTION GUIDELINES / SEAL NOT TEAR	100%	E-0013	(PASS) / FAIL	1940	04/30/21
0030-A	QUALITY	SOP-4_00026_WI-G11	01	SEAL STRENGTH FOR MEDICAL PACKAGING- /1-LB MIN PEEL	FIRST-LAST 1/100	E-0044	N/A	N/A	N/A
0030-B	QUALITY	SOP-4_00026_WI-G12	01	DYE PENETRATION TEST FOR MEDICAL PACKAGING/ NO SEAL LEAKS	FIRST-LAST 1/100	E-0036	N/A	N/A	N/A

RESULTS 0030-A		RESULTS 0030-B	
FREQUENCY	RESULTS	FREQUENCY	RESULTS
FIRST	(PASS) FAIL	FIRST	(PASS) FAIL
50-100	(PASS) FAIL	50-100	(PASS) FAIL
100-200	(PASS) FAIL	100-200	(PASS) FAIL
150-300	(PASS) FAIL	150-300	(PASS) FAIL
200-400	(PASS) FAIL	200-400	(PASS) FAIL
250-500	(PASS) FAIL	250-500	(PASS) FAIL
300-600	(PASS) FAIL	300-600	(PASS) FAIL
350-700	(PASS) FAIL	350-700	(PASS) FAIL
400-800	(PASS) FAIL	400-800	(PASS) FAIL
450-900	(PASS) FAIL	450-900	(PASS) FAIL
NA 1000	NA PASS/FAIL	NA 1000	NA PASS/FAIL
LAST	(PASS) FAIL	LAST	(PASS) FAIL

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR #	N/A

RESULTS RECORDED BY:	CLOCK ID	DATE
	1940	04/30/2021

FINAL LINE CLEARANCE			CLOCK ID	DATE
			1940	04/30/2021

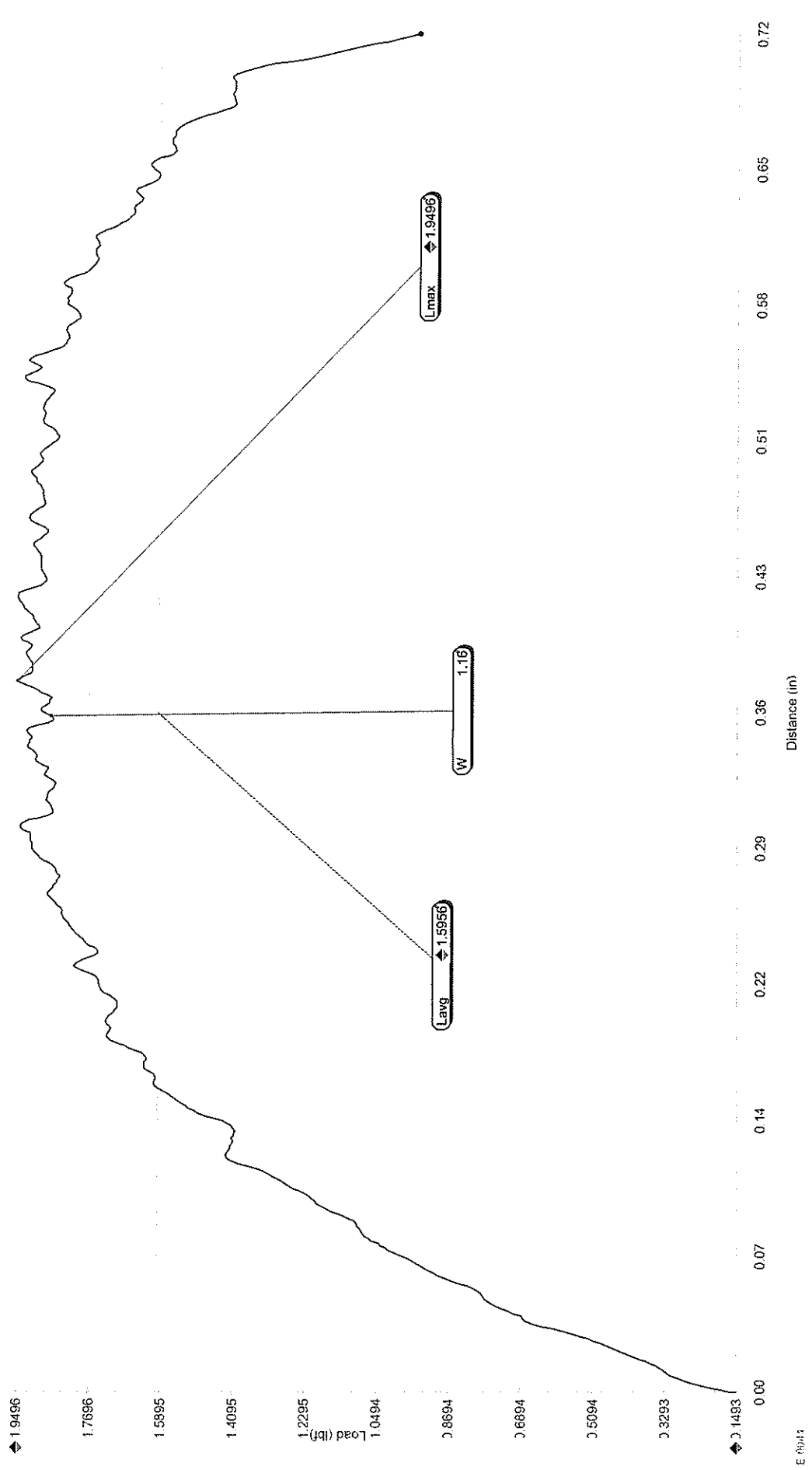






Run	Date	Operator	JOB	SAMPLE#	Location	L <sub>avg</sub>	L <sub>max</sub>	W	Comment
1175	4/29/21	1940	XJ3459	FIRST	EXSURCO	1.5956	1.9496	1.16	

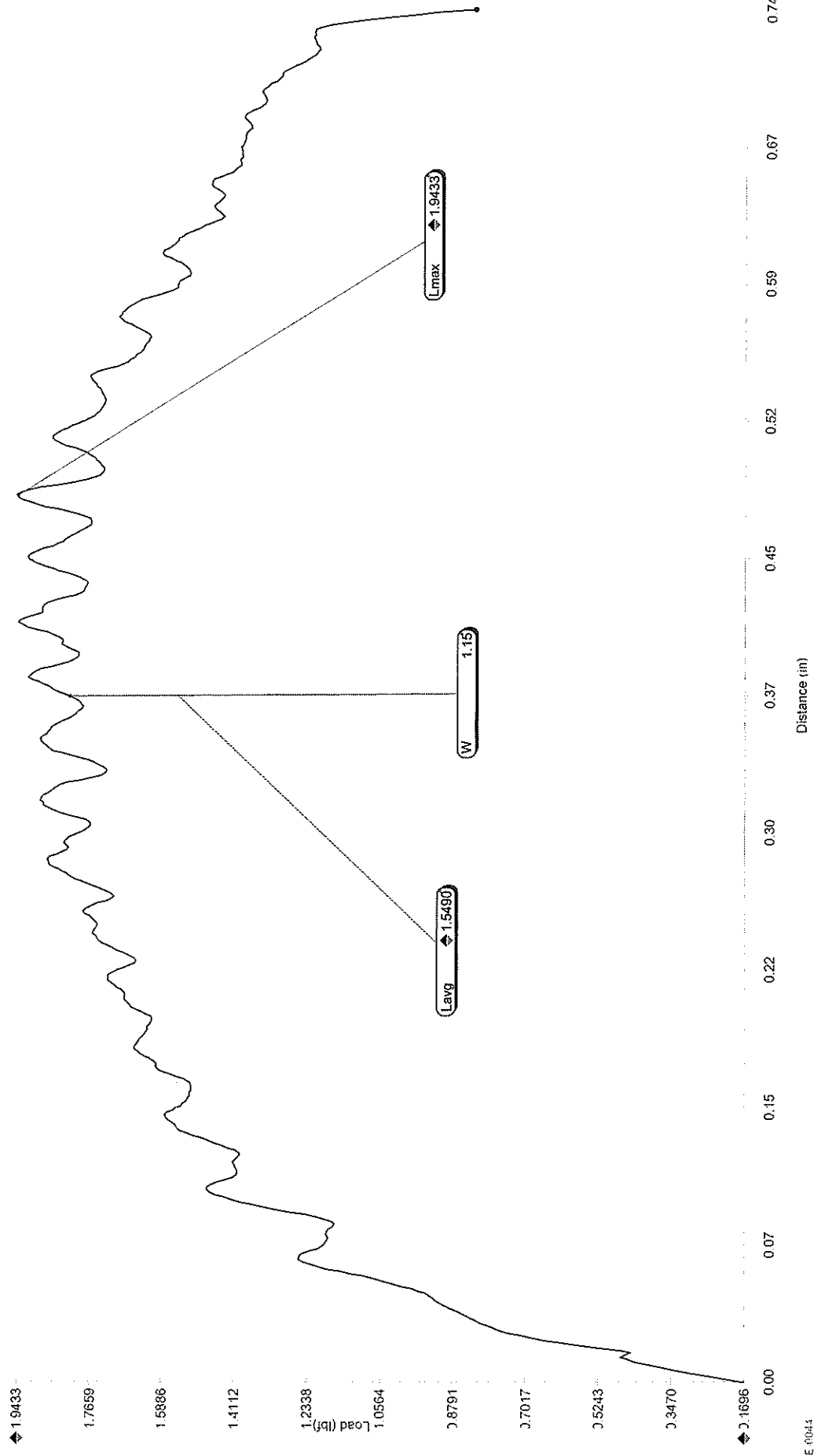
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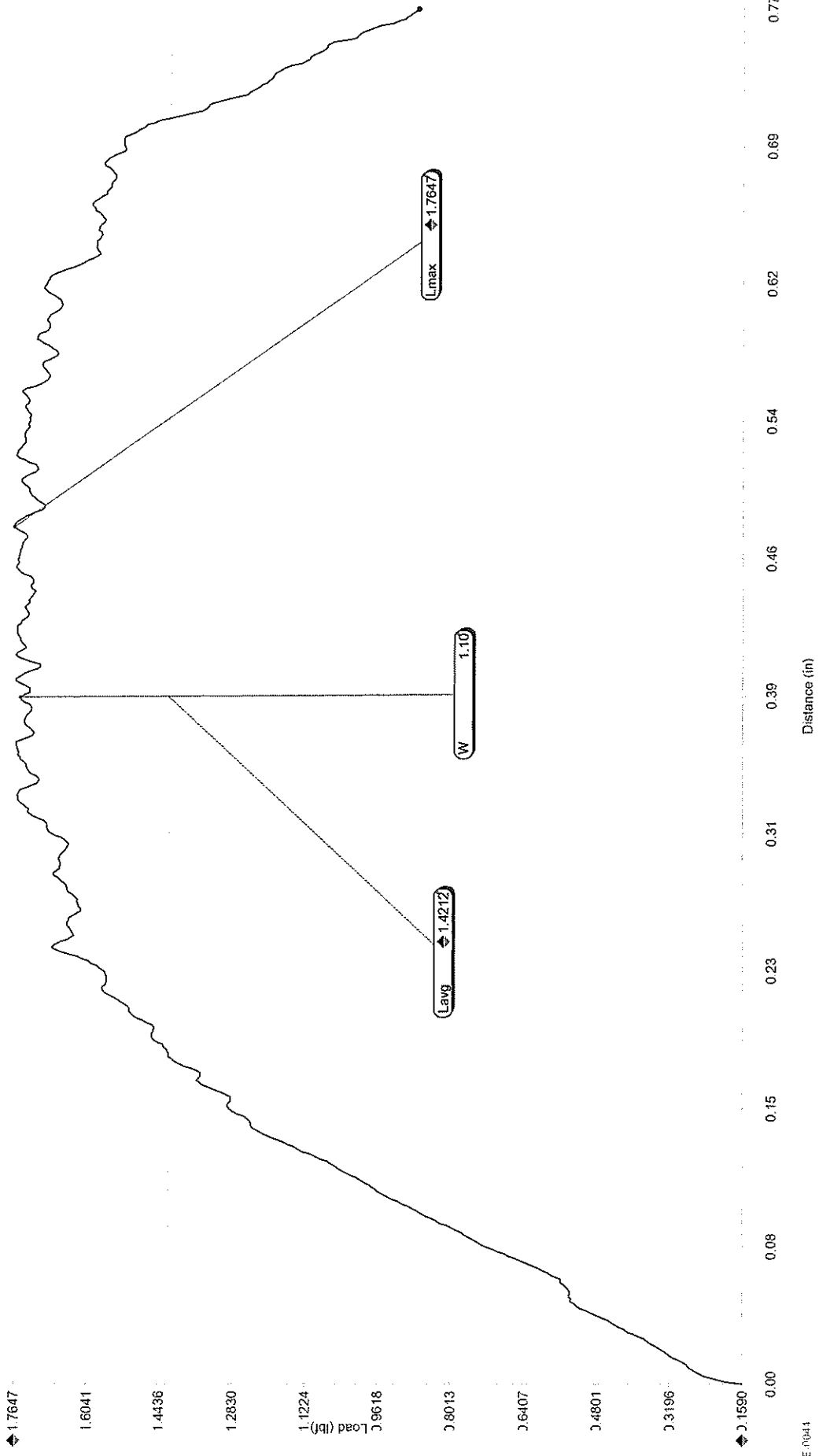
Run	Date	Operator	JOB	SAMPLE#	Location	L <sub>avg</sub>	L <sub>max</sub>	W	Comment
1176	4/29/21	1940	XJ3459	50	EXSURCO	1.5490	1.9433	1.15	

15:34:49 4/30/2021



Run	Date	Operator	JOB	SAMPLE#	Location	L <sub>max</sub>	L <sub>avg</sub>	W	Comment
117	4/30/21	1940	XJ3459	100	EXSURCO	1.7647	1.4212	1.10	

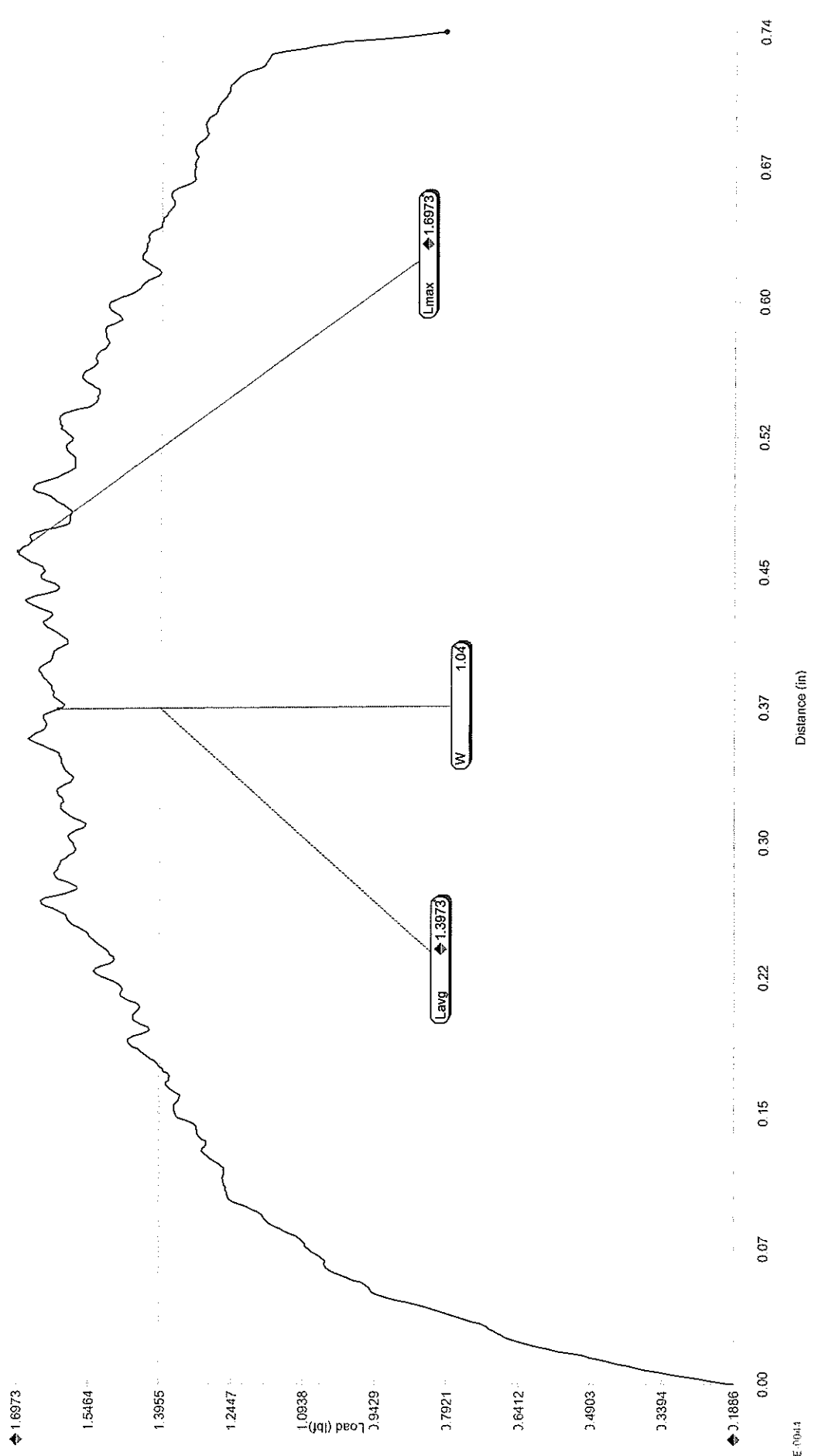
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Run	Date	Operator	JOB	SAMPLE#	Location	L <sub>max</sub>	L <sub>avg</sub>	W	Comment
1186	4/30/21	1940	XJ3459	150	EXSURCO	1.6973	1.3973	1.04	

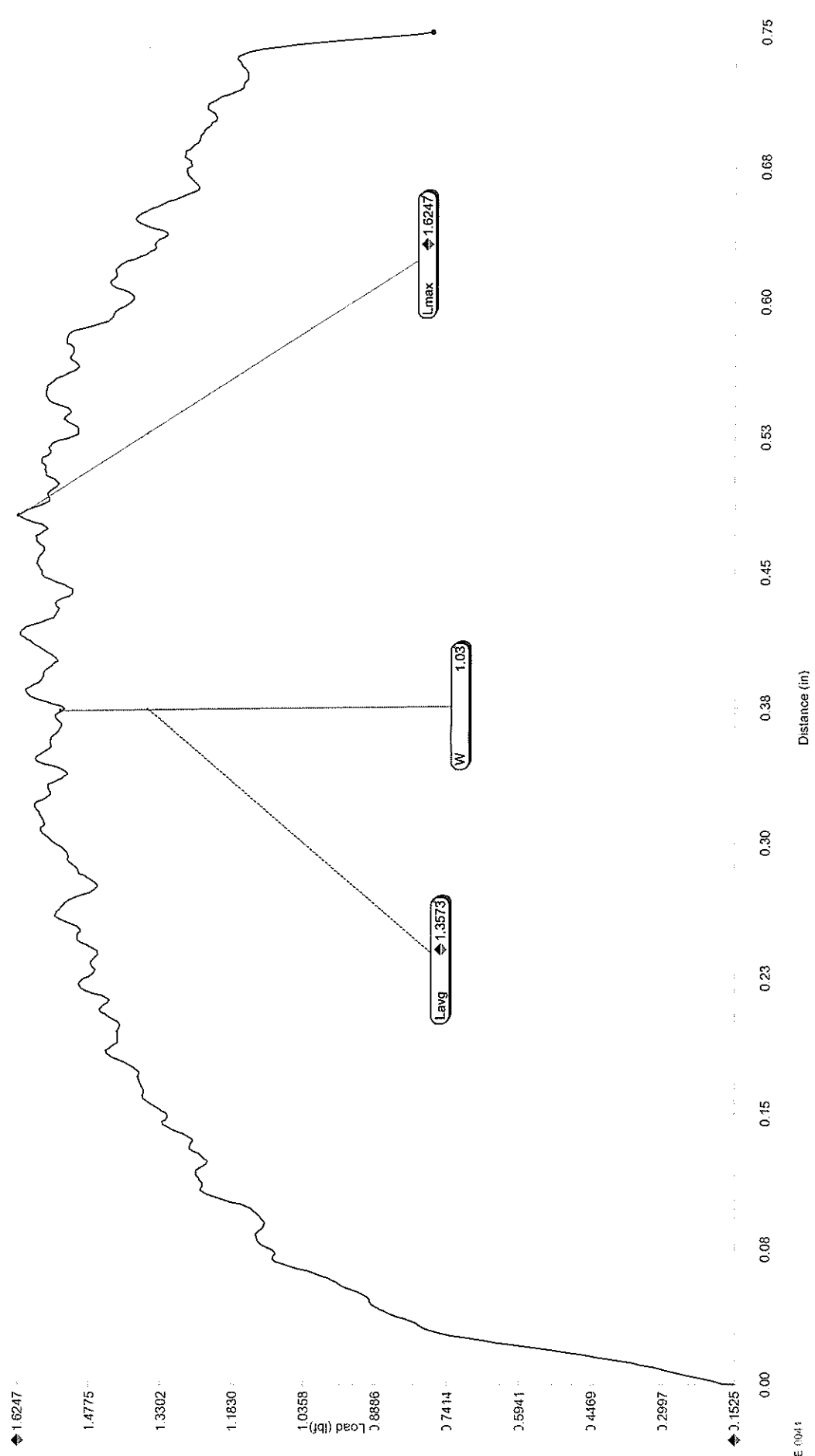
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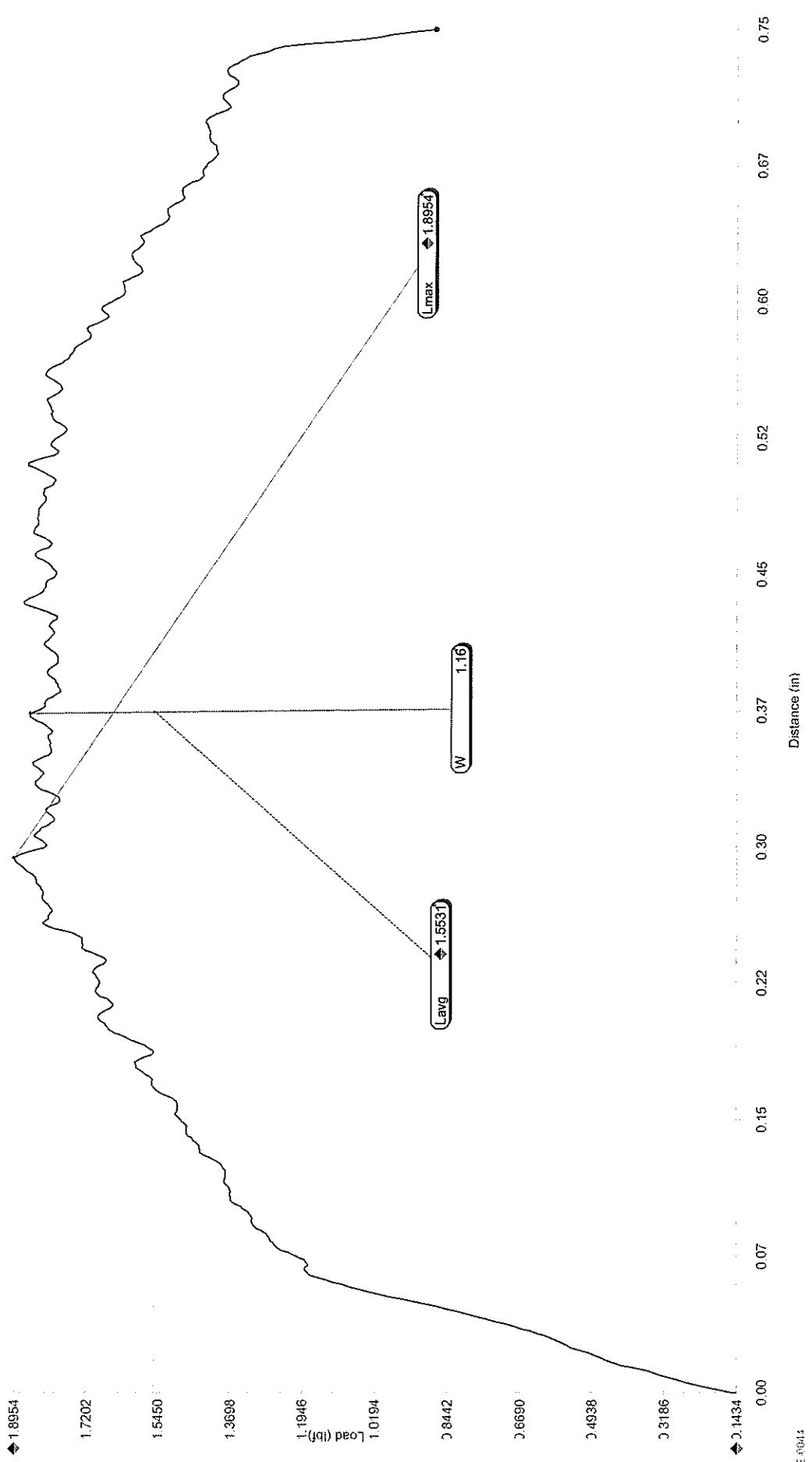
Run	Date	Operator	JOB	SAMPLE#	Location	L <sub>max</sub>	L <sub>avg</sub>	W	Comment
118	4/30/21	1940	XJ3469	200	EXSURCO	1.6247	1.3573	1.03	

15:35 14 4:00:00:001



Run	Date	Operator	JOB	SAMPLE#	Location	L <sub>max</sub>	L <sub>avg</sub>	W	Comment
1184	4/30/21	1940	XJ3459	250	EXSURCO	1.8954	1.5531	1.16	

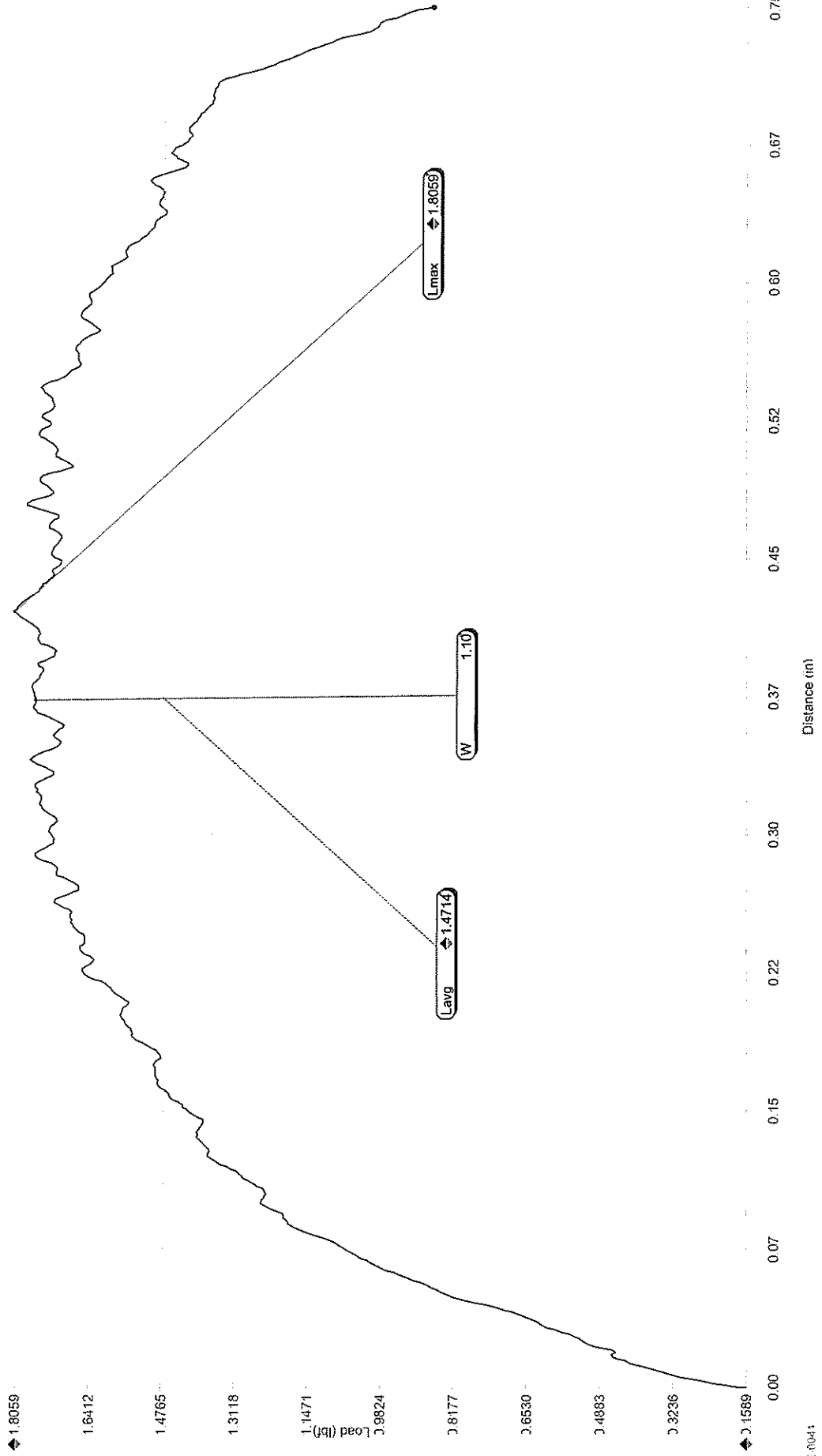
15:35:22 4/30/2021





Run	Date	Operator	JOB	SAMPLE#	Location	L-max	L-avg	W	Comment
1185	4/30/21	1940	XJ3459	300	EXSURCO	1.8059	1.4714	1.10	

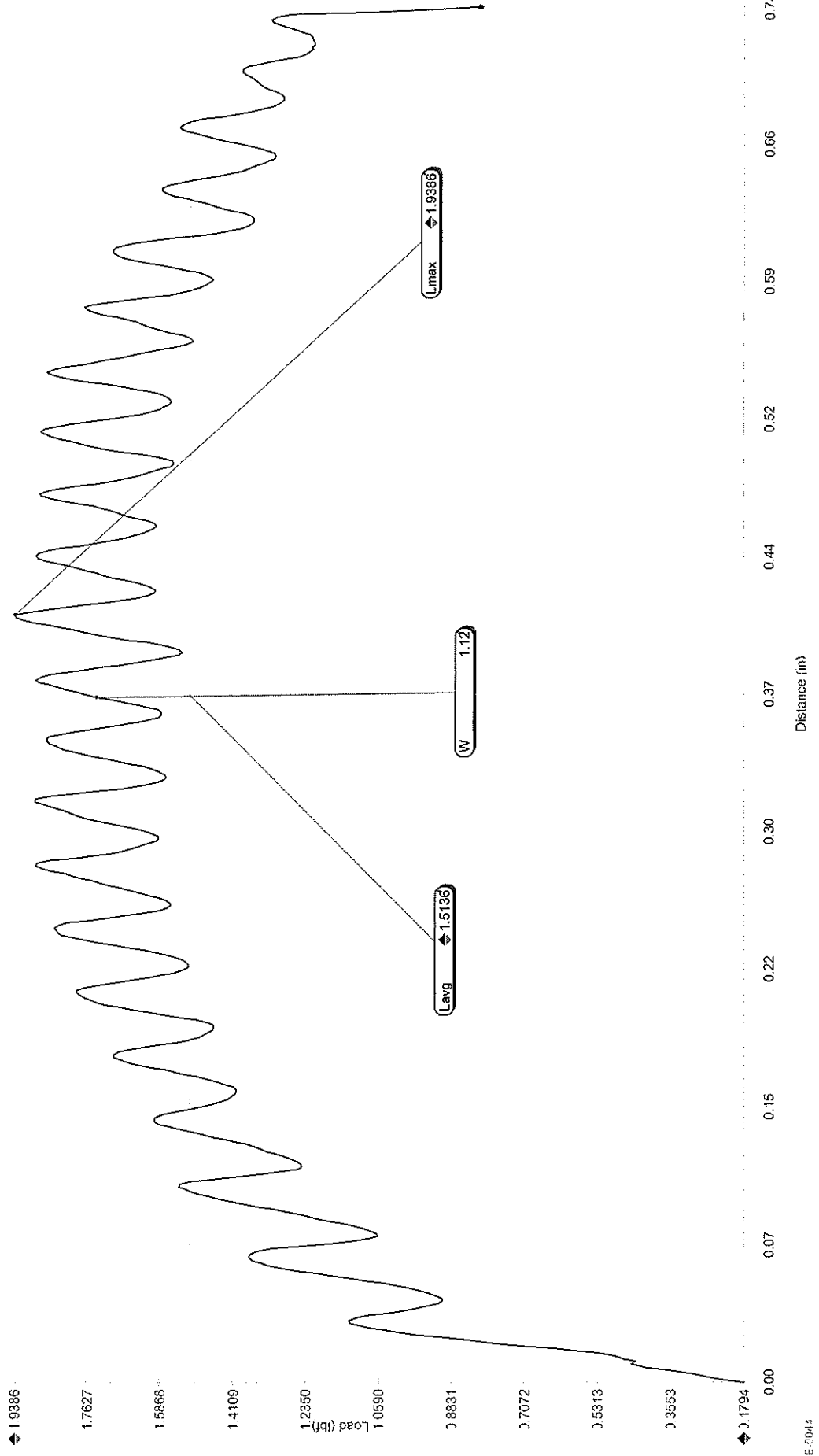
15:35:29 4/30/2021





Run	Date	Operator	JOB	SAMPLE#	Location	L-max	L-avg	W	Comment
1186	4/30/21	1940	XJ3459	350	EXSURCO	1.9386	1.5136	1.12	

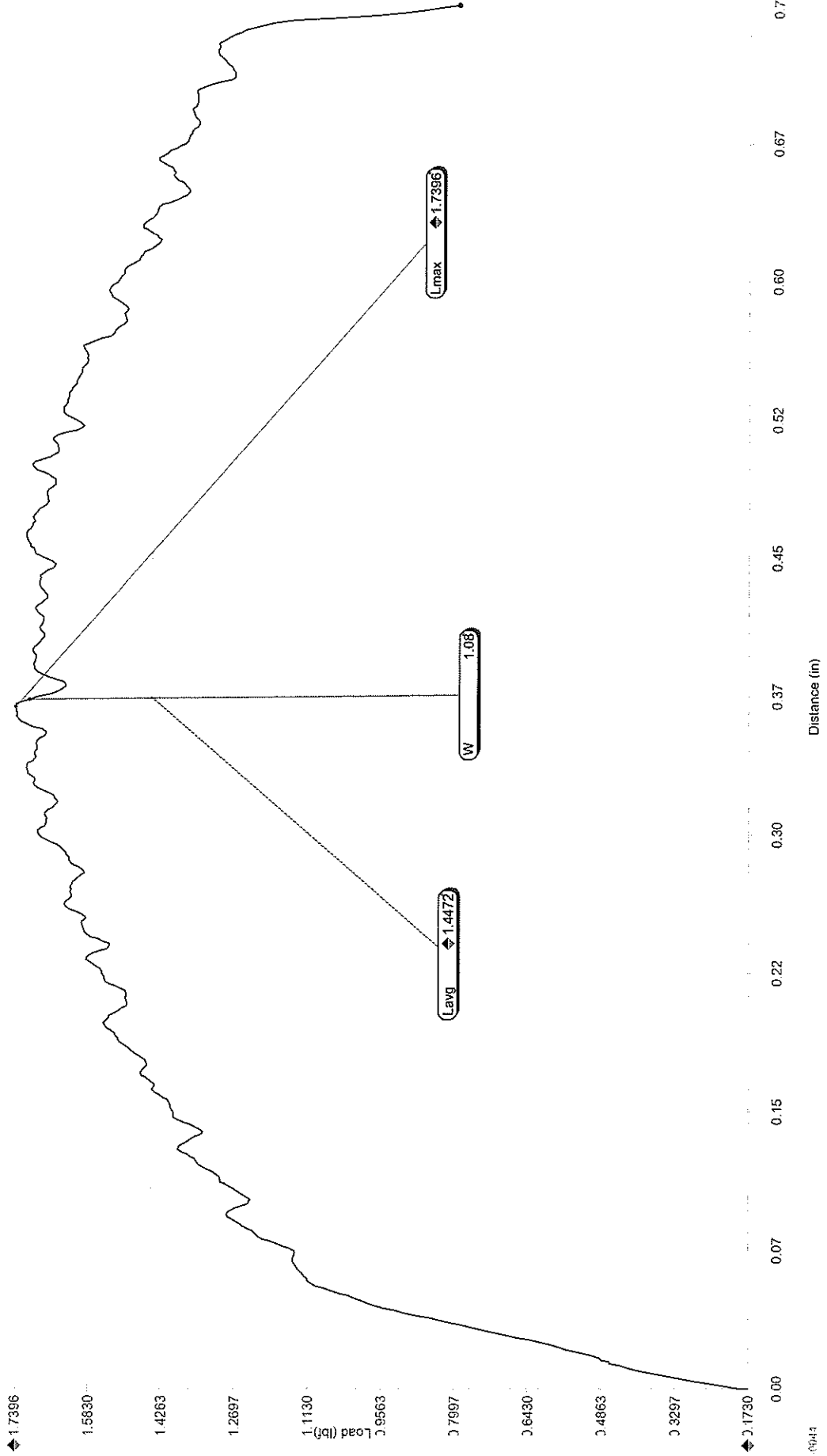
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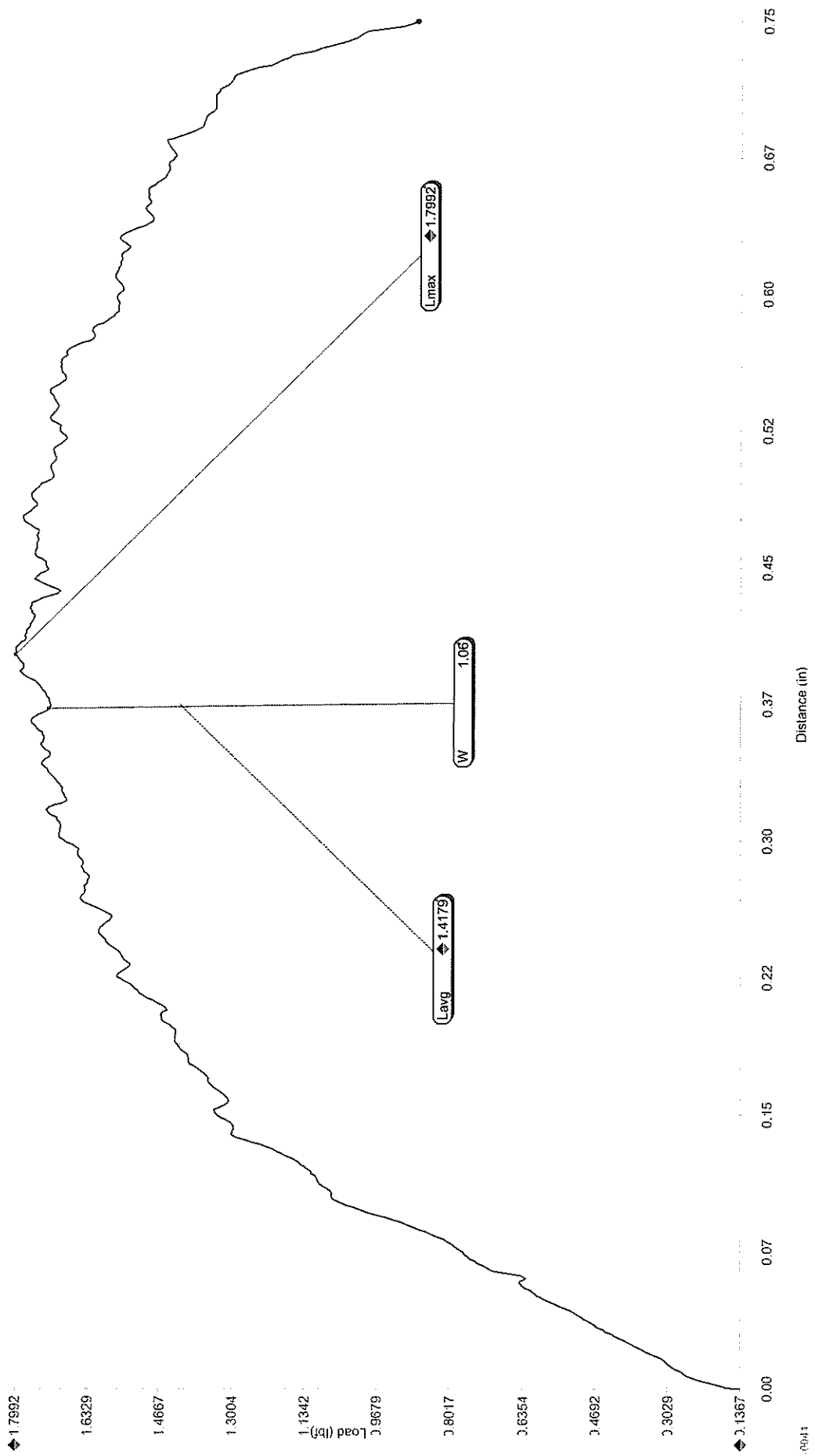
Run	Date	Operator	JOB	SAMPLE#	Location	L <sub>max</sub>	L <sub>avg</sub>	W	Comment
1187	4/30/21	1940	XJ3459	400	EXSURCO	1.7396	1.4472	1.08	

15:39:49 4/30/2021



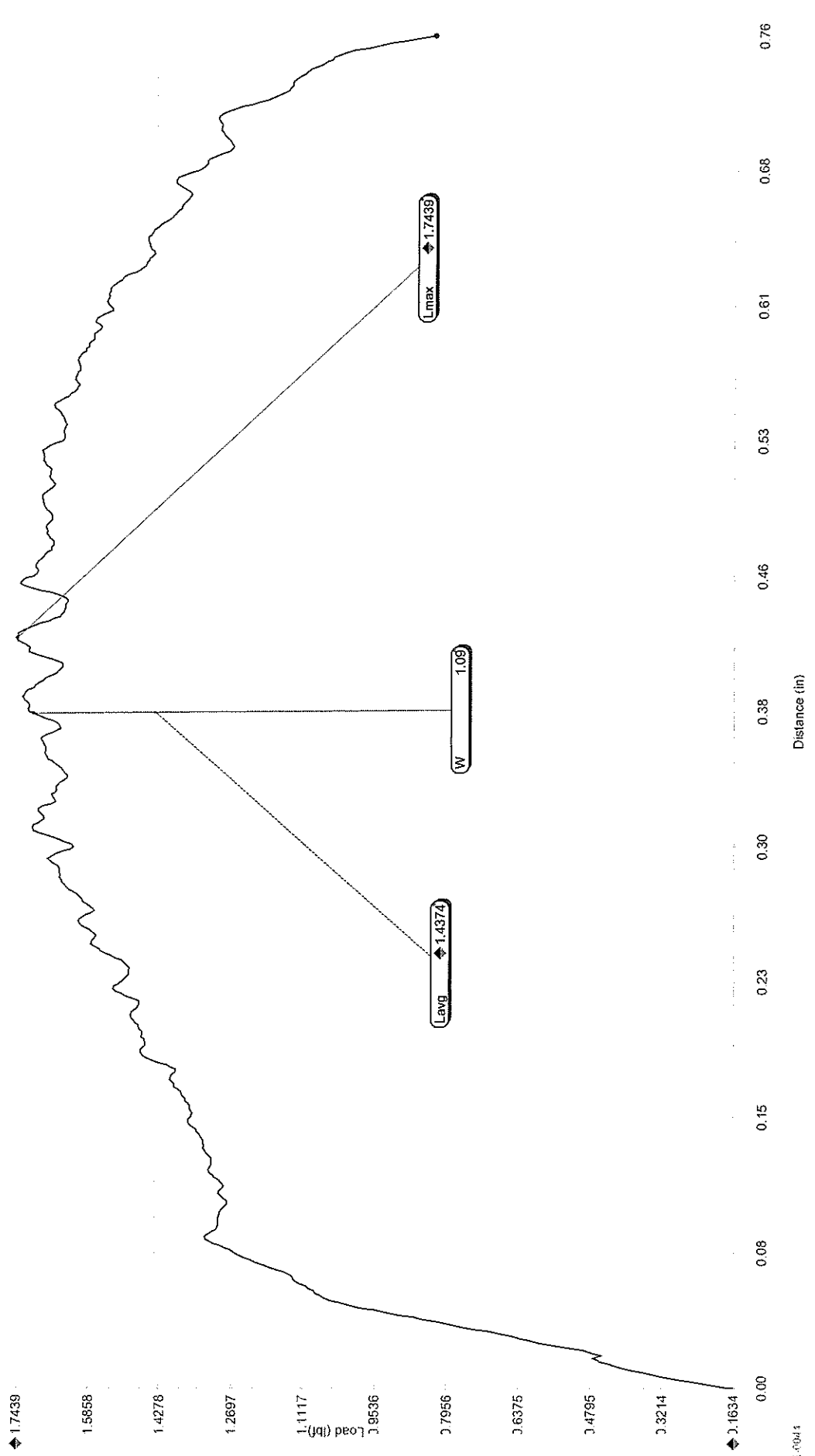
Run	Date	Operator	JOB	SAMPLE#	Location	L <sub>max</sub>	L <sub>avg</sub>	W	Comment
1186	4/30/21	1940	XJ3459	450	EXSURCO	1.7992	1.4179	1.06	

15:35:52 4/30/2021



Run	Date	Operator	JOB	SAMPLE#	Location	L <sub>max</sub>	L <sub>avg</sub>	W	Comment
1180	4/30/21	1940	XJ3458	LAST	EXSURCO	1.7439	1.4374	1.09	

15 36 06 4302624



JOB:	XJ3459	LOT:	X-00000000000080	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO. /REV.	X100593/E				

**OPERATION 0040 PREPARE FOR OUTSIDE STERILIZATION/IN-PROCESS INSPECTION**

INITIAL LINE CLEARANCE	CLOCK ID	DATE
	1847	04-29-21

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
0040	SHIPPING	SOP-4_00026_W1-SK09	05 ①	PACK, STERILIZATION-AMALGATOME SK HEAD	1847	04-29-21

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR #	NA

FINAL LINE CLEARANCE	CLOCK ID	DATE
		05-03-21

JOB:	X13459	LOT:	X-000000000000880	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

**OPERATION P060 STERILIZE PER VALIDATION**

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	REVISION	DESCRIPTION
P060	OUTSIDE SERVICE	SOP-4_00027_TMP01	01	CERTIFICATE OF CONFORMANCE GENERATION	N/A	X100593, PACK, AMALGATOME SK HEAD, 5 PC

**OPERATION 0070 FINAL INSPECT**

INITIAL LINE CLEARANCE	CLOCK ID	DATE
	1940	05/11/2021

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
0070-A	QUALITY	SOP-4_00026_WI-G13	02	E-0013 VISUAL INSPECTION GUIDELINES	1940	05/17/2021
0070-B	QUALITY	SOP-4_00027_TMP01	01	CERTIFICATE OF CONFORMANCE GENERATION	1940	05/11/2021

0070-A	SPECIFICATION	METHOD	GAGE	SAMPLE SIZE	RESULTS	GAGES USED	PASS OR FAIL
1	VERIFY QUANTITY OF CASES PROCESSED ON CERTIFICATE OF PROCESSING	VISUAL	E-0013	EACH LOT	Verified 20 cases	E-0013	PASS/FAIL
2	PACKAGING AND PRESERVATION	VISUAL	E-0013	EACH SKID	Pass No DAMAGE	E-0013	PASS/FAIL
3	DOSIMETRY DATA 25/45 KGY	VISUAL	E-0013	PER LOT	Min. = 27.2 kgy MAX. = 39.8 kgy	E-0013	PASS/FAIL
4	VERIFY LOT MATCHES LOT NUMBER IDENTIFIED ON JOB TRAVELER	VISUAL	E-0013	EACH CASE	X-80	E-0013	PASS/FAIL

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR #	N/A

FINAL LINE CLEARANCE	CLOCK ID	DATE
	1940	05/17/2021



JOB:	XJ3459	LOT:	X-00000000000080	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

COMMENTS/N/A
① Packed Per Redline DRF-00131 - JK 05-05-21
② Not used and Returned to stock: 10 pcs X100595 Lot X-59, 13 pcs X100051 Lot X-28, 11 pcs X100048 Lot X-26, 11 pcs X100040 Lot X-27, 10 pcs X100055 Lot X-45 - JK 05-05-21

JT-X100593 QUALITY MANAGER	PRINT NAME	SIGNATURE	DATE
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**REVISION HISTORY**

REVISION	CCR #	DESCRIPTION	EFFECTIVE DATE	CHANGE OWNER
01	00344	Initial Release Added Certificate of Conformance generation to Final Inspection operations. Add more wash result boxes. Add label expiration note operation 0002. Add "AS NEEDED" to label stock and ribbon in BOM. Replaced Clock ID and date columns with reviewer sign off under table. Remove DHR requirement from header.	3-10-2017	Jake Widener
02	00544		03-01-2019	Kayli Camp
03	00592	Remove X100730 from BOM. Updated X100787 QTY to 0.0001 mL. Remove inspection criteria in OP 0040.	09-03-2019	Jake Widener
04	00579	Change SD in header to SK. Add Wash in Delivery location for X100595. Correct typo from 0020 to 0010. Removed "Type" column, and added row 4 from table 0070-A. Added more results blocks to wash testing.	02-19-2020	Jake Widener

③ Rejected: 12 pcs X1000612 Lot X-15: Debris in pouch or black specs in pouch material,  
2 pcs X100055 Lot X-45: Damaged during rework, 2 pcs X100051 Lot X-28: Damaged  
During rework, 19 pcs X100048 Lot X-26: Failed runtest. - JK 05-05-21



# STERIS: Gamma Certificate Of Processing

Prepared for: EXSURCO MEDICAL INC (6263)

Gamma Process Run ID: 1073-3685A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
X100457	X-0000000000118	16	Case
X100593	X-0000000000079	20	Case
X100593	X-0000000000080	20	Case
X100593	X-0000000000081	10	Case

Processing Run Start Date: 10-May-21 05:28 AM                      Approx. Downtime (hours): 0.22

Processing Run End Date: 10-May-21 12:09 PM

Minimum Specified Dose (kGy): 25.0	Minimum Delivered Dose (kGy): 27.2
Maximum Specified Dose (kGy): 45.0	Maximum Delivered Dose (kGy): 39.8

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

### Other Information

PO# X000004171/ X000004172/ X000004173/ X000004174

**Gamma Process Run Approval authorized by STERIS**

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

### Processing Location

2500 Commerce Drive  
Libertyville IL 60048  
Phone: 847-247-4782

**STERIS: Gamma Dosimetry Record**  
**EXSURCO MEDICAL INC (6263)**

Irradiator / Method: IR-218 - ON-STD

Run ID  
**1073-3685A**

<u>Carrier</u>	<u>Seq</u>	<u>Coordinate</u>	<u>Barcode ID</u>	<u>Insert</u>	<u>Instrument</u>	<u>Dose (kGy)</u>	<u>Final Dose (kGy)</u>	<u>Comment</u>
1	1	0C1	OBY608001839	TH0033	0454	27.2	27.2	
1	2	9A5	OBY608088076	TH0033	0454	35.1	35.1	
1	3	9E5	OBY608088003	TH0033	0454	34.7	34.7	
2	1	0C1	OBY608088367	TH0033	0454	27.9	27.9	
2	2	TBA5	OBY608088128	TH0033	0454	36.7	36.7	
2	3	TBE5	OBY608088473	TH0033	0454	37.6	37.6	
5	1	0C1	OBY608088063	TH0033	0454	30.5	30.5	
5	2	TBA5	OBY608088096	TH0033	0454	39.4	39.4	
5	3	TBE5	OBY608088219	TH0033	0454	39.1	39.1	
7	1	0C1	OBY608088253	TH0033	0454	30.6	30.6	
7	2	TBA5	OBY608088263	TH0033	0454	39.6	39.6	
7	3	TBE5	OBY608088119	TH0033	0454	39.8	39.8	
8	1	0C1	OBY608088247	TH0033	0454	30.6	30.6	
8	2	TBA5	OBY608088347	TH0033	0454	38.5	38.5	
8	3	TBE5	OBY608088343	TH0033	0454	37.9	37.9	

Minimum Dose for Record (kGy): 27.2

Maximum Dose for Record (kGy): 39.8

Signature Manifest

Prepared By: **Brendan Mullaney (Operations Leadership Development Program)**

Date/Time E-Signed: 2021-05-10 03:27 PM

Document Content Revision: 1

Processing Location  
 2500 Commerce Drive  
 Libertyville IL 60048  
 Phone: 847-247-4782



REV	MADE BY	ECN	DESCRIPTION	DATE	APPROVED
D	DRS	EP001783	1) ADDED GAMMA IRRADIATION 25-45 KGy PER D0002305 TEST REPORT TO NOTE #8	12-08-2014	
E	TLW	EP003541 CCR_00592	1)* WAS "D"; 2) REMOVED ASSEMBLY PICTURES AND NOTES; 3) ADDED MODEL VIEWS OF X100608, X100612, X100613, AND X100303; 4) UPDATED SHEET ADDRESS; 5) ADDED "N/A"; 6) REMOVED NOTES 1-4; 7) REMOVED "USING UN-84 MOTOR" FROM NOTE 7; 8) MADE NOTE 8 MORE CONCISE; 9) REMOVED NOTE 9	08-20-2019	



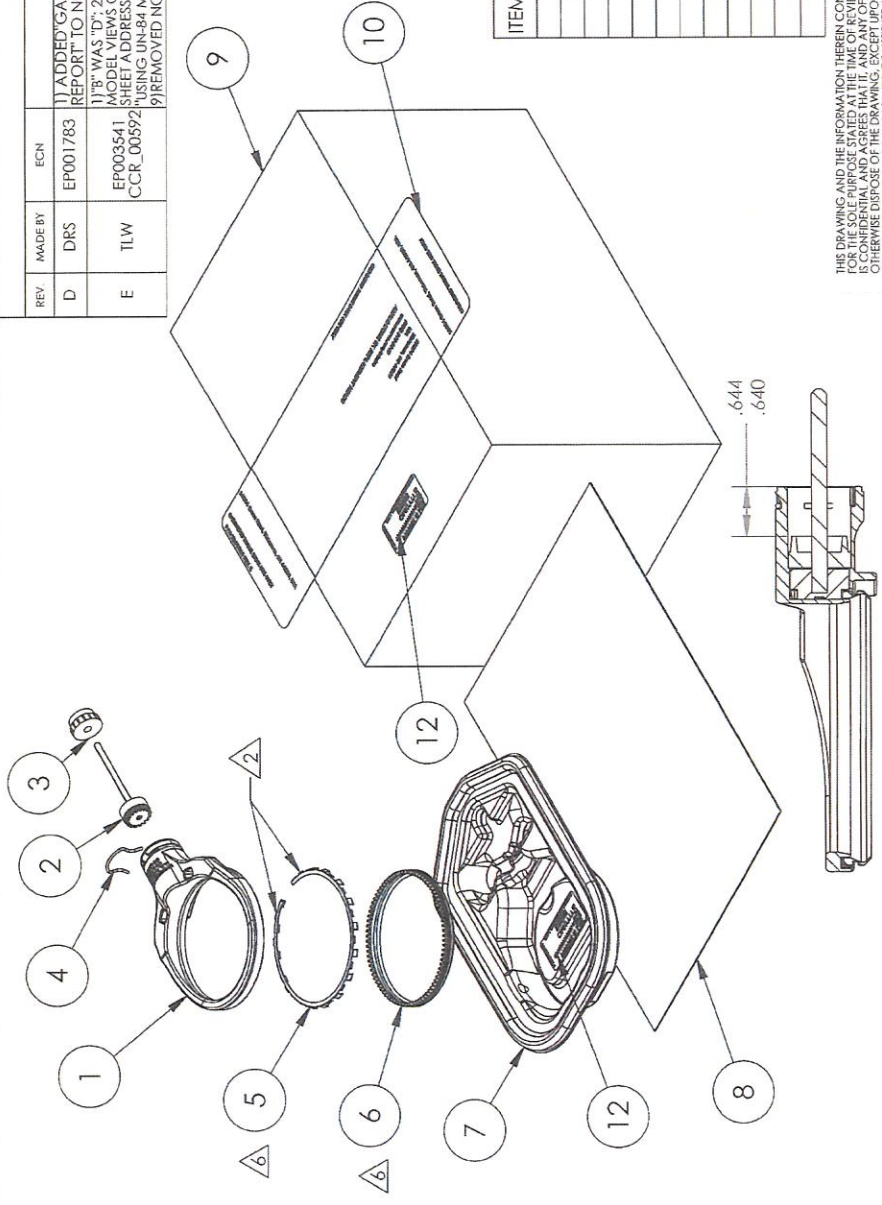
(E3) (E2) (5)

**APPROVED ORIGINAL**  
Approved by:

MFG *[Signature]* 8-26-19  
ENGR *[Signature]* 8-26-19  
QA *[Signature]* 8-26-19

\* = NOT SHOWN

ITEM NO.	QTY.	PART NO.	DESCRIPTION
1	5	X100055	FRAME, MOLDED,
2	5	X100046	PINION ASSEMBLY,
3	5	X100048	RETAINER, PINION, AMAL SK
4	5	X100050	CLIP, SPRING
5	5	X100051	RING, BLADE RETAINING,
6	5	X100595	BLADE, STAINLESS STEEL,
7	5	X100596	TRAY, STERILIZATION
8	5	X100612	POUCH, STERILIZATION, AMAL SK
9	1	X100608	BOX, 5 PC. AMALGATOME SK HEADS
10	1	X100613	LABEL, 5 PC BOX, AMAL SK
11*	0.0001ml	X100787	MINERAL OIL, STERILE
12	6	X100303	LABEL, LOT CONTROL



**SECTION A-A**  
**SCALE 1 : 1.5**

- NOTES:
- (E7) (E8) (E9) (D1) (E4) 1. (REMOVED)
  - 2. (REMOVED)
  - 3. (REMOVED)
  - 4. (REMOVED)
  - 5. THIS ASSEMBLY CONTAINS ONE OR MORE PARTS THAT HAVE REGULATORY REQUIREMENTS.
  - 6. (REMOVED)
  - 7. PERFORM 30 SECOND RUN TEST PER APPROVED PROCEDURE ON FINISHED ASSEMBLY PRIOR TO PACKAGING.
  - 8. (REMOVED)
  - 9. (REMOVED)

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INITIALS: DWN JAS  
CHK  
ENG  
DATE: 06-06-2013

PACK, AMALGATOME SK HEAD, 5 PC

ECN: EP000956  
REFNWS: X100044  
MODEL: AMALGATOME SK

SHEET 1 OF 1  
DWG NO. X100593  
SCALE 1:3

