



Certificate of Conformance

Certificate Number: EXMJ3445X79

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.¹

Product Item Number:	X100593
Item Description:	Pack, Amalgatome SK Head, 5 PC
Item Lot Number:	X-0000000000079
Expiration Date:	2023-04

The blades were manufactured using a validated sterilization process:

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

05/13/2021

 Date



 Quality Manager

05-11-2021

 Date

¹ Manufacturing data filed within the Quality Management System and available onsite.

JOB:	X13445	LOT:	X-00000000000079	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
		1847	04-13-21

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-26/X-27	16 / 500	WASH/ASSEMBLY
X100048	RETAINER, PINION, AMAL SK	5	PC	N/A	X-26	531	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	509	WASH/ASSEMBLY
X100596	TRAY, STERILIZATION	5	PC	N/A	X-4	500	ASSEMBLY
X100612	POUCH, STERILIZATION, AMAL SK	5	PC	N/A	X-15	511/414	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-09	AS NEEDED	ASSEMBLY
X101312	INK, ZEBRA PREMIUM 51000 RESIN, BLACK	0.0001	PC	N/A	X-17	AS NEEDED	ASSEMBLY
X100595	Blade, Stainless Steel, Amalgatome SK	5	PC	N/A	X-54/X-55/X-52	910/491	WASH/ASSEMBLY
X100787	Mineral Oil, Sterile	0.0001	ML	N/A	X-05	AS NEEDED	ASSEMBLY

* DENOTES PHANTOM BUILD

CLOCK ID	DATE
1847	04-13-21

JOB:	X13445	LOT:	X-00000000000079	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	1940	4/12/2021

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

ITEM #: X100593
LOT X-00000000000079
STERILE IR
 EXSURCO LOT CONTROL LABEL

FIRST

ITEM #: X100593
LOT X-00000000000079
STERILE IR
 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	04/12/21

QTY. ACCEPTED	600
QTY. REJECTED	0
MRR#	NA

FINAL LINE CLEARANCE	CLOCK ID	DATE
	1940	04-13-21
	1847	



JOB:	X13445	LOT:	X-00000000000079	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	4.13.21

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
0010	WASH	SOP-4_00026_WI-SK03	01	X100593-AMALGATOME SK ULTRASONIC WASH	1831	4.13.21

BATCH RESULTS TANK #1: Conductivity (µS)

1	920.3	4	910.1	7	914.7	10	916.9	13	921.0	16	927.2	19	931.5	22	25	28
2	913.5	5	913.2	8	920.8	11	919.7	14	921.3	17	932.1	20	931.8	23	26	29
3	913.2	6	911.6	9	917.0	12	919.4	15	913.6	18	929.0	21	927.1	24	27	30

BATCH RESULTS TANK #2: Resistivity (Ω)

1	2.4m	4	294.6k	7	288.1k	10	243.8k	13	230.0k	16	281.2k	19	271.2k	22	25	28
2	382.5k	5	275.4k	8	249.4k	11	341.4k	14	215.2k	17	230.2k	20	199.9k	23	26	29
3	363.8k	6	230.5k	9	256.5k	12	312.2k	15	278.9k	18	342.7k	21	215.4k	24	27	30

BATCH RESULTS TANK #3: Resistivity (Ω)

1	4.7m	4	4.3m	7	4.3m	10	3.9m	13	3.6m	16	3.3m	19	3.2m	22	25	28
2	4.3m	5	4.7m	8	4.0m	11	3.7m	14	3.2m	17	3.6m	20	3.2m	23	26	29
3	4.1m	6	4.1m	9	4.0m	12	3.4m	15	3.4m	18	3.5m	21	2.9m	24	27	30

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR#	NA

FINAL LINE CLEARANCE	CLOCK ID	DATE
	1831	4.13.21

JOB:	X13445	LOT:	X-00000000000079	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

OPERATION 0020 ASSEMBLE

INITIAL LINE CLEARANCE	CLOCK ID	DATE
	1831	4-14-21

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	4-14-21

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR#	NA

FINAL LINE CLEARANCE	CLOCK ID	DATE
	1847	04-15-21

JOB:	X13445	LOT:	X-00000000000079	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	4.14.21

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	4-14-21

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR#	NA

FINAL LINE CLEARANCE		CLOCK ID	DATE
		1847	04-19-21

JOB:	X13445	LOT:	X-00000000000079	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	04-15-21

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
0030	CLEANROOM	SOP-4_00026_WI-SK04	04	X100593-AMALGATOME SK STERILE PACKAGING	1847	04-15-21

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR #	NA

FINAL LINE CLEARANCE	CLOCK ID	DATE
	1847	04-19-21

JOB:	X13445	LOT:	X-00000000000079	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	04/16/2021

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	04/19/21
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

FREQUENCY	RESULTS 0030-A	FREQUENCY	RESULTS 0030-B
FIRST	(PASS) FAIL	FIRST	(PASS) FAIL
50	(PASS) FAIL	50	(PASS) FAIL
100	(PASS) FAIL	100	(PASS) FAIL
150	(PASS) FAIL	150	(PASS) FAIL
200	(PASS) FAIL	200	(PASS) FAIL
250	(PASS) FAIL	250	(PASS) FAIL
300	(PASS) FAIL	300	(PASS) FAIL
350	(PASS) FAIL	350	(PASS) FAIL
400	(PASS) FAIL	400	(PASS) FAIL
450	(PASS) FAIL	450	(PASS) FAIL
NA	(PASS) FAIL	NA	(PASS) FAIL
LAST	(PASS) FAIL	LAST	(PASS) FAIL

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR #	NA

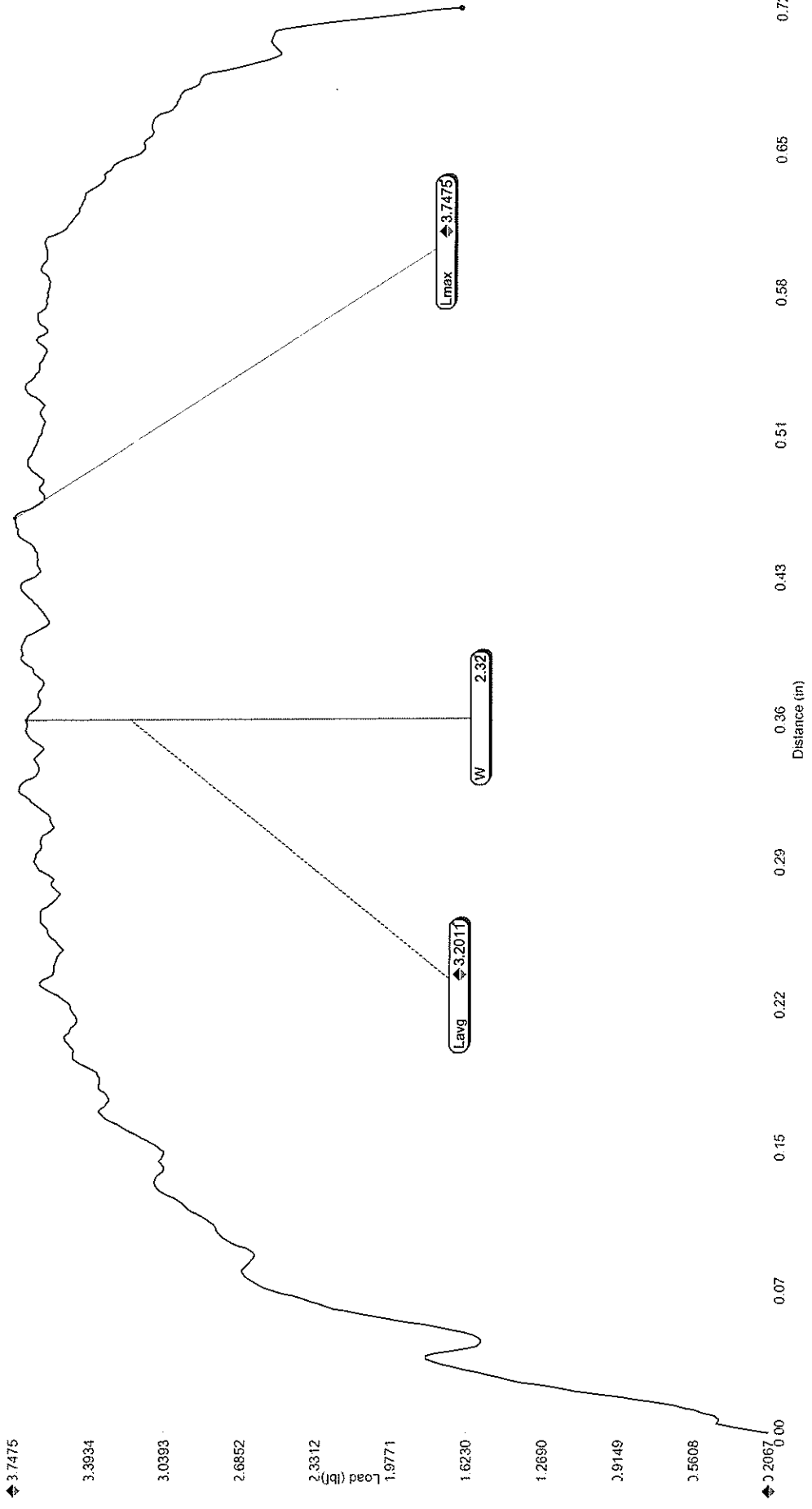
RESULTS RECORDED BY:	CLOCK ID	DATE
	1940	04/19/2021

FINAL LINE CLEARANCE			CLOCK ID	DATE
			1940	04/19/2021

EXSURCO[®] medical

Run	Date	Operator	JOB	SAMPLE#	Location	L _{max}	L _{avg}	W	Comment
1153	4/16/21	1940	XJ9445	FIRST	EXSURCO	← 3.7475	← 3.2011	2.32	

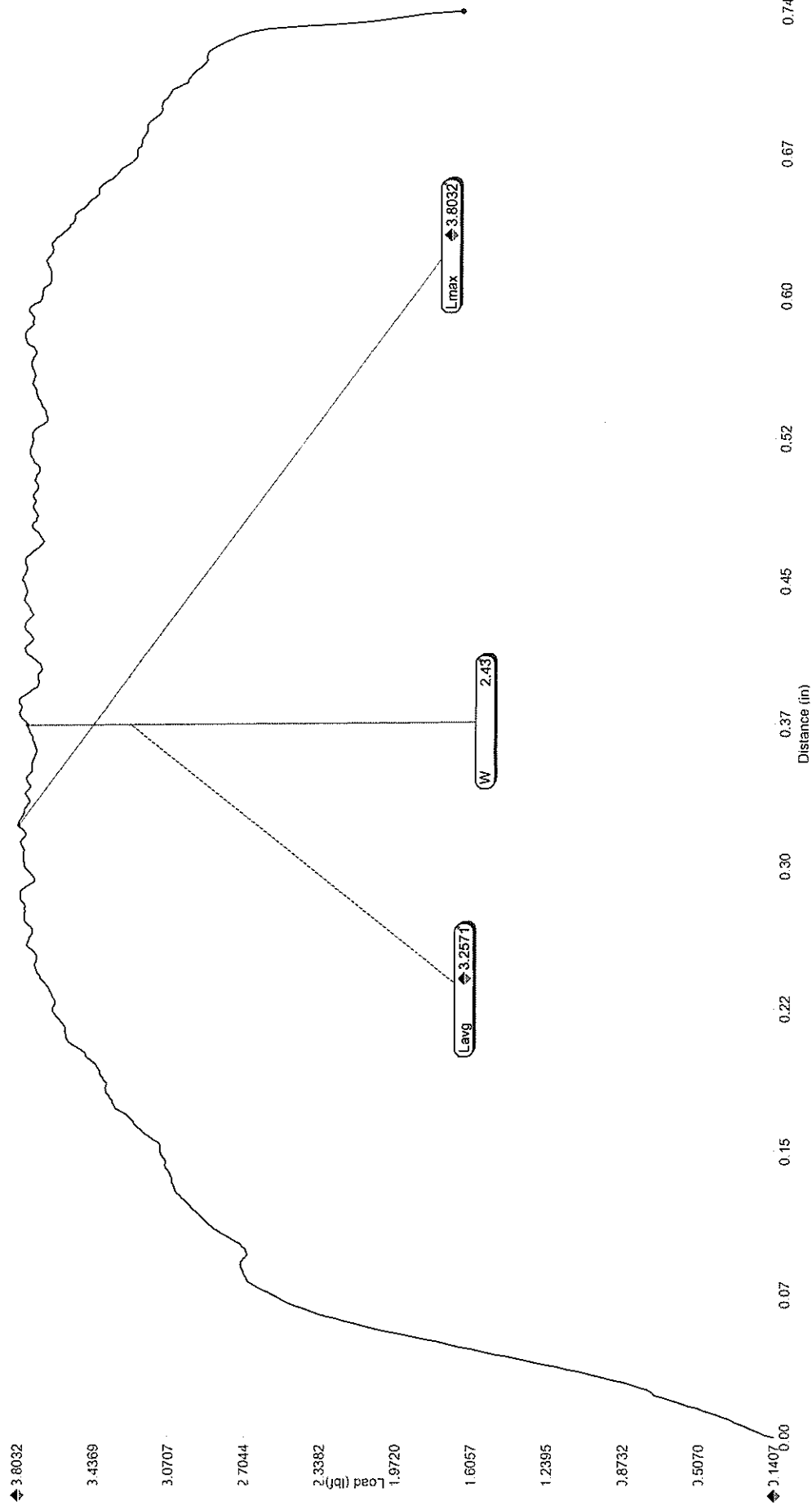
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EXSURCO[®] medical

Run	154	Date	4/16/21	Operator	XJ9445	JOB	90	SAMPLE#	EXSURCO	Location	3.8032	Lmax	Lavg	W	Comment
														2.43	

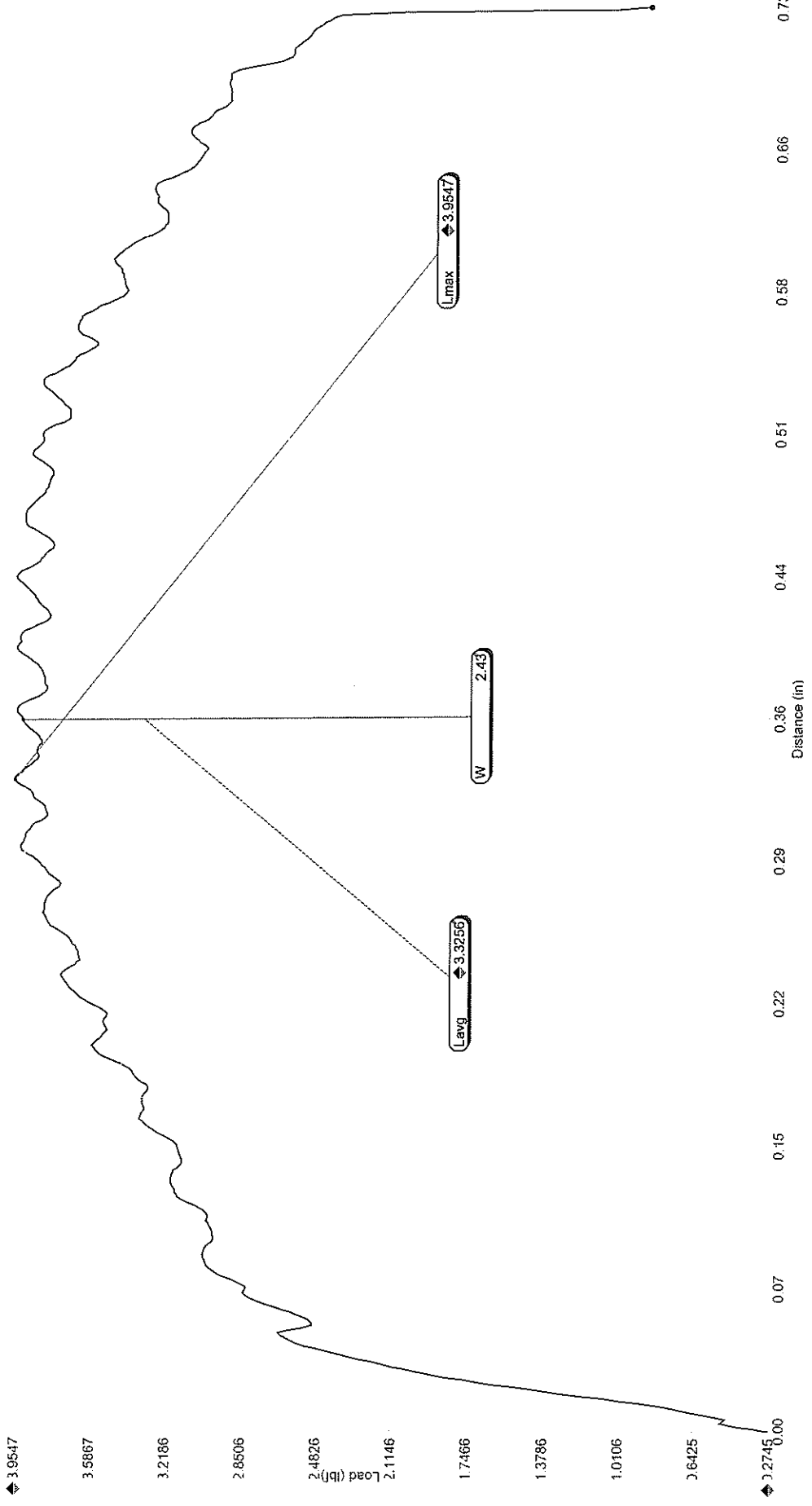
15 24 10 41602021



EXSURCO[®] medical

Run	1155	Date	4/16/21	Operator	1940	JOB	XJ8445	SAMPLE#	100	Location	EXSURCO	L _{max}	3.9547	L _{avg}	3.3256	W	2.43	Comment	
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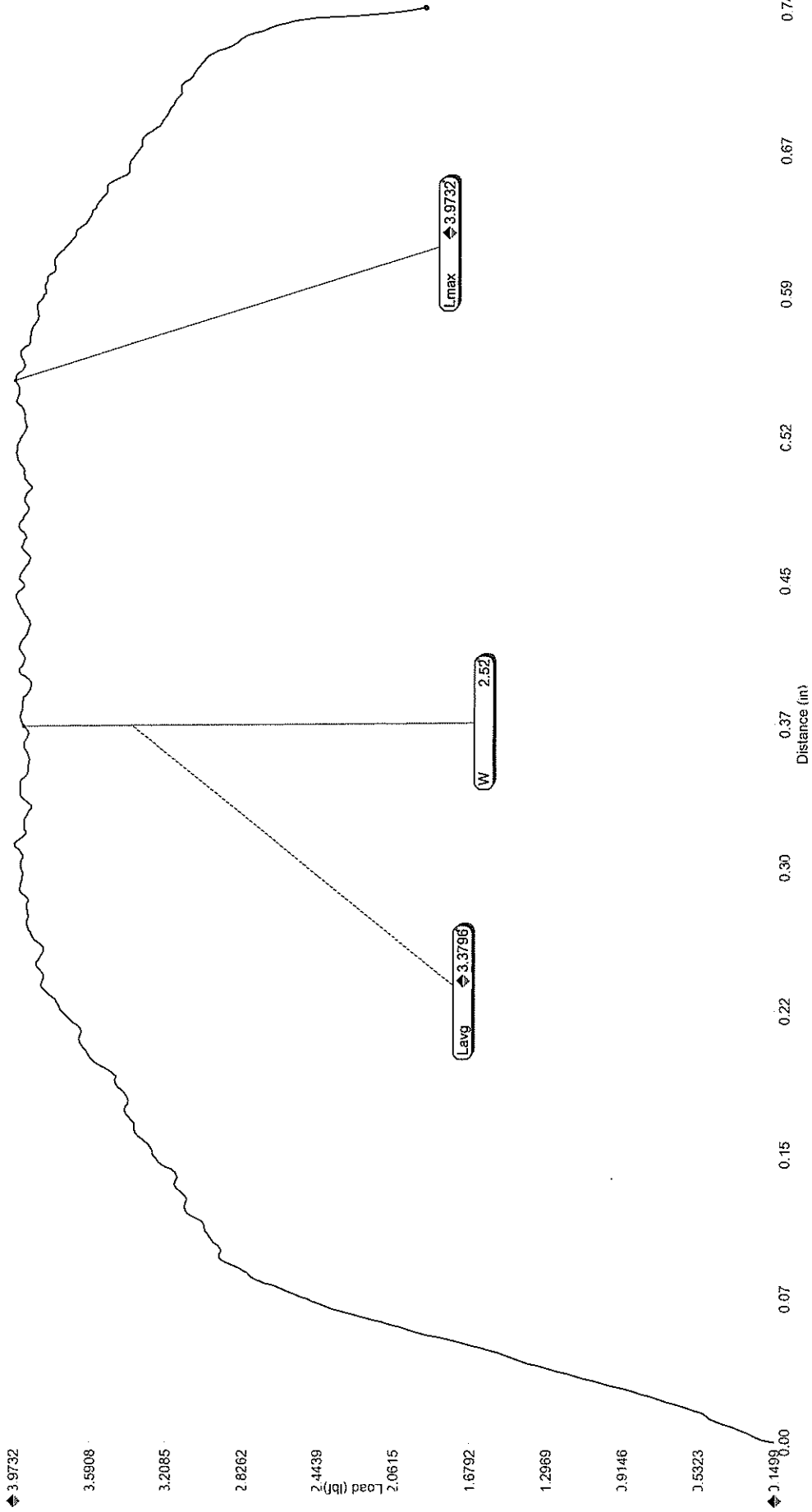
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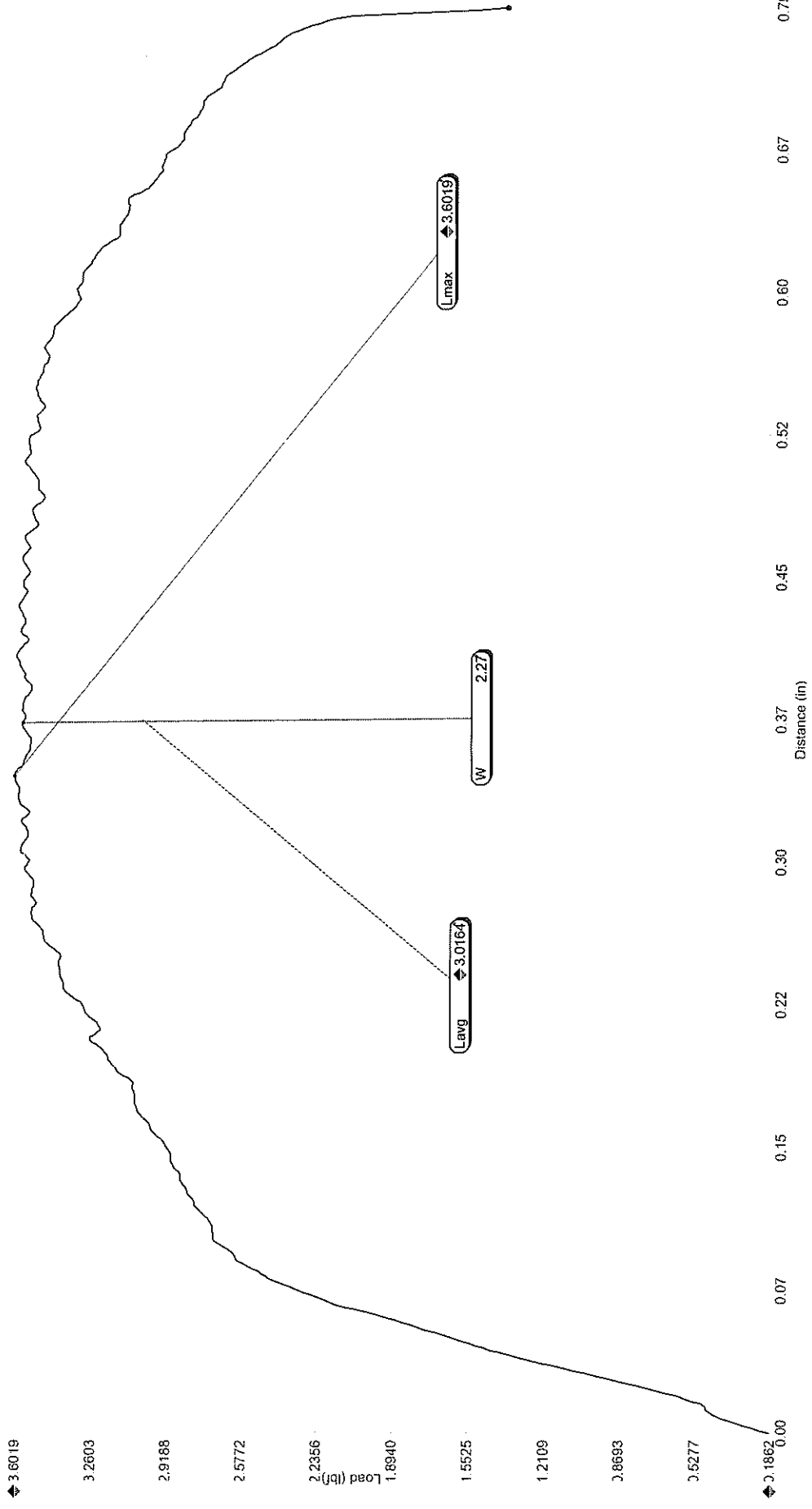
Run	Date	Operator	JOB	SAMPLE#	Location	L _{max}	L _{avg}	W	Comment
1156	4/16/21	1940	XJ5445	150	EXSURCO	+3.9732	+3.3796	2.52	



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Run	1157	Date	4/16/21	1940	Operator	XJ3445	JOB		SAMPLE#	200	Location	EXSURCO	Lmax	+3.6019	Lavg	-3.0164	W	2.27	Comment	
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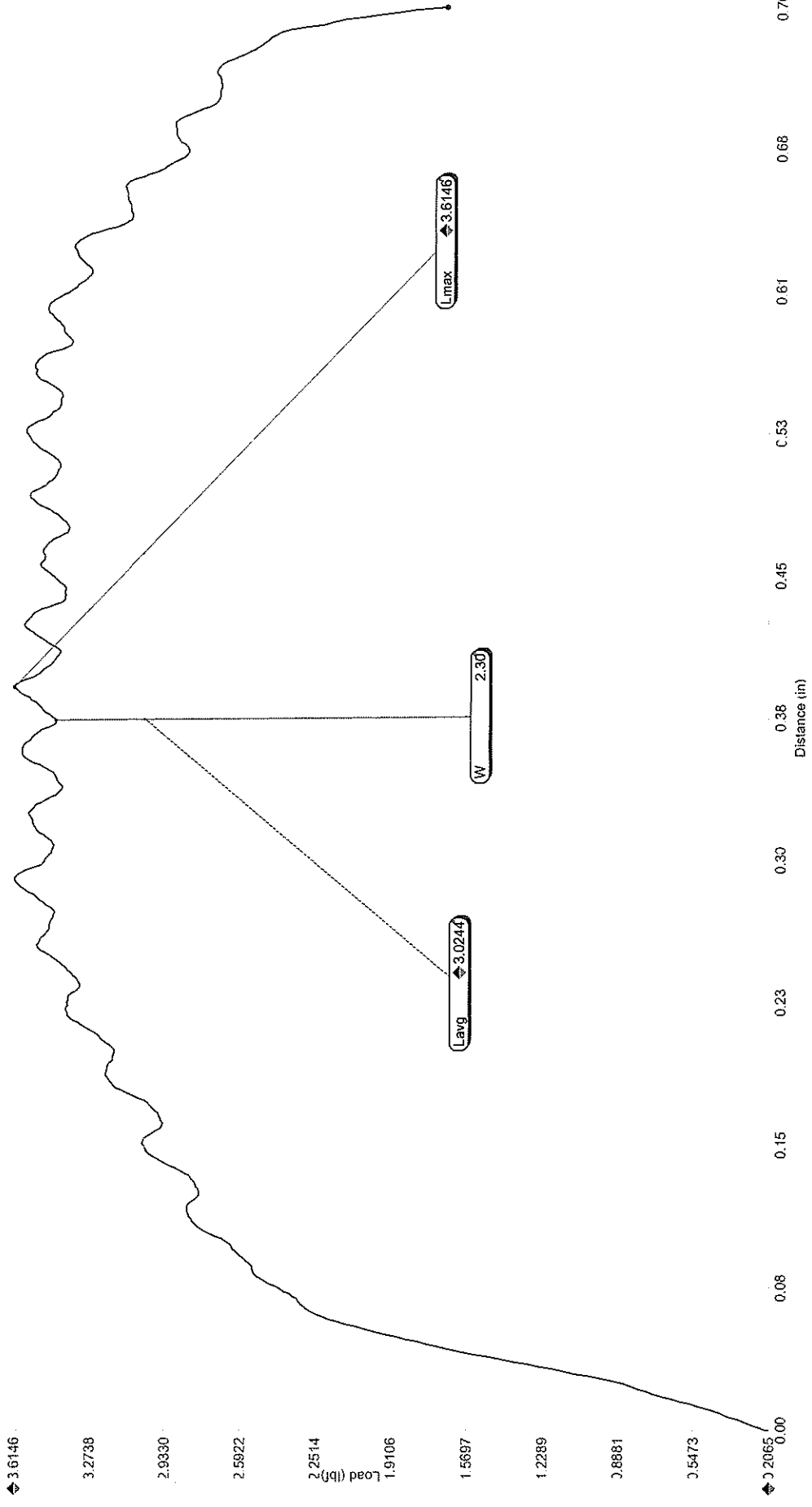
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EXSURCO[®] medical

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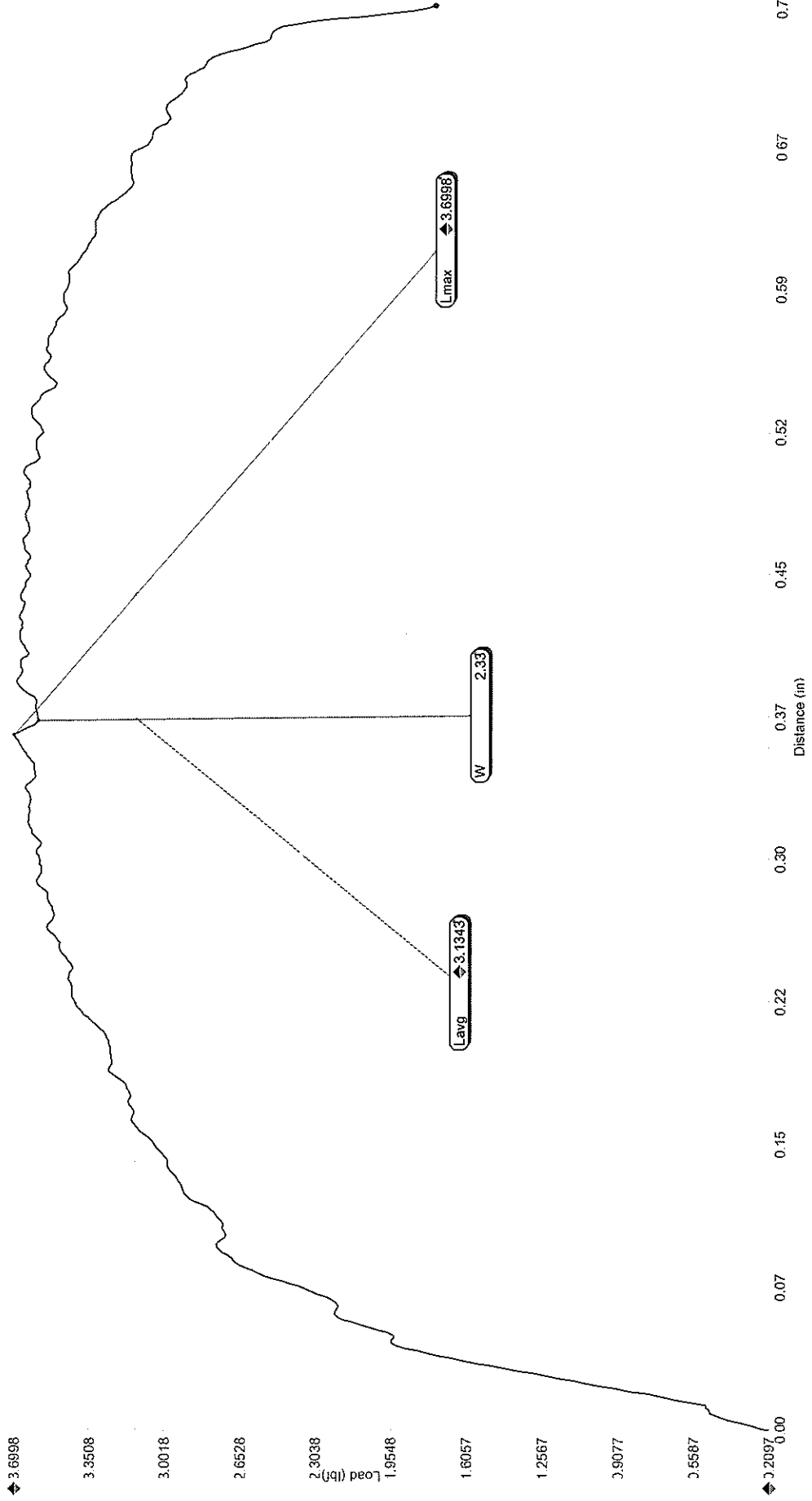
Run	Date	Operator	JOB	SAMPLE#	Location	L _{max}	L _{avg}	W	Comment
1156	4/19/21	1940	XJ5445	250	EXSURCO	↕ 3.6146	↕ 3.0244	2.30	





15 25:28 4/19/2021

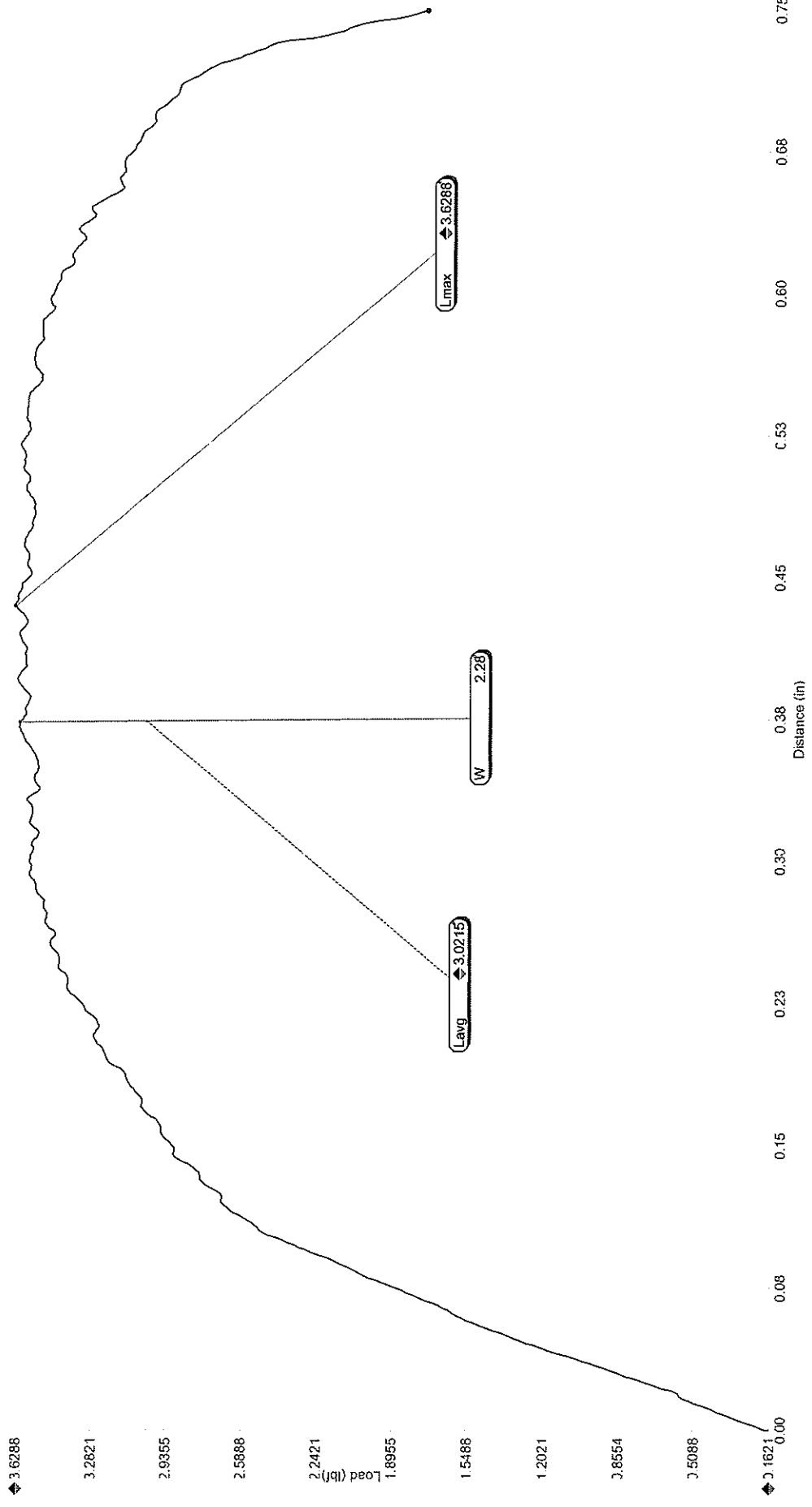
Run	Date	Operator	JOB	SAMPLE#	Location	L _{avg}	L _{max}	W	Comment
1155	4/19/21	1940	XJ3445	300	EXSURCO	3.1343	3.6998	2.33	



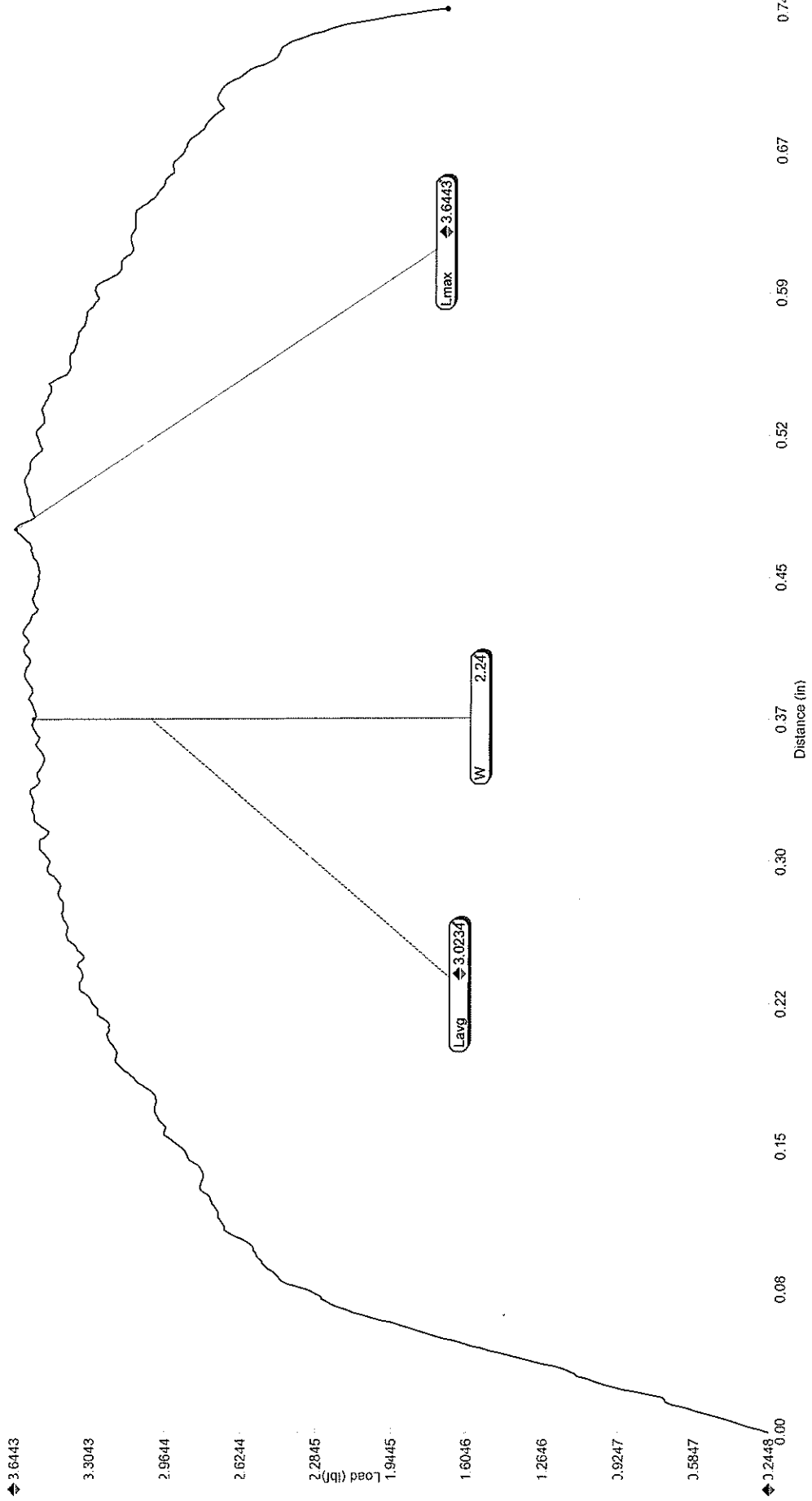
EXSURCO[®] medical

15 25 39 44 02 02 1

Run	Date	Operator	JOB	SAMPLE#	Location	L _{avg}	W	Comment
1160	4/19/21	1940	XJ9445	350	EXSURCO	3.0215	2.28	

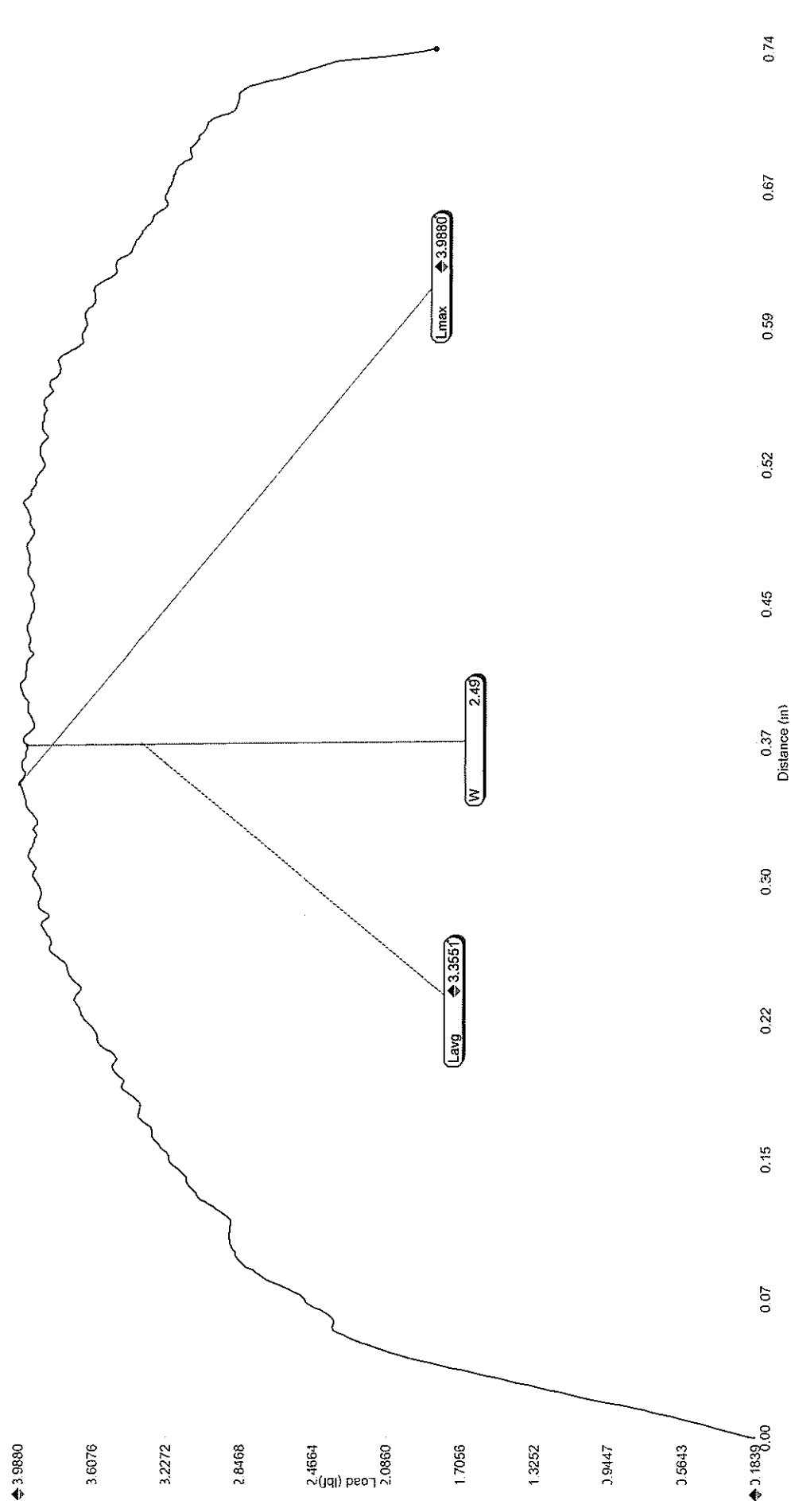


Run	Date	Operator	JOB	SAMPLE#	Location	L _{avg}	L _{max}	W	Comment
1161	4/19/21	1940	XJ0445	400	EXSURCO	3.0234	3.6443	2.24	



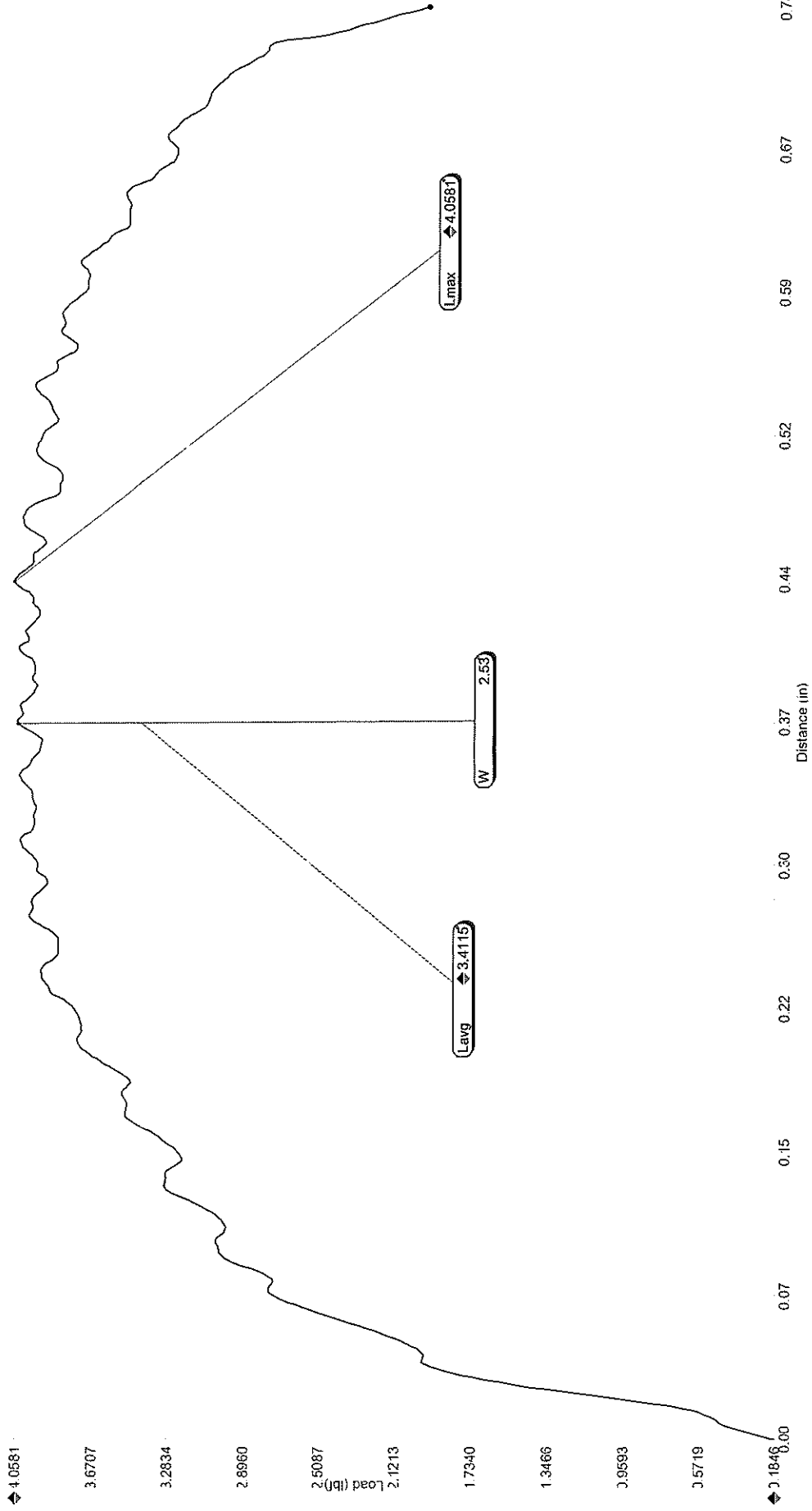
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Run	Date	Operator	JOB	SAMPLE#	Location	L _{max}	L _{avg}	W	Comment
1162	4/19/21	1940	XJ3445	450	EXSURCO	3.9880	3.3551	2.49	



Run	Date	Operator	JOB	SAMPLE#	Location	L _{max}	L _{avg}	W	Comment
1163	4/19/21	1940	XJ3445	LAST	EXSURCO	4.0581	3.4115	2.53	

15 26 14 47:02:021



JOB:	XJ3445	LOT:	X-00000000000079	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 04-14-21

OPERATION	WORK STATION	DOCUMENT	REVISION	DESCRIPTION	CLOCK ID	DATE
0040	SHIPPING	SOP-4_00026_WI-SK09	050	PACK, STERILIZATION-AMALGATOME SK HEAD	1847	04-14-21

QTY. ACCEPTED	100
QTY. REJECTED	0
MRR #	NA

FINAL LINE CLEARANCE	CLOCK ID	DATE
		1831 4-26-21

JOB:	XJ3445	LOT:	X-00000000000079	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	ITEM NUMBER	REVISION	DESCRIPTION
P060	OUTSIDE SERVICE	X100593	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	E-0013	PASS/FAIL
3	DOSIMETRY DATA 25/45 KGy	VISUAL	E-0013	PER LOT	NO DAMAGE 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-79	E-0013	PASS/FAIL

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

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

JOB:	XJ3445	LOT:	X-00000000000079	TEST QTY.	0
DMR/REV.	DMR-X100593_SK/0002	SERIAL(S):	N/A	BUILD QTY.	100
DWG.NO./REV.	X100593/E				

COMMENTS/IN/A
① Error: supposed to be circled not crossed out. KSL 04/19/21
② Packed Per Redline DRF-00131 - JK 05-05-21
③ Not Used and returned to stock: 9 pcs X100055 Lot X-45, 17 pcs X100048 Lot X-26

JT-X100593_SK REVIEWED BY 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 cont.: 14 pcs X100046 Lot X-27, 8 pcs X100057 Lot X-28. - JK 05-05-21
 ④ Rejected: 14 pcs X100612 Lot X-15: Black Specs in Clear Side of Pouch, 3 pcs X100055 Lot X-45:
 2 Failed runtest; 1 failed visual inspection; 2 pcs X100051 Lot X-28: Failed runtest,
 2 pcs X100046 Lot Unknown: Failed runtest; 14 pcs X100048 Lot X-26: Failed runtest,
 1 pcs X100595 Lot unknown: 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	0BY608001839	TH0033	0454	27.2	27.2	
1	2	9A5	0BY608088076	TH0033	0454	35.1	35.1	
1	3	9E5	0BY608088003	TH0033	0454	34.7	34.7	
2	1	0C1	0BY608088367	TH0033	0454	27.9	27.9	
2	2	TBA5	0BY608088128	TH0033	0454	36.7	36.7	
2	3	TBE5	0BY608088473	TH0033	0454	37.6	37.6	
5	1	0C1	0BY608088063	TH0033	0454	30.5	30.5	
5	2	TBA5	0BY608088096	TH0033	0454	39.4	39.4	
5	3	TBE5	0BY608088219	TH0033	0454	39.1	39.1	
7	1	0C1	0BY608088253	TH0033	0454	30.6	30.6	
7	2	TBA5	0BY608088263	TH0033	0454	39.6	39.6	
7	3	TBE5	0BY608088119	TH0033	0454	39.8	39.8	
8	1	0C1	0BY608088247	TH0033	0454	30.6	30.6	
8	2	TBA5	0BY608088347	TH0033	0454	38.5	38.5	
8	3	TBE5	0BY608088343	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	1) "WAS TO"; 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 B MORE CONCISE; 9) REMOVED NOTE 9	08-20-2019	

REG

(E3) (E2) (5)

APPROVED ORIGINAL

Approved by: MFG Tom Wright 8-26-19
ENGR Paul Wright 8-26-19
QA [Signature] 8-26-19

* = NOT SHOWN

ITEM NO.	QTY.	PART NO.	DESCRIPTION
1	5	X100555	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

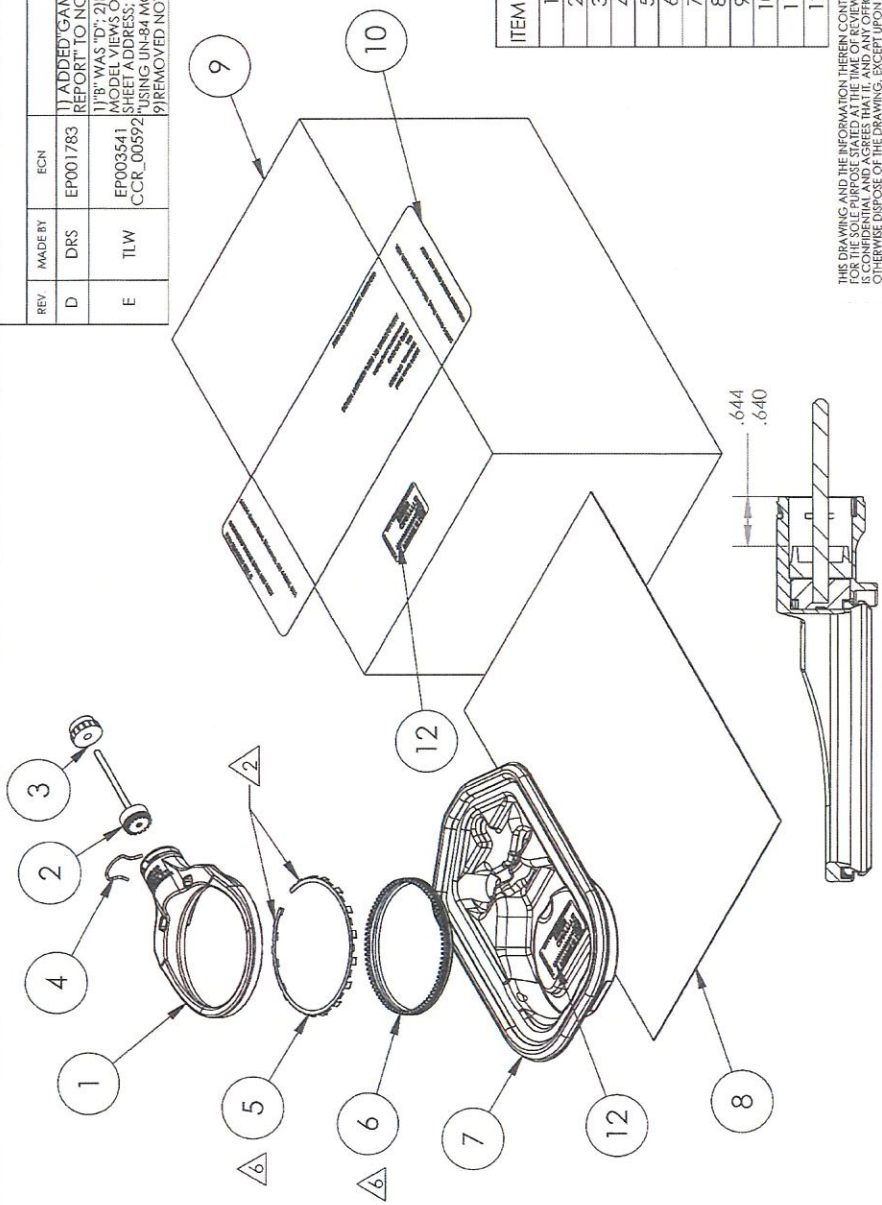
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UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
 TOLERANCES ON:
 DIMENSIONS: +.01
 3 PL. DIMENSIONS: +.005
 FRACTIONS: ± 1/32
 ANGLES: ± 1°
 FLATNESS/WR: ± .005 RMIN
 ROUNDNESS: ± .005 R DIA.
 .020 MAX.

INITIALS: DWN JAS DATE: 06-06-2013
 CHK: ENG: ECN: EP000956
 THIRD ANGLE PROJECTION
 REF: X100044
 MODEL: AMALGATOME SK
 SCALE: 1:3
 DWG NO. **X100593**
 SHEET 1 OF 1

SECTION A-A
SCALE 1 : 1.5

9. (REMOVED)
 8. COMPLETED PACKAGED BLADES TO BE STERILIZED BY GAMMA PER APPROVED PROCEDURE.
 7. PERFORM 30 SECOND RUN TEST PER APPROVED PROCEDURE ON FINISHED ASSEMBLY PRIOR TO PACKAGING.
 6. APPLY TWO DROPS OF X100787 TO BLADE AT RETAINER CONTACT POINT.
 5. THIS ASSEMBLY CONTAINS ONE OR MORE PARTS THAT HAVE REGULATORY REQUIREMENTS.
 4. (REMOVED)
 3. (REMOVED)
 2. (REMOVED)
 1. (REMOVED)



NOTES:



PACK, AMALGATOME SK HEAD, 5 PC

