



## Material: SA0155-01 Rev F

Material Type: ZFRT Description: Edwards Flex Shaft Commander 155885

Production Version: 7988

Plant / Business Unit: 1213 / AC5

Order Type: ZSTD

Project Phase:

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
50	KITTING3 Kitting Devices  Kitting Devices	<p>Kitting Devices</p> <p>Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP</p> <p>Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>Am 68 1:30 pm 20 Jan 24</u></p> <p>Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>Am 68 5:55 pm 20 Jan 24</u></p> <p>Record Dryer Shelf #: <u>N/A</u></p>				KLA7

Notes: N/A 2504, 2484

N/A

N/A

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# Production Order: 500000297257



Production Order Document  
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## Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	RM0158-01	E	<u>E</u>	PC	200	N/A <u>58497</u>	N/A <u>200</u>		
		TL0167-02	E	<u>E</u>	PC	70	N/A <u>N/A</u>	Bulk		
		TL0165-05	J	<u>J</u>	PC	5	N/A <u>N/A</u>	Bulk		
		TL0165-03	J	<u>J</u>	PC	5	N/A <u>N/A</u>	Bulk	N/A	N/A
		141967-01	02	<u>62</u>	PC	500	<sup>X031</sup> <u>85500/85501</u> <sup>22JAN24</sup> <u>N/A</u>	<sup>22JAN24</sup> <u>275</u> <u>①8 85501</u> <u>225</u>		
		RM7349-02	C	<u>C</u>	PC	543	<u>82870</u> <u>82858</u> <u>82734</u>	<u>100</u> <u>100</u> <u>250</u>		
		RM7348-01	C	<u>C</u>	PC	500	<sup>X031</sup> <u>86867</u> <sup>22JAN24</sup> <u>78689</u>	<u>150</u>		
							<u>78688/82884</u>	<u>150/150</u>		

Notes:

N/A

N/A

N/A

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## Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details					Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	RM4001-01	B	<u>B</u>	PC	125 22JAN24	XCS 82103 N/A 82695	N/A		
		RM0607-01	D	<u>D</u>	PC	56	71863 N/A	100 125 N/A		
		RM0498-01	C	<u>C</u>	PC	500	0000287640 0000275490	200 227		
		RM0362-01	E	<u>E</u>	PC	594	78858 N/A	600 N/A		
		RM0009-04	I	<u>I</u>	PC	1	82971 N/A	Bulk N/A	N/A	N/A
		RM0009-04	I	<u>I</u>	PC	1	82971 N/A	Bulk N/A		
		MM1538-01	A	<u>A</u>	PC	500	0000278970 N/A	500 N/A		
		MM1537-01	A	<u>A</u>	PC	1000	0000284209	1000 N/A		

Notes:

N/A

N/A

N/A

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## Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details					Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	MM1536-01	B	P	PC	500	0000281412	N/A 500		
		MM0180-01	E	E	PC	500	0000282490	N/A 400		
		MM0179-01	D	D	PC	500	0000282489	100		
		MM0178-01	E	E	PC	500	0000276172	500		
		MM0177-01	C	C	PC	500	0000284208	N/A 500	N/A	N/A
		MM0176-01	D	D	PC	500	0000281411	N/A 500		
		MM0074-01	G	G	PC	500	0000271036	80		
							0000293932	511		
							N/A	N/A		

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A	N/A	N/A	N/A	N/A
100	CATASY01  Catheter Assembly 1    Line Clearance  Confirmation Reqd(Milestone )	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	22 Jan 24	CB58
150	CATASY01  Catheter Assembly 1    Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly	500	0	22 Jan 24	CD19 AM47 YK40

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
200	CATASY01 Catheter Assembly 1  Loading Braid Stock Confirmation Reqd(Milestone )	Loading Braid Stock	500	0	22 Jan 24	SC10 MC17
250	CATASY01 Catheter Assembly 1  Trim Braid Wire at Proximal End		500	0	22 Jan 24	PY67 AIGS
Notes:		N/A				
		N/A				
		N/A				

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Trim Braid Wire at Proximal End  Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
300	CATASY01  Catheter Assembly 1  	Insert Cut Hypo Tube  Insert Cut Hypo Tube  Confirmation Reqd(Milestone )	500	0	22Jan24	AL67 AJ65 PL28
350	CATASY01  Catheter Assembly 1	Load Tubing	500	0	22Jan24	RL47 CX60 BN04 MC17

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Load Tubing  Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
400	CATASY01 Catheter Assembly 1  Reflow  Reflow  Confirmation Reqd(Milestone)		500	0	225 cu 24	AL42 SN67 AM47
450	CATASY01 Catheter	FEP Removal	500	0	225 cu 24	YK40
Notes:						
N/A						
N/A						
N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Assembly 1					
N/A	FEP Removal	N/A	N/A	N/A	N/A	N/A
	Confirmation Reqd(Milestone )					
500	CATASY01 Catheter Assembly 1	In-process Inspection and Rework Material Consumed: Part #: 1000-1153-01 Batch #: 87656 Qty: N/A Part #: Pn4001-01 Batch #: 10382103 Qty: 18 Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	472	OF-1H(11) EW-1H(1H) HH-LHT 225 Jan 24 28	SX11 VC09 AR02 HL61	
N/A	N/A	N/A	N/A	N/A	N/A	N/A
Notes:						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
550	CATASY01  Catheter Assembly 1  	Remove Heat Shrink & Mandrel	462	DL-4H11 EA+① FM-III  225cm 24 ⑩	PT09 FB01 DV39 AX82 RS23	
600	CATASY01  Catheter Assembly 1    Distal Tip Assembly    Confirmation	Distal Tip Assembly	462	○  225cm 24	MH10 VA96 FB01 AX82 RS23	

Notes:

n/a

n/a

n/a

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①CB58 21Jan24



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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
750	CATASY01  Catheter Assembly 1  	Tip Inspection/ Flash Removal Material Consumed: Part #: RM40010 Batch #: 82095 Qty: 10 Part #: RM06070 Batch #: 71863 Qty: 4 Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	462	0 <i>225cm 24</i>	I683 STX48 HV36	
800	CATASY01  Catheter Assembly 1  	Major Mandrel Removal	460	ACD-1C <i>225cm 24</i> (2)	BD64 AL42 TRN SS44 SS52	
Notes:						
<i>N/A</i>						
<i>N/A</i>						
<i>N/A</i>						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Major Mandrel Removal  N/A Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
850	CATASY01  Catheter Assembly 1  	Cut to Length Record DIM05 gage result for the first 5 parts at the start of operation: 1. Pass 2. Pass 3. Pass 4. Pass 5. Pass  Cut to Length  Confirmation Reqd(Milestone )	458	SKV-11 ② 22 Jan 24	KL45 AL49 TAN SS52	
900	QUALITY1  Quality Inspection & Review	Quality Inspection and Review Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	N/A	N/A	N/A	N/A
Notes:						
<i>N/A</i>						
<i>N/A</i>						
<i>N/A</i>						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Quality Inspection & Review  Confirmation Reqd(Milestone )	<p>Re-Inspect after re-work.</p> <p>Required Inspection Visual/OD Inspection Record Inspection Data in SAP ROS Record Laser Micrometer Information: TMI: <u>0700-01</u> Cal Due: <u>31 May 2024</u></p> <p>TMI: <u>N/A</u> Cal Due: <u>N/A</u></p> <p>Material Consumed:</p> <p>Part #: <u>RM0158-01</u> Batch #: <u>58497</u> Qty: <u>2</u></p> <p>Part #: <u>RM4001-01</u> Batch #: <u>82095</u> Qty: <u>12</u></p> <p>Part #: <u>RM0607-01</u> Batch #: <u>71863</u> Qty: <u>5</u></p> <p>Part #: <u>1000-1153-01</u> Batch #: <u>87656</u> Qty: <u>N/A</u></p> <p>Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u></p>	A39	<p>DIS-HHHT ①</p> <p>HHHT ①</p> <p>DEL-111</p> <p>WK-111</p> <p>DS-1</p> <p>Fm-111</p> <p>MAR-1</p> <p>EW-HHHT ①</p> <p>HII-DIS</p> <p>EH-1</p> <p>ASUS-HHHT ①</p> <p>A709-111</p> <p>#903-1</p> <p>(19)</p>	22 Jan 24	KL45 LS46 KX54 MC17 PY46 L155 KT217 D429
950	QUALITY1  Quality Inspection & Review	<p>Quality Inspection &amp; Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: <u>N/A</u> Cal Due: <u>N/A</u></p> <p>Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

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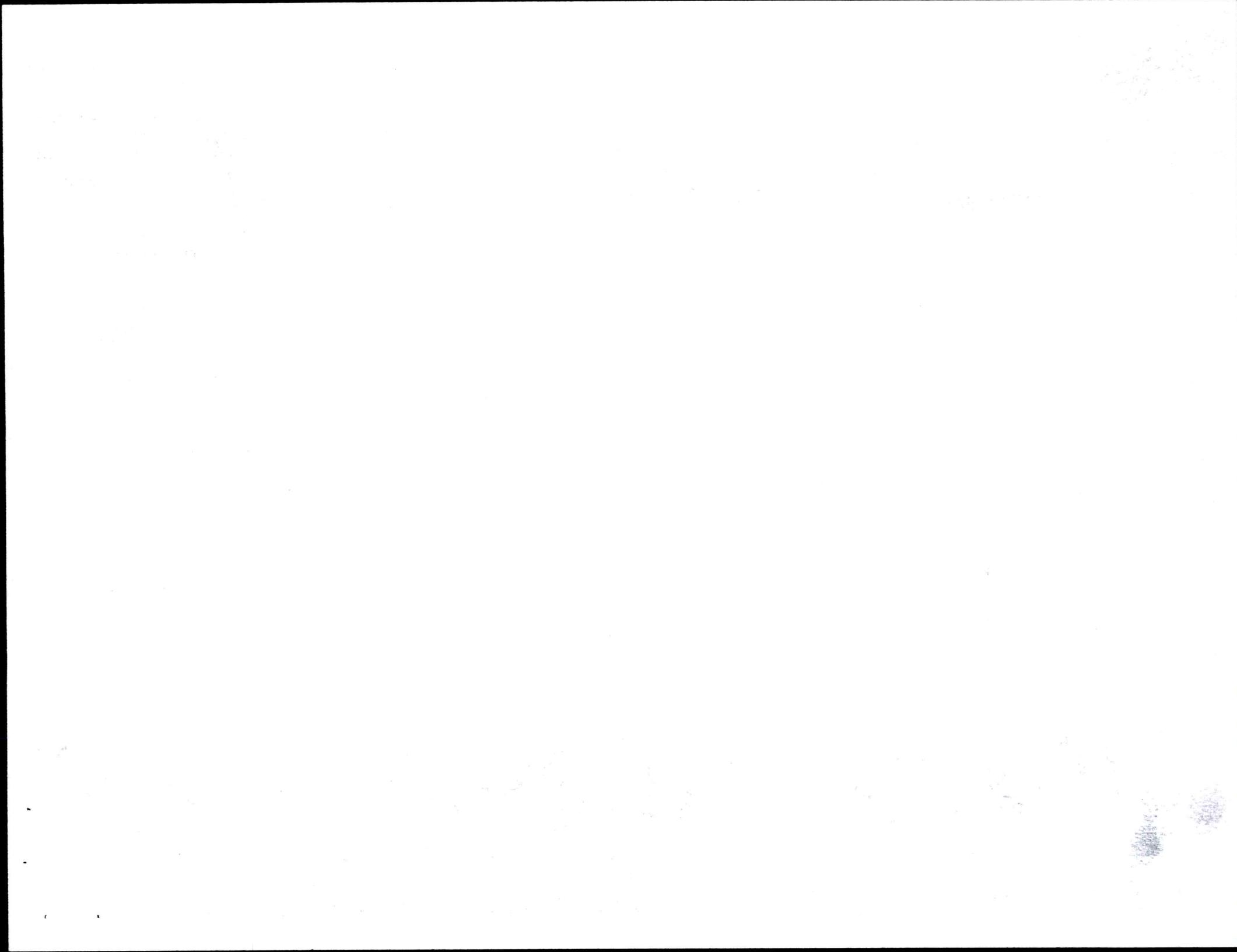


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① PY46 22 Jan 24

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Opr. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 <b>N/A</b> Quality Inspection & Review  Confirmation Reqd(Milestone )	TMI: <u>N/A</u> Cal Due: <u>N/A</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>30Sep2025</u> TMI: <u>0692</u> Cal Due: <u>30Sep2025</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	<u>33</u>	STR-1 DIS-4H (SP) ⑥	<u>22JUN24</u>	PVb
1000	<b>QUALITY1</b>  Quality Inspection & Review  <b>N/A</b> Quality Inspection & Review  Confirmation Reqd(Milestone )	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: <u>1056</u> Cal Due: <u>31May2024</u> Record Length Gage Information: TMI: <u>0889D</u> Cal Due: <u>30Sep2024</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30Sep2024</u>	<u>428</u>	LT-4H ⑤	<u>22JUN24</u>	PVb CB58 SS44

Notes:

N/AN/AN/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A	N/A	N/A	N/A	N/A
1050	QUALITY1  Quality Inspection & Review    Quality Inspection & Review  Confirmation Reqd(Milestone )	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	384	SCR - HFT 1 (TT) DL - III (TT) BP - III MP - III FB - II VD - HFT EW - HFT 1 DIS - HFT II SCR - II FM - III PBC - I  44	22 Jan 24	XN26 SV43
1100	CATASY01  Catheter Assembly 1    Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initial/Date): XC31 22 JAN 24	N/A	N/A	22 JAN 24	XC31
Notes:						
N/A						
N/A						
N/A						

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**Production Order: 500000297257**



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**Material: SA0155-01 Rev F**

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
1150	<b>PACKINT1</b> Packing assembly  Package Confirmation Reqd(Milestone )	Package Package, Label, and Ship Finished Parts	-384	○	23 Jan 24	AP10

**Notes:**

N/A AP10 23 Jan 24)

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**Material: SA0155-01 Rev F**

Batch Number: 0000297257

By: AP10

Date: 23 Jan 24

Reviewed By:

RB29

Date:

23 JAN 24

Notes:

N/A AP10 23 Jan 24

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**PO #:** 500000297257

OP #: 750 Shift #: 1st

**Document No: 6102646**  
**Rev: A**  
**Document Type: Manufacturing Form**  
**Title: SA0155-01 Tipping Rework Form**

Total Parts Reworked:		77	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		12
DIM07 US / WC	DIM07 Undersized (Window Closed)		3
EH	Exposed Hypotube		16
N/A	Glue, stopper		46
Inspected By (Sign and Date):		Hr 36 22 Jan 24	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

**Data Uploaded for Engineering Review (Check):**



**PO #:** 500000297257

OP #: 900 Shift #: 1st

Document No: 6102619

Rev: B

**Document Type: Manufacturing Form**

**Title: SA0155-01 Dimensional/Visual Rework Form**

Total Parts Reworked:			
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		① 32 33
EW	Exposed Wire	N/A	N/A
MP	Micropores	N/A	N/A
SCR	Scratch		71
SKV	Skive Marks	N/A	N/A
VD	Voids	1	11
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized	1	21
DIM06 OS	DIM06 OD Oversized	N/A	N/A
DIM09 US	DIM09 OD Undersized	N/A	N/A

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

① PY46 23 Jan 24

**Data Uploaded for Engineering Review (Check):**

PRODUCTION ORDER# 50000297257

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm12036	N/A	11:15AM	190F	KL4S	21 JAN 24	12:28PM	190F	KL4S	21 JAN 24	25
Tm10409	N/A	12:00 PM	190F	KL4S	21 JAN 24	1:10 PM	190F	KL4S	21 JAN 24	37
Tm12036	N/A	12:30PM	190F	KL4S	21 JAN 24	1:40PM	190F	KL4S	21 JAN 24	23
Tm10409	N/A	1:35PM	190F	BD64	21 Jan 24	2:45PM	190F	BD64	21 Jan 24	26
Tm12036	N/A	2:25PM	190F	BD64	21 Jan 24	3:35PM	190F	BD64	21 Jan 24	24
Tm10409	N/A	3:00PM	190F	BD64	21 Jan 24	4:10PM	190F	BD64	21 Jan 24	29
Tm10409	N/A	4:40am	190F	SSH4	22 Jan 24	5:50am	190F	SSH4	22 Jan 24	57
Tm12036	N/A	5:30am	190F	SSH4	22 Jan 24	6:40am	190F	SSH4	22 Jan 24	43
Tm10409	N/A	6:00am	190F	SSH4	22 Jan 24	7:10am	190F	SSH4	22 Jan 24	40
Tm12036	N/A	6:40AM	190F	SSH4	22 Jan 24	7:50AM	190F	SSH4	22 Jan 24	67
Tm12036	N/A	8:20am	190F	SSH4	22 Jan 24	9:30am	190F	SSH4	22 Jan 24	44
Tm10409	N/A	8:55am	190F	SSH4	22 Jan 24	10:05am	190F	SSH4	22 Jan 24	25
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000297257

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	4:10pm	430	cm99	20Jan24	6:22pm	415	cm99	20Jan24	16
Tm10942	44	6:46AM	430	AM47	21JAN24	6:58 AM	415	AM47	21JAN24	16
Tm10942	44	7:35am	430	cm99	21Jan24	7:47am	415	cm99	21Jan24	16
Tm10942	44	8:09 am	430	fv16	21Jan24	8:21 am	415	fv16	21Jan24	16
Tm10942	44	8:39am	430	AM47	21JAN24	8:51AM	415	AM47	21JAN24	16
Tm10942	44	9:42 AM	430	AL67	21 Jan 24	9:54 AM	415	AL67	21 Jan 24	16
Tm10942	44	10:17AM	430	fv16	21Jan24	10:29AM	415	fv16	21Jan24	16
Tm10942	44	10:31am	430	cm99	21Jan24	10:43am	415	cm99	21Jan24	16
Tm10942	44	11:05AM	430	CD19	21Jan24	11:17AM	415	CD19	21Jan24	16
Tm10942	44	① 12:10PM +2:10PM	430	CD19	21Jan24	12:22PM	415	CD19	21Jan24	16
Tm10942	44	1:22PM	430	KL45	21JAN24	1:34PM	415	KL45	21JAN24	16
Tm10942	44	1:45 pm	430	CB58	21Jan24	1:57pm	415	CB58	21Jan24	16

① cm99 21Jan24



**Document No:** 5105589  
**FM5104665 Rev:** C  
**Document Type:** Manufacturing Form  
**Title:** SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000297257

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FM5104665 Rev: C  
Document Type: Manufacturing Form  
Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000297257

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	6:22pm	430	RV16	20Jan24	6:34pm	415	RV16	20Jan24	16
TM10745	44	7:00 AM	430	AM47	21JAN24	7:12 AM	415	AM47	21JAN24	16
TM10745	44	7:25 AM	430	AM47	21JAN24	7:37 AM	415	AM47	21JAN24	16
TM10745	44	7:56am	430	cm99	21Jan24	8:08am	415	cm99	21Jan24	16
TM10745	44	8:27am	430	cm99	21Jan24	8:39am	415	cm99	21Jan24	16
TM10745	44	9:27 AM	430	AL67	21Jan24	9:39 AM	415	AL67	21 Jan 24	16
TM10745	44	10:00 AM	430	AM47	21JAN24	10:12 AM	415	AM47	21JAN24	16
TM10745	44	10:43am	430	cm99	21Jan24	10:55am	415	cm99	21Jan24	16
TM10745	44	11:34am	430	cm99	21Jan24	11:46am	415	cm99	21Jan24	16
TM10745	44	11:52 AM	430	RV16	21Jan24	12:04PM	415	RV16	21 Jan 24	16
TM10745	44	1:10PM	430	CD19	21Jan24	1:22PM	415	CD19	21Jan24	16
TM10745	44	1:30pm	430	CB58	21Jan24	1:42pm	415	CB58	21Jan24	16

① RV16 21Jan24



**Document No:** 5105589  
**FM5104665 Rev:** C  
**Document Type:** Manufacturing Form  
**Title:** SA0155-01 Reflow Log Sheet Form

**PRODUCTION ORDER#** 50000297257

OP 400

Page 1 of 1

Status CURRENT Effective 5/8/2023



Document No: 5106073

Rev: E

Document Type: Manufacturing Form

Title: SA0155-01 Visual Rework Form

PO #: 500000297257

OP #: 500 Shift #: 3d

Total Parts Reworked:		150	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	
EH	Exposed Hypotube		45
EW	Exposed Wire		98
MP	Micropores	N/A	N/A
SCR	Scratch		2
SKV	Skive Marks		5
VD	Voids		12
N/A	N/A	N/A	N/A

Inspected By (Sign and Date):

veoq, AR02 21 Jan 24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):



Document No: 6102646  
Rev: A  
Document Type: Manufacturing Form  
Title: SA0155-01 Tipping Rework Form

PO #: 560 000 297 257 OP #: 750 Shift #: 3

Total Parts Reworked:		48	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		15
DIM07 US / WC	DIM07 Undersized (Window Closed)		8
EH	Exposed Hypotube		18
GD	Glue Damage		7
Inspected By (Sign and Date):		IL83 21Jan24	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):  



Document No: 6102619  
Rev: B  
Document Type: Manufacturing Form  
Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 50000297257 OP #: 900 Shift #: 3

Total Parts Reworked:		100	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	~14	~14
EH	Exposed Hypotube	~14	N/A
EW	Exposed Wire		30
MP	Micropores	~14	N/A
SCR	Scratch		50
SKV	Skive Marks		5
VD	Voids		15
DIM01 US	DIM01 OD Undersized	~14	N/A
DIM06 US	DIM06 OD Undersized	~14	N/A
DIM06 OS	DIM06 OD Oversized	~14	N/A
DIM09 US	DIM09 OD Undersized	~14	N/A
Inspected By (Sign and Date):		KX54 LS 40 MC17	21 Jan 24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):

①CB58 21Jan24

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Page 1 of 1

Status CURRENT Effective 5/8/2023



Document No: 5106073  
Rev: E  
Document Type: Manufacturing Form  
Title: SA0155-01 Visual Rework Form

PO #: 500000297257 OP #: 500 Shift #: 1st

Total Parts Reworked:		35	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		5
EW	Exposed Wire		26
MP	Micropores	N/A	N/A
SCR	Scratch	N/A	N/A
SKV	Skive Marks		2
VD	Voids		2
N/A	N/A	N/A	N/A

Inspected By (Sign and Date):

HG1

VC 09

22 Jan 24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):

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MEDICAL  
INSTITUTE

**CONTROLLED COPY** DEVIATION AUTHORIZATION FORM Extension to 24 SEP 2015  
\* See attached email extension to 24 SEP 2015  
1502  
24 AUG 23  
23 OCT 2015  
**DEVIATION AUTHORIZATION FORM** Extension to 24 SEP 2015  
1502

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MEDICAL

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**\* See attached email extension to 24 SEP 23**

24 AUG 23  
1512  
24 AUG 23

LA UNION FURNITURE CO. LTD. 2150-2153

**Requestor Name:** Udhesh Kapadnis

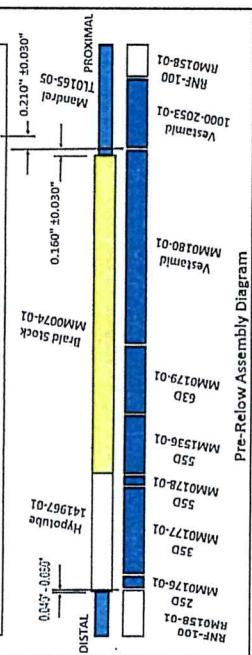
Document Number Affected	Revision
3107610	L

Deviation From:

QIP3107610, Section 8.0 Inspection Requirements  
(Supplemental Visual Inspection) OP 1050:  
Current QIP3107610 does not state to inspect for the  
correct extrusion configuration.

...בְּנֵי יִשְׂרָאֵל וְבְנֵי יִהוָה אֱלֹהֵינוּ.

FEP RM0362-01 or 1000-1153-01



## Deviation To:

This DA allows addition inspection for correct assembly of extrusion material MM0179-01 and MM1536-01 during performing QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050. See instructions attached to this DA.

**Justification:** Recently it has been found that operators are incorrectly assembling MM0179-01 and MM1536-01. The event documents in NC-26390, and NC-26426. Only few of experienced inspectors can detect finished unit that contains incorrect extrusion configuration, and inexperienced inspectors may not which potential non-conformance unit sent to customer. Interim correction action has been implemented at OP 250, 300, 350 to detect unit built with out of oriented extrusions. This DA is adding another layer of inspection at final QC inspection to avoid incorrect assembly defects.

Part Number Affected	Revision	
SA0155-01	H	
Start Date:	End Date:	Lot Number:
26 Jul 2023	25 Aug 2023	N/A

## Risk Assessment:

Is there any potential risk(s) that may occur as a result of the proposed deviation including the following:

Control Plans   
Details (if any): N/A

If yes to any of the above, what controls are being put in place to mitigate the risk.

<b>Corrective Action Required:</b>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<b>If no, explain:</b> No corrective action is required for this event as there are no changes to the current process, consumption of material, or how the product is produced. This added inspection guidelines are to avoid incorrect extrusion assembly defects.		

**If no, explain:** No corrective action is required for this event as there are no changes to the current process, consumption of material, or how the product is produced. This added inspection guidelines are to avoid incorrect extrusion assembly defects.

**Training Required:**  Yes  No **If no explain:**

① UK55, 23JW 2023



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## Group Training Record

### Description/Objectives of Training:

DA- Inspection at final QC, Op#1050.

#### Procedure:

- 100% inspection at Op#1050 per the instructions below.
- Inspect 1 part at a time.
- Inspection is focused on the correct MM0179-01 and MM1536-01 assembly.
- Use the example MM0179-01 and ~~MM1536-02~~ fixture for inspection. (See image 1)  
**① MM0179-01** **10AUG23** **1512** **Type Connection**

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Image-1

#### Step 1:

- Visually locate the MM0180-01 (Vestamid) transition to MM0179-01 on the completed part approximately 9.75" from the distal end using magnification light 2.25X minimum.
- Align the fixture MM0179-01 extrusion proximal end to the Vestamid transition on completed part.  
(See image 2)



Image-2

- Visually verify the MM0179-01 distal end of the fixture is approximately at the same location on the completed part. (See image 3)

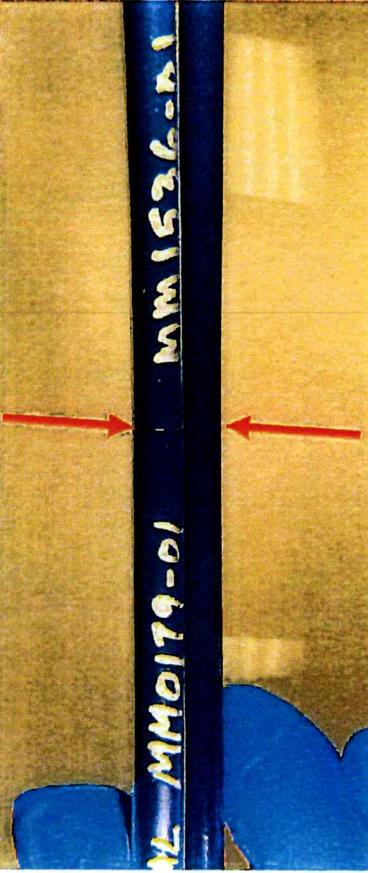


Image-3

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
- If the part transition is aligned, move to Step 2.

## **CONTROLLED COPY**

### **Step 2:**

- Visually verify the MM1536-01 distal end of the fixture is approximately at the same location on the completed part. (See image 4)

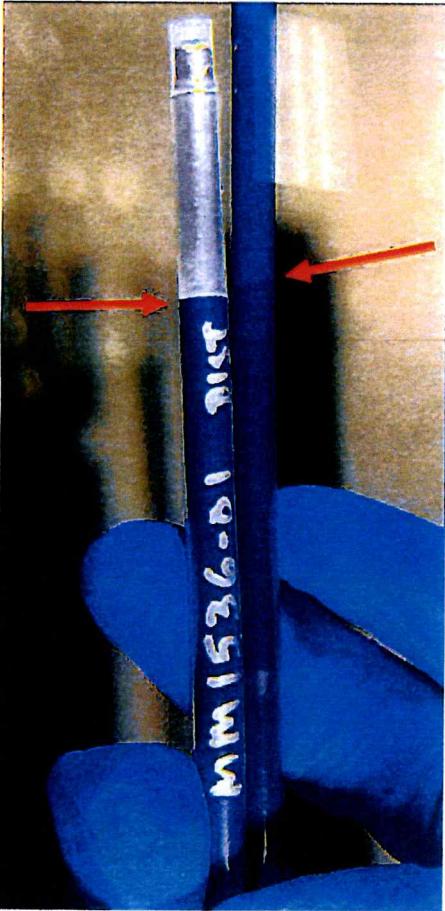


Image- 4

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
- If the part transition is aligned, the part passes inspection.
- Use Image 5 as a guide for GOOD and BAD extrusion transition alignment.

<b>1</b>	<b>MM0179-01</b>	<b>MM1536-01</b>
<b>GOOD PART</b>		
<b>2</b>	<b>MM1536-01</b>	<b>MM0179-01</b>
		<b>MM0179-01 and MM1536-01 Wrong Order - BAD PART</b>
<b>3</b>	<b>MM0179-01</b>	<b>MM0179-01</b>
		<b>Two MM0179-01 - BAD PART</b>
<b>4</b>	<b>MM1536-01</b>	<b>MM1536-01</b>
		<b>Two MM1536-01 - BAD PART</b>

Image - 5

Title	Approval Name	Approval Signature	Date
Mgr. Quality Engineering	Hai Nguyen		25 Jul 2023
Mgr. Manufacturing Engineering	Jake Stanislawski		25 Jul 2023
Mgr. Operations	Matthew Benson		25 Jul 2023

FM0002.RevF

Deviation Authorization

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Edits to 14 Mar 2023 12/12/2023  
Edits to 13 Feb 2023 12/22/2023  
**CONTROLLED COPY** DEVIATION AUTHORIZATION NUMBER: DA2564

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## DEVIATION AUTHORIZATION FORM

Requestor Name: Krishna Selvaraj			
Document Number Affected	Revision		
Doc #3005206 (MPI0238)	BP		
Deviation From:	Deviation To:		
<b>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</b> Using a laser micrometer, check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.	<b>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</b> Using a laser micrometer at <b>OPER900 (TMI0700-01)</b> , check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.		
<b>Justification:</b> TMI0602 lasermic which is currently used in SA0155-01 Flex commander product at OPER850 for Dim 6 inspection has mechanical failure and confirmed as not usable. TMI0700-01 lasermic is used at OPER900 for 100% inspection for Dim 1, Dim 6 and Dim 9. Since TMI0700-01 is already qualified to inspect Dim 6 per ES0647: Laser micrometer equivalency test, there is no additional risk in using TMI0700-01 for OPER850 Dim 6 inspection till TMI0602 issue is resolved.			
Part Number Affected	Revision		
SA0155-01	H		
Start Date:	End Date:	Lot Number:	
16 Nov 23	15 DEC 23	N/A	
<b>Risk Assessment:</b> Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: Control Plans <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No FMEA's <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Validations <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Details (if any): N/A			
If yes to any of the above, what controls are being put in place to mitigate the risk - N/A			
<b>Corrective Action Required:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
<b>If no, explain:</b> This is a temporary change to use TMI0700-01. DA will be removed once the lasermic TMI0602 issues are resolved and accepted for usage.			
<b>Training Required:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, explain:</b> N/A			
Title	Approval Name	Approval Signature	Date
Engineering Manager	Jake Stanislowski		16 Nov 2023
Quality Manager	Jay Zabel		16 Nov 2023
Operations Manager	Matthew Benson		16 Nov 2023

Maximum Force Reached During Tensile Test (10 samples accepted from final inspection for each lot shall be selected and tensile tested)																
Sample # -->	1	2	3	4	5	6	7	8	9	10	Avg	St Dev	K	Calculated Lower bound	Min Spec	Pass / Fail
Seg A	27.55	24	27.84	26.1	25.36	25.52	25.15	27.34	25.06	22.76	25.668	1.6067621	4.378	18.6335955	8.542	PASS
Seg B	71.99	70.88	62.95	64.9	58.14	61.93	64.84	64.84	62.64	65.32	64.843	4.0771478	3.981	48.6118745	8.542	PASS
Seg C	81.69	72.17	77.11	77.01	74.28	75.54	74.88	75.87	76.26	78.12	76.293	2.5263502	2.911	68.9387944	8.542	PASS

All Force Values are recorded in Pound-Force and Distance is in Inches  
Specification for lower bound is 38N was converted to 8.542Lbf  
First Peak Force was collected during test and has been included in the raw data file ( this information will not be captured / summarized in the DA due to it is not required to used for DA acceptance.

### EDW Commander Flex - Bend and Tensile Strength Testing

LOT #: 500000297257

Date: 23JAN24

Inspector Name: Andrew Wipf

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24


23Jan24