

Production Order: 500000296543



Production Order Document
Production Order Qty: 500

PC
Sheet: 1 of 1

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 	<p>Kitting Devices Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>HP02 8:30am 18 Jan 24</u> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>Am 68 6:30 am 19 Jan 24</u> Record Dryer Shelf #: <u>n/a</u></p> <table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>1000-2053-01</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>000027880</u></td> <td><u>500</u></td> </tr> <tr> <td>MM1537-02</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>0000288401</u></td> <td><u>500</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	1000-2053-01	A <u>A</u>	PC	500	<u>000027880</u>	<u>500</u>	MM1537-02	A <u>A</u>	PC	500	<u>0000288401</u>	<u>500</u>	N/A	N/A	17 JAN 24 22 Jan 24 GJES
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																		
1000-2053-01	A <u>A</u>	PC	500	<u>000027880</u>	<u>500</u>																		
MM1537-02	A <u>A</u>	PC	500	<u>0000288401</u>	<u>500</u>																		

Notes: JA 2484, 2564

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	RM0158-01	E	<u>E</u>	PC	200	<u>58497</u>	<u>N/A</u>	<u>N/A</u>		
		TL0167-02	E	<u>E</u>	PC	70	<u>N/A</u>	<u>N/A</u>	<u>Bulk</u>		
		TL0165-05	J	<u>J</u>	PC	5	<u>N/A</u>	<u>N/A</u>	<u>Bulk</u>		
		TL0165-03	J	<u>J</u>	PC	5	<u>N/A</u>	<u>N/A</u>	<u>Bulk</u>		
		141967-01	02	<u>02</u>	PC	500	<u>85500</u>	<u>N/A</u>	<u>525</u>	<u>N/A</u>	<u>N/A</u>
		RM7349-02	C	<u>c</u>	PC	543	<u>82858</u>	<u>N/A</u>	<u>600</u>	<u>N/A</u>	
		RM7348-01	C	<u>c</u>	PC	500	<u>82884</u>	<u>82883</u>	<u>450</u>	<u>150</u>	

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	RM4001-01	B	<u>B</u>	PC	125	<u>82461</u>	<u>100</u>			
		RM0607-01	D	<u>D</u>	PC	56	<u>78322</u>	<u>N/A</u>			
		RM0498-01	C	<u>C</u>	PC	500	<u>0000275491</u>	<u>465</u>			
		RM0362-01	E	<u>E</u>	PC	594	<u>85888</u>	<u>600</u>			
		RM0009-04	I	<u>I</u>	PC	1	<u>① 82991</u> <u>82971</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
		RM0009-04	I	<u>I</u>	PC	1	<u>82971</u>	<u>Bulk</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
		MM1538-01	A	<u>A</u>	PC	500	<u>0000278970</u>	<u>500</u>			
		MM1537-01	A	<u>A</u>	PC	1000	<u>0000284709</u>	<u>1000</u>			

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	MM1536-01	B	<u>B</u>	PC	500	<u>0000281413</u>	<u>60</u>		
		MM0180-01	E	<u>E</u>	PC	500	<u>0000281412</u>	<u>500</u>		
		MM0179-01	D	<u>D</u>	PC	500	<u>0000271063</u>	<u>40</u>		
		MM0178-01	E	<u>E</u>	PC	500	<u>0000282489</u>	<u>500</u>		
		MM0177-01	C	<u>C</u>	PC	500	<u>0000276172</u>	<u>N/A</u>		
		MM0176-01	D	<u>D</u>	PC	500	<u>0000272345</u>	<u>500</u>		
		MM0074-01	G	<u>G</u>	PC	500	<u>0000276174</u> <u>0000271050</u> <u>① 000027</u>	<u>40</u>		
		MM0177-01	C	<u>C</u>	PC	500	<u>0000284208</u>	<u>500</u>		
		MM0176-01	D	<u>D</u>	PC	500	<u>0000268423</u>	<u>40</u>		

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 Perform Line Clearance and Heat Gun Setting	500	0	19Jan24 CB38	
	Line Clearance					
	Confirmation Rreq(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	19Jan24 AM47 SN67	YK40 SP34 JC92
	Major and Minor Mandrel Assembly					
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	500	0	19Jan24 MC17	MY150
	Loading Braid Stock					
	Confirmation Reqd(Milestone)					
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	500	0	19Jan24 PY67 PL22 TRN R47	CY97
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 Confirmation Reqd(Milestone)	Insert Cut Hypo Tube	500	0	19Jan24	Pizz AIGS
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	19Jan24	CX63 B064

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	 Load Tubing Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
400	CATASY01 Catheter Assembly 1 Reflow Confirmation Reqd(Milestone)		500	0	19Jan24	RL47 4L67 SNL67
450	CATASY01 Catheter	FEP Removal	500	0	19Jan24	AM47 YK110
Notes:						
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	Assembly 1 FEP Removal Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
500	CATASY01 Catheter Assembly 1 In-process Inspection and Rework Confirmation Reqd(Milestone)	In-process Inspection and Rework Material Consumed: Part #: 1000-1153-01 Batch #: 87655 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	486	EW-14144 1111 14	20Jan24	LL61 AR02 SXII CB81
N/A	N/A	N/A N/A N/A N/A	N/A	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
550	CATASY01 Catheter Assembly 1 	Remove Heat Shrink & Mandrel Remove Heat Shrink & Mandrel Confirmation Reqd(Milestone)	478	WATT-4H III ⑧	20Jan24	FBO1 CDP TRN MHID VA96
600	CATASY01 Catheter Assembly 1 	Distal Tip Assembly	478	0	20Jan24	FBO1 PH59 MHID

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	Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
650	CATASY01 Catheter Assembly 1 	Loading Heat Shrink	478	0	20Jan24	FB01 LH45
	Loading Heat Shrink					
	Confirmation Reqd(Milestone)					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: 0936A Cal Due: 31MAY24 TMI: 2083C Cal Due: 31MAY24 TMI: 0386 Cal Due: 31MAY24 TMI: 0521 Cal Due: 31MAY24 Tipping	478	0	20Jan24	IC83
Notes:						
N/A						
N/A						
N/A						

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Op. 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 	<p>Tip Inspection/ Flash Removal</p> <p>Material Consumed:</p> <table> <tr> <td>Part #: RM4001-01</td> <td>Batch #:</td> <td>82461</td> <td>Qty:</td> <td>N/A</td> </tr> <tr> <td>Part #: RM0607-01</td> <td>Batch #:</td> <td>78322</td> <td>Qty:</td> <td>N/A</td> </tr> <tr> <td>Part #: N/A</td> <td>Batch #:</td> <td>N/A</td> <td>Qty:</td> <td>N/A</td> </tr> <tr> <td>Part #: N/A</td> <td>Batch #:</td> <td>N/A</td> <td>Qty:</td> <td>N/A</td> </tr> <tr> <td>Part #: N/A</td> <td>Batch #:</td> <td>N/A</td> <td>Qty:</td> <td>N/A</td> </tr> </table>	Part #: RM4001-01	Batch #:	82461	Qty:	N/A	Part #: RM0607-01	Batch #:	78322	Qty:	N/A	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	475	EH-111 ③	20Jan24	JL83 BE60
Part #: RM4001-01	Batch #:	82461	Qty:	N/A																											
Part #: RM0607-01	Batch #:	78322	Qty:	N/A																											
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																											
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	472	ACD-111 ③	20Jan24	SN67 BD64 KL45																									

Notes:

N/A

N/A

N/A

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N/A	Major Mandrel Removal Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
850	CATASY01 Catheter Assembly 1  Cut to Length Confirmation Reqd(Milestone)	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	472	0	20Jan24	AL42 TRN KL45
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:						
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	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: 0700-01 Cal Due: 31MAY2024 TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A Material Consumed: Part #: 1000-1153-01 Batch #: 87655 Qty: N/A Part #: RM0158-01 Batch #: 58497 Qty: N/A Part #: RM4001-01 Batch #: 82461 Qty: N/A Part #: RM0607-01 Batch #: 78322 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A</p>	451	FM-11 (SP) DL-111 (SP) DEL-4M111 SKU-11 (TT) EW-1111 SCR-11 21	20Jan24	MC17 TRN 6155 KT217 KX54 DLO7
950	QUALITY1 Quality Inspection & Review	<p>Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: N/A Cal Due: N/A Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

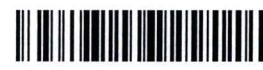
N/A

N/A

N/A

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N/A	 Quality Inspection & Review	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>30 Sep 2025</u> TMI: <u>0692</u> Cal Due: <u>30 Sep 2025</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	441	DIS-44111 STR-111 <u>10</u>	20 Jan 24	AL42 TRN KLLS
1000	 QUALITY1	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: <u>1056</u> Cal Due: <u>31 May 2024</u> Record Length Gage Information: TMI: <u>0889</u> D Cal Due: <u>30 Sep 2024</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30 Sep 2024</u>	432	LT-11K1111 <u>9</u>	20 Jan 24	CB58

Notes:

N/A

N/A

N/A

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N/A	N/A	N/A	N/A	N/A	N/A	N/A
1050	QUALITY1 Quality Inspection & Review 	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	404	SCR - HET 1 CFK - IIII DIS - IIII BP - II PBC - II PM - II EW - II Del - I FL - I ET - I DNT - I Mar - I GNII - I (28)	22 Jan 24	XN26 SV43
1100	CATASY01 Catheter Assembly 1 	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): GS85 22 Jan 24	N/A	N/A	22 Jan 24	GS85
Notes:						
N/A						
N/A						
N/A						

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N/A	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
1150	PACKINT1 Packing assembly  Package Confirmation Reqd(Milestone)	Package Package, Label, and Ship Finished Parts	404	0	23 Jan 24	A010

Notes:

N/A A010 23 Jan 24

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Batch Number: 0000296543

By: AP10

Date: 23 Jan 24

Reviewed By:

RB29

Date:

23 JAH 24

Notes:

N/A AP10 23 Jan 24

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Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000296543

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	8:28AM	430	RL47	19 Jan 24	8:40 AM	415	RL47	19 Jan 24	16
TM10745	44	9:15AM	430	PV16	19 Jan 24	9:27AM	415	PV16	19 Jan 24	16
TM10745	44	9:37AM	430	PV16	19 Jan 24	9:49AM	415	PV16	19 Jan 24	16
TM10745	44	10:08AM	430	AL67	19 Jan 24	10:20 AM	415	AL67	19 Jan 24	16
TM10745	44	11:15AM	430	RL47	19 Jan 24	11:27AM	415	RL47	19 Jan 24	16
TM10745	44	11:43AM	430	RL47	19 Jan 24	11:55AM	415	RL47	19 Jan 24	16
TM10745	44	12:21pm	430	YK40	19 Jan 24	12:33pm	415	YK40	19 Jan 24	16
TM10745	44	1:28PM	430	PL22	19 Jan 24	1:40PM	415	PL22	19 Jan 24	16
TM10745	44	1:47pm	430	SN67	19 Jan 24	1:59pm	415	SN67	19 Jan 24	16
TM10745	44	2:26 PM	430	AL67	19 Jan 24	2:38 PM	415	AL67	19 Jan 24	16
TM10745	44	3:09PM	430	SN67	19 Jan 24	3:21pm	415	SN67	19 Jan 24	16
TM10745	44	4:35pm	430	JG92	19 Jan 24	4:47pm	415	JG92	19 Jan 24	16

(1) RL47 19Jan24



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

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Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10942	44	9:26AM	430	YK40	19 Jan 24	9:38AM	415	YK40	19 Jan 24	16
TM10942	44	9:48 AM	430	RV16	19 Jan 24	10:00 AM	415	RV16	19 Jan 24	16
TM10942	44	10:22 AM	430	RL47	19 Jan 24	10:34 AM	415	RL47	19 Jan 24	16
TM10942	44	10:34 AM	430	SD34	19 Jan 24	10:46 AM	415	SD34	19 Jan 24	16
TM10942	44	11:00 AM	430	AL67	19 Jan 24	11:12 AM	415	AL67	19 Jan 24	16
TM10942	44	11:33 AM	430	AL67	19 Jan 24	11:45 AM	415	AL67	19 Jan 24	16
TM10942	44	12:02 PM	430	RV16	19 Jan 24	12:14 PM	415	RV16	19 Jan 24	16
TM10942	44	1:17 PM	430	KL45	19 JAN 24	1:29 PM	415	KL45	19 JAN 24	16
TM10942	44	1:59 PM	430	AL67	19 Jan 24	2:11 PM	415	AL67	19 Jan 24	16
TM10942	44	2:41 PM	430	SD34	19 Jan 24	2:53 PM	415	SD34	19 Jan 24	16
TM10942	44	4:55 PM	430	JG92	19 Jan 24	5:07 PM	415	JG92	19 Jan 24	16
TM10942	44	5:38PM	436	SN67	19 Jan 24	5:50PM	415	SN67	19 Jan 24	16



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

PRODUCTION ORDER# 50000296543

OP 400

~~Demographic~~

① Cm99 20Jan24

PRODUCTION ORDER# 500000296543

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM12036	N/A	11:20 AM	190F	KL4S	19JAN24	12:30 PM	190F	KL4S	19JAN24	34
TM10409	N/A	12:15 pm	190F	SN67	19 Jan 24	1:25pm	190F	SN67	19 Jan 24	46
TM10409	N/A	1:30PM	190F	BD64	19Jan24	2:40PM	190F	BD64	19Jan24	30
TM12036	N/A	1:55PM	190F	BD64	19Jan24	3:05PM	190F	BD64	19Jan24	36
TM10409	N/A	3:00 PM	190F	BD64	19Jan24	4:10PM	190F	BD64	19Jan24	56
TM10409	N/A	4:15PM	190F	BD64	19Jan24	5:25PM	190F	BD64	19Jan24	24
TM12036	N/A	5:15PM	190F	BD64	19Jan24	6:25PM	190F	BD64	19Jan24	27
TM10409	N/A	4:50AM	190F	KL4S	20JAN24	6:05AM	190F	KL4S	20JAN24	45
TM10409	N/A	6:55AM	190F	AL42	20 JAN 24	8:05 AM	190F	AL42	20 JAN 24	21
TM12036	N/A	8:00 AM	190F	KL4S	20JAN24	9:10 AM	190F	KL4S	20JAN24	43
TM10409	N/A	8:25AM	190F	KL4S	20JAN24	9:45 AM	190F	KL4S	20JAN24	27
TM12036	N/A	9:34AM	190F	KL4S	20JAN24	10:44 AM	190F	KL4S	20JAN24	35
TM10409	N/A	10:09 AM	190F	KL4S	20JAN24	11:19 AM	190F	KL4S	20JAN24	48



500000296543

PO #:

500000296543

OP #: 500

Shift #: 3rd

Document No: 5106073

Rev: E

Document Type: Manufacturing Form

Title: SA0155-01 Visual Rework Form

Total Parts Reworked:		108	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		5
EH	Exposed Hypotube		30
EW	Exposed Wire		60
MP	Micropores		1
SCR	Scratch	N/A	N/A
SKV	Skive Marks		3
VD	Voids		10
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		LLCPL, SXII, 2546.AR02	19 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):

①CB58 19 Jan 24



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

PO #: 500000296543 **OP #:** 500 **Shift #:** 3rd

Total Parts Reworked:		40	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		5
EW	Exposed Wire	+ + + +	27
MP	Micropores	N/A	N/A
SCR	Scratch		1
SKV	Skive Marks		2
VD	Voids		3
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		CB81, APR 24, LS46	
Note: Indicate tally marks in groups of 5. Crosses indicate non-reworkable defects.			

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 #: 500000296543

OP #: 750 Shift #: 3

Total Parts Reworked:		39	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		3
DIM07 US / WC	DIM07 Undersized (Window Closed)	NA	NA
EH	Exposed Hypotube		17
GD/AB	Glue Damage / Air Bubbles		19
Inspected By (Sign and Date):		B160	20 JAN 2024

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 #: 500000296543 OP #: 900 Shift #: 3

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

Total Parts Reworked:		193	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		6
EH	Exposed Hypotube		9
EW	Exposed Wire		82
MP	Micropores		57
SCR	Scratch		83
SKV	Skive Marks		9
VD	Voids		16
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		10
DIM06 OS	DIM06 OD Oversized		6
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		<u>DL07, KX54</u>	<u>20 Jan 24</u>

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: 6102646
Rev: A
Document Type: Manufacturing Form
Title: SA0155-01 Tipping Rework Form

PO #: 500 000 246 543 OP #: 750 Shift #: 3

Total Parts Reworked:		49	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)	XX XX XX	17
DIM07 US / WC	DIM07 Undersized (Window Closed)	XX	7
EH	Exposed Hypotube	XX XX XX	15
GD	Glue Damage	XX XX	10
Inspected By (Sign and Date):		IC83 20 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): X

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Exten
DNet

Investor Name: Udhesh Kanadnis
Address to 316-0033 D.E.A.L.
Date: 22-08-1978

CONTROLLED COPY DEVIATION AUTHORIZATION FORM NUMBER: 2484
* See attached email extension to 24 SEP 23
TS
24 AUG 23
28 SEP 23
EXPIRES TO 23 OCT 2023
24 SEP 23

CONTROLLED COPY/DEVIATION AUTHORIZATION NUMBER: 2484

* See attached email extension to JSEI-13

24 AUG 73 528
23 Oct 2023

h Kanadnis

3107610

Document Number Affected	Revision
3107610	L
<p>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.</p> <p>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.</p>	<p>Wire Out Hole</p> <p>0.157"-0.158"</p> <p>0.160"-0.030"</p> <p>Hypothube</p> <p>Dome Seal</p> <p>PROXIMAL</p> <p>DISTAL</p> <p>MM0074-01</p> <p>MM1536-01</p> <p>MM1536-01</p> <p>MM0179-01</p> <p>FEP MM0179-01 or 1000-1-153-01</p> <p>Pre-Relief Assembly Diagram</p>

Deviation From:

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

Wire Out Hole

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

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

Control Plans Yes No FMEA's Yes No Validations Yes No

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

Corrective Action Required:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
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:	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	If no, explain:	

① UK55, 23JW 2023



DA | DA | 2484
2468 | ①

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 **MM1536-01** **Type Connection TS12** **10AUG23**



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)

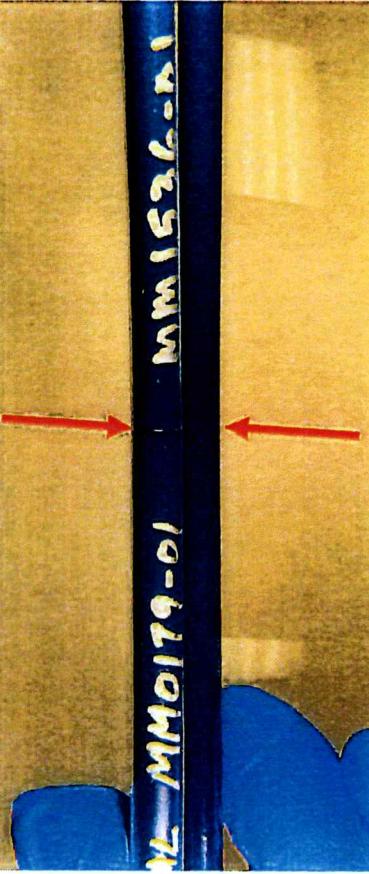


Image-3

- 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.

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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)

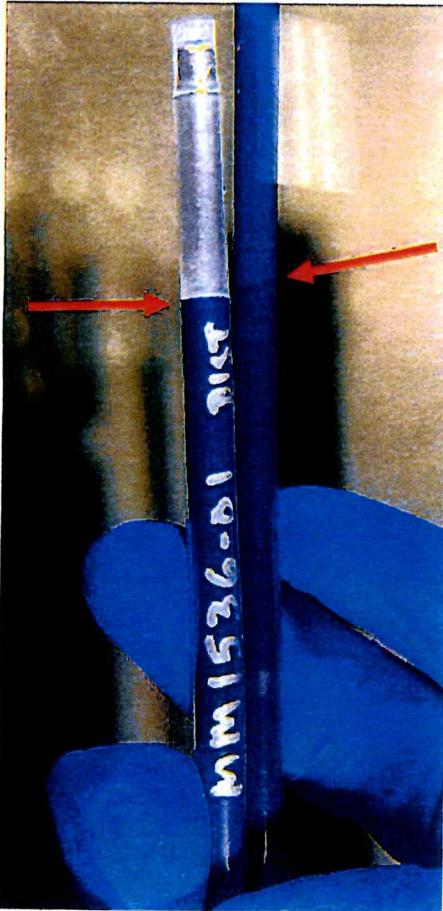


Image- 4

- 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.

1	MM0179-01	MM1536-01
GOOD PART		
2	MM1536-01	MM0179-01
MM0179-01 and MM1536-01 Wrong Order - BAD PART		
3	MM0179-01	MM0179-01
Two MM0179-01 - BAD PART		
4	MM1536-01	MM1536-01
Two MM1536-01 - BAD PART		

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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Entered to Hansh 3228 12/15/2023
Entered to 13 Feb 2024 3228 V/Sales
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:	
Doc #3005206 (Flex Commander MPI0238): OPER850.11:	
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.	

Justification:

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	
Risk Assessment: 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			
Corrective Action Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
If no, explain: This is a temporary change to use TMI0700-01. DA will be removed once the lasermic TMI0602 issues are resolved and accepted for usage.			
Training Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If no, explain: 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	28.54	25.13	25.81	29.37	28.58	28.91	29.17	29.39	27.07	26.36	27.833	1.596615	4.378	20.8430203	8.542	PASS
Seg B	63.3	60.41	56.98	63.98	60.24	61.9	58.98	62.15	59.64	57.32	60.49	2.363152	3.981	51.0822906	8.542	PASS
Seg C	79.32	79.05	75.04	73.64	80.04	79.39	77.65	76.44	76.95	75.74	77.326	2.132636	2.911	71.1178956	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 #: 500000296543

Date: 22 Jan 24

Inspector Name: Javier Olivares

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24

J001 22 jan 24