

Production Order: 500000297270



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 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>GS85 7:00 AM 24 Jan 24</u> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>GS85 1:25 PM 25 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>0000278830</u></td> <td><u>500</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td><u>N/A</u></td> <td><u>N/A</u></td> </tr> <tr> <td>MM1537-02</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>0000283401</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>0000278830</u>	<u>500</u>					<u>N/A</u>	<u>N/A</u>	MM1537-02	A <u>A</u>	PC	500	<u>0000283401</u>	<u>500</u>	N/A	N/A	25/Jan/24 CB58
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																								
1000-2053-01	A <u>A</u>	PC	500	<u>0000278830</u>	<u>500</u>																								
				<u>N/A</u>	<u>N/A</u>																								
MM1537-02	A <u>A</u>	PC	500	<u>0000283401</u>	<u>500</u>																								

Notes: DA 2484, 2564 DA 2484, DA 2564

N/A

N/A

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① CB58 26 Jan 24

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N/A	N/A	RM0158-01	E	<u>E</u>	PC	200	<u>58497</u>	<u>N/A</u>	<u>200</u>	
		TL0167-02	E	<u>N/A</u>	PC	70	<u>N/A</u>	<u>N/A</u>	<u>Bulk</u>	
		TL0165-05	J	<u>N/A</u>	PC	5	<u>N/A</u>	<u>N/A</u>	<u>Bulk</u>	
		TL0165-03	J	<u>N/A</u>	PC	5	<u>N/A</u>	<u>N/A</u>	<u>Bulk</u>	
		141967-01	02	<u>02</u>	PC	500	<u>85793</u>	<u>N/A</u>	<u>525</u>	
		RM7349-02	C	<u>C</u>	PC	543	<u>82836</u>	<u>N/A</u>	<u>600</u>	
		RM7348-01	C	<u>C</u>	PC	500	<u>85428</u>	<u>N/A</u>	<u>500</u>	
							<u>N/A</u>	<u>N/A</u>		

Notes:

N/A

N/A

N/A

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N/A	N/A	RM4001-01	B	<u>B</u>	PC	125	<u>82460</u>	<u>200</u>			
		RM0607-01	D	<u>D</u>	PC	56	<u>78849</u>	<u>N/A</u>			
		RM0498-01	C	<u>C</u>	PC	500	<u>0000287642</u>	<u>80</u>			
		RM0362-01	E	<u>E</u>	PC	594	<u>85884</u>	<u>500</u>			
		RM0009-04	I	<u>I</u>	PC	1	<u>N/A</u>	<u>N/A</u>			
		RM0009-04	I	<u>I</u>	PC	1	<u>82971</u>	<u>Bulk</u>			
		MM1538-01	A	<u>A</u>	PC	500	<u>0000278970</u>	<u>N/A</u>			
		MM1537-01	A	<u>A</u>	PC	1000	<u>0000284209</u>	<u>500</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
<i>N/A</i>	<i>N/A</i>	MM1536-01	B	<u>B</u>	PC	500	<u>0000281412</u>	<u>N/A</u>	<u>500</u>	
		MM0180-01	E	<u>E</u>	PC	500	<u>0000287541</u>	<u>N/A</u>	<u>500</u>	
		MM0179-01	D	<u>D</u>	PC	500	<u>0000276172</u>	<u>N/A</u>	<u>500</u>	
		MM0178-01	E	<u>E</u>	PC	500	<u>0000276174</u>	<u>N/A</u>	<u>500</u>	<i>N/A</i>
		MM0177-01	C	<u>C</u>	PC	500	<u>0000284208</u>	<u>N/A</u>	<u>500</u>	<i>N/A</i>
		MM0176-01	D	<u>D</u>	PC	500	<u>0000281411</u>	<u>N/A</u>	<u>500</u>	
		MM0074-01	G	<u>G</u>	PC	500	<u>0000291660</u>	<u>N/A</u>	<u>520</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	25Jan24	KLES CB58
	Line Clearance Confirmation Rreqd(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	25Jan24	NK67 AF54 AX05 Y014 V078 SH23
	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	25Jan24	VP EZ SXII ST96 DX35
	Loading Braid Stock					
	Confirmation Reqd(Milestone)					
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	500	0	25Jan24	AL34 LY97 CL30 DX35
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	25 Jan 24	JV25 cp22 Gis 22 SH23
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	25 Jan 24	LM46 DV39 cl05 Gis 22

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)	Reflow	500	0	25 Jan 24	RN27 AF54 Pm 96 SY47 SH85
450	CATASY01 Catheter FEP Removal		500	0	25 Jan 24	Pm 96 JY90
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	N/A	N/A	N/A	N/A
	FEP Removal					
	Confirmation Reqd(Milestone)					
500	CATASY01 Catheter Assembly 1 	<p>In-process Inspection and Rework</p> <p>Material Consumed:</p> <p>Part #: 1000-1153-01 Batch #: 871054 Qty: 7</p> <p>Part #: N/A Batch #: N/A Qty: N/A</p>	486	<p>EH-144</p> <p>EW-1111</p> <p>SKV-1</p> <p>Fm-1</p> <p>VD-1</p> <p>OF-11</p> <p>(14)</p>	25Jan24	CB81 VC09 NL91 P66
	In-process Inspection and Rework					
	Confirmation Reqd(Milestone)					
N/A	N/A	N/A	N/A	N/A	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
550	CATASY01 Catheter Assembly 1  Remove Heat Shrink & Mandrel Confirmation Reqd(Milestone)	Remove Heat Shrink & Mandrel	486	0	25Jan24	PP40 Y936 (JRN) MV78
600	CATASY01 Catheter Assembly 1  Distal Tip Assembly Confirmation	Distal Tip Assembly	486	0	25Jan24	ML60 SV46

Notes:

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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 Confirmation Reqd(Milestone)	Loading Heat Shrink	486	0	25 Jun 24	ML36
700	CATASY01 Catheter Assembly 1  Tipping	Tipping Record Tipping Oven Information: TMI: 0521 Cal Due: 31 May 24 TMI: 2083C Cal Due: 31 May 24 TMI: 0386 Cal Due: 31 May 24 TMI: 0936A Cal Due: 31 May 24	486	0	25 Jun 24	ML36

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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 #: <u>BM4001-01</u></td> <td>Batch #:</td> <td><u>82460</u></td> <td>Qty:</td> <td><u>N/A</u></td> </tr> <tr> <td>Part #: <u>PM0607-01</u></td> <td>Batch #:</td> <td><u>78849</u></td> <td>Qty:</td> <td><u>N/A</u></td> </tr> <tr> <td>Part #: <u>N/A</u></td> <td>Batch #:</td> <td><u>N/A</u></td> <td>Qty:</td> <td><u>N/A</u></td> </tr> <tr> <td>Part #: <u>N/A</u></td> <td>Batch #:</td> <td><u>N/A</u></td> <td>Qty:</td> <td><u>N/A</u></td> </tr> <tr> <td>Part #: <u>N/A</u></td> <td>Batch #:</td> <td><u>N/A</u></td> <td>Qty:</td> <td><u>N/A</u></td> </tr> </table> <p>Tip Inspection/ Flash Removal</p> <p>Confirmation Reqd(Milestone)</p>	Part #: <u>BM4001-01</u>	Batch #:	<u>82460</u>	Qty:	<u>N/A</u>	Part #: <u>PM0607-01</u>	Batch #:	<u>78849</u>	Qty:	<u>N/A</u>	Part #: <u>N/A</u>	Batch #:	<u>N/A</u>	Qty:	<u>N/A</u>	Part #: <u>N/A</u>	Batch #:	<u>N/A</u>	Qty:	<u>N/A</u>	Part #: <u>N/A</u>	Batch #:	<u>N/A</u>	Qty:	<u>N/A</u>	486	0	26Jan24	HT72 mm02
Part #: <u>BM4001-01</u>	Batch #:	<u>82460</u>	Qty:	<u>N/A</u>																											
Part #: <u>PM0607-01</u>	Batch #:	<u>78849</u>	Qty:	<u>N/A</u>																											
Part #: <u>N/A</u>	Batch #:	<u>N/A</u>	Qty:	<u>N/A</u>																											
Part #: <u>N/A</u>	Batch #:	<u>N/A</u>	Qty:	<u>N/A</u>																											
Part #: <u>N/A</u>	Batch #:	<u>N/A</u>	Qty:	<u>N/A</u>																											
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	481	ACD-HH (5)	26Jan24	SC88 KL45																									

Notes:

N/A

N/A

N/A

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	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	481	0	26Jan24	7936 KL45 PY4G
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	MV33 ML65 ML46 SH04 DL01
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	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:</p> <p>TMI: 0700-01 Cal Due: 31 May 24</p> <p>TMI: N/A Cal Due: N/A</p> <p>Material Consumed:</p> <p>Part #: 1000-1153-01 Batch #: 87654 Qty: N/A</p> <p>Part #: RM4001-01 Batch #: 82460 Qty: N/A</p> <p>Part #: RM0607-01 Batch #: 78849 Qty: N/A</p> <p>Part #: RM0158-01 Batch #: 58497 Qty: N/A</p> <p>Part #: N/A Batch #: N/A Qty: N/A</p>	466	MAR-III DEL-II #60S-III #60S-II #10S-III 15	26 Jan 24	XL91 KL67 KT47 KX54
950	QUALITY1 Quality Inspection & Review	<p>Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information:</p> <p>TMI: N/A Cal Due: N/A</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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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
950	 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>30Sep25</u> TMI: <u>0692</u> Cal Due: <u>30Sep25</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	450	DIS(SP) HHT DIS-HHT STR-HHT WK-1	26Jan24	XL91 KL67 NLY <u>16</u>
1000	QUALITY1 Quality Inspection & Review 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>31 May 24</u> Record Length Gage Information: TMI: <u>0889D</u> Cal Due: <u>30Sep24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30Sep24</u>	449	LT-1	26Jan24	XL91 KL67 CB58 <u>1</u>

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N/AN/AN/A

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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	(423)	10-SCR (MT) 3-SCR 6-EW 1-VD 1-MEX 1-FL 1-GNII 2-DEL 1-FM (26)	26Jan24 26Jan24	SV43 26Jan24 26Jan24
1100	CATASY01 Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initial/Date): <u>CB58 26Jan24</u>	N/A	N/A	26Jan24	CB58

Notes:

N/A

N/A

N/A

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1100	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	1123	0 26 Jan 24	A010	

Notes:

N/A A010 26 Jan 24 /

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Batch Number: 0000297270

By: AP10

Date: 26 Jan 24

Reviewed By: T413

Date: 26 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# 500000297270

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	1:35pm	430	KL95	25Jan24	1:47pm	415	KL95	25Jan24	16
Tm10745	44	2:08pm	430	KL95	25Jan24	2:20pm	415	KL95	25Jan24	16
Tm10745	44	2:30pm	430	AF54	25Jan24	2:42pm	415	AF54	25Jan24	16
Tm10745	44	3:00pm	430	NK62	25Jan24	3:12pm	415	NK62	25Jan24	16
Tm10745	44	4:25pm	430	JY90	25Jan24	4:37pm	415	JY90	25Jan24	16
Tm10745	44	4:58pm	428	SH85	25Jan24	5:10pm	415	SH85	25Jan24	16
Tm10745	44	7:6:38pm	430	Sy47	25Jan24	6:50pm	415	Sy47	25Jan24	16
Tm10745	44	7:10pm	429	Sy47	25Jan24	7:22pm	415	Sy47	25Jan24	16
Tm10745	44	7:35pm	430	Sy47	25Jan24	7:47pm	415	Sy47	25Jan24	16
Tm10745	44	8:07pm	430	SH85	25Jan24	8:19pm	415	SA07	25Jan24	15
Tm10745	44	9:06pm	430	CL30	25Jan24	9:12pm	415	SH85	25Jan24	16
Tm10745	44	9:26pm	429	SH85	25Jan24	9:38pm	415	SH85	25Jan24	16

0 Sy47 25Jan24



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

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

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OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	1:50pm	430	TA36	25 Jan 24	2:02pm	415	TA36	25 Jan 24	16
Tm10942	44	2:20pm	430	KL95	① 25 Jan 24 ② 2:32pm	2:32pm	415	KL95	25 Jan 24	16
JM10942	44	2:45 pm	429	RN27	25 Jan 24	2:55 pm	415	RN27	25 Jan 24	16
Tm10942	44	4:10pm	430	JY90	25 Jan 24	4:22pm	415	JY90	25 Jan 24	16
Tm10942	44	4:44pm	430	Sy47	25 Jan 24	4:56pm	415	Sy47	25 Jan 24	16
Tm10942	44	5:17 pm	429	Sy47	25 Jan 24	5:29pm	415	SH85	25 Jan 24	16
Tm10942	44	6:22pm	430	SH85	25 Jan 24	6:34pm	415	SH85	25 Jan 24	16
Tm10942	44	6:52pm	429	SH85	25 Jan 24	7:04pm	415	SH85	25 Jan 24	16
Tm10942	44	7:27pm	429	SH85	25 Jan 24	7:39pm	415	SH85	25 Jan 24	16
Tm10942	44	7:52pm	428	Sy47	25 Jan 24	8:04pm	415	SH85	25 Jan 24	16
Tm10942	44	9:13pm	430	SH85	25 Jan 24	9:25pm	415	SH85	25 Jan 24	16
Tm10942	44	9:39pm	428	SH85	25 Jan 24	9:51pm	415	SH85	② 25 Jan 24 ① 26 Jan 24	16

① EL45 25Jan24

② CB58 26Jan24

② CB58 26Jan24



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

PRODUCTION ORDER# 500000297270

OP 400

① SH8526 Jan 24



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

PO #: 500000297270 OP #: 500 Shift #: 2

Total Parts Reworked:		<u>32</u>	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	<u>N/A</u>	<u>N/A</u>
EH	Exposed Hypotube	<u> </u>	<u>6</u>
EW	Exposed Wire	<u> </u>	<u>21</u>
MP	Micropores	<u> </u>	<u>2</u>
SCR	Scratch	<u>N/A</u>	<u>N/A</u>
SKV	Skive Marks	<u> </u>	<u>5</u>
VD	Voids	<u>N/A</u>	<u>N/A</u>
<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
Inspected By (Sign and Date):		<u>Andy</u> 25 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: 5106073
Rev: E
Document Type: Manufacturing Form
Title: SA0155-01 Visual Rework Form

PO #: 500000297270 OP #: 500 Shift #: 2nd

Total Parts Reworked:		<u>30</u>	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	<u>N/A</u>	<u>N/A</u>
EH	Exposed Hypotube	<u>N/A</u>	<u>N/A</u>
EW	Exposed Wire	<u>XXXXXX</u>	<u>15</u>
MP	Micropores	<u>N/A</u>	<u>N/A</u>
SCR	Scratch	<u>///</u>	<u>4</u>
SKV	Skive Marks	<u>XX</u>	<u>5</u>
VD	Voids	<u>XXXX</u>	<u>7</u>
<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
Inspected By (Sign and Date):		<u>Vanneej Lor</u> <u>25 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.

Data Uploaded for Engineering Review (Check):



PO #: 500000297270 OP #: 750 Shift #: 2nd

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		50	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		10
DIM07 US / WC	DIM07 Undersized (Window Closed)	<u> </u> <u> </u>	30
EH	Exposed Hypotube		10
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		MM02	25 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):

PRODUCTION ORDER# 500000297270

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM12036	N/A	5:14pm	190°F	SG88	25 Jan 24	6:24pm	190°F	SG88	25 Jan 24	40
TM10409	N/A	6:42pm	190°F	SG88	25 Jan 24	7:52pm	190°F	SG88	25 Jan 24	37
TM12036	N/A	7:20pm	190°F	SG88	25 Jan 24	8:30pm	190°F	SG88	25 Jan 24	50
TM10409	N/A	7:55pm	190°F	SG88	25 Jan 24	9:05pm	190°F	SG88	25 Jan 24	37
TM10409	N/A	9:15PM	190°F	SG88	25 Jan 24	10:25pm	190°F	SG88	25 Jan 24	35
TM12036	N/A	10:00pm	190°F	SG88	25 Jan 24	11:10pm	190°F	SG88	25 Jan 24	43
TM10409	N/A	10:40pm	190°F	SG88	25 Jan 24	11:50pm	190°F	SG88	25 Jan 24	51
TM12036	N/A	11:40PM	190°F	SG88	25 Jan 24	12:50AM	190°F	SG88	25 JAN 24	② 32
TM10409	N/A	12:06AM	190°F	SG88	26 Jan 24	1:06AM	190°F	SG88	26 Jan 24	33
TM12036	N/A	1:12AM	190°F	SG88	26 Jan 24	2:22AM	190°F	SG88	26 Jan 24	59
TM10409	N/A	5:02AM	190°F	KL45	26 JAN 24	6:12AM	190°F	KL45	26 JAN 24	30
TM12036	N/A	5:30AM	190°F	KL45	26 JAN 24	6:40AM	190°F	KL45	26 JAN 24	34
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

① SG88 25 Jan 24

② SG88 25 Jan 24

② KL45 26 JAN 24



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000297270

OP #: 900 Shift #: 2

Total Parts Reworked:		60	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	N/A	0
EW	Exposed Wire		15
MP	Micropores		20
SCR	Scratch		45
SKV	Skive Marks		3
VD	Voids	N/A	0
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized	N/A	0
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		Liu Q. 26 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 #: 5000XP297270

OP #: 900 Shift #: 2nd

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

Total Parts Reworked:		108	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	NA	0
EH	Exposed Hypotube	NA	0
EW	Exposed Wire		4
MP	Micropores		24
SCR	Scratch		45
SKV	Skive Marks		2
VD	Voids		16
DIM01 US	DIM01 OD Undersized	NA	0
DIM06 US	DIM06 OD Undersized		35
DIM06 OS	DIM06 OD Oversized	NA	0
DIM09 US	DIM09 OD Undersized	NA	0

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):

- CONFIDENTIAL -

Page 1 of 1

Status CURRENT Effective 5/8/2023



PO #: 500000297270

OP #: 900 Shift #: 3

Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

Total Parts Reworked:		48	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	N/A	N/A
EW	Exposed Wire	///	3
MP	Micropores		8
SCR	Scratch		39
SKV	Skive Marks		2
VD	Voids		7
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		4
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.

Data Uploaded for Engineering Review (Check):

Basis to 2024 3228 1/1/23
Ex-Ex to 19 Feb 2024 3228 1/1/23
Extend to 22 Nov 2023 3228 1/1/23
Based to 20 Dec 2023 3228 1/1/23

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MEDICAL
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DEVIATION AUTHORIZATION NUMBER: 2484
* See attached email extension to 24SEP23
1512
24AUG23
23OCT2023
21Sep23

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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.

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.

Pre-Release Assembly Diagram:

Pre-Release Assembly Diagram

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	End Date:	Revision
SA0155-01	25 Aug 2023	H

Start Date: 26 Jul 2023 **End Date:** 25 Aug 2023 **Lot Number:** N/A

Risk Assessment:			
Is there any potential risk(s) that may occur as a result of the proposed deviation including the following:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Validations
Control Plans			
Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/> Yes
FMEA's			
Yes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input 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.			

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

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

FM0002.RevF Deviation Authorization

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Edited to 11/10/2023
 Edited to 13 Feb 2024 11/10/2023
CONTROLLED COPY DEVIATION AUTHORIZATION NUMBER: DA2564


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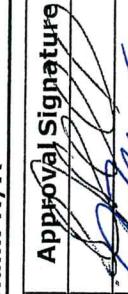
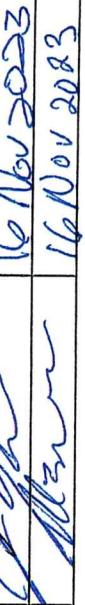
DEVIATION AUTHORIZATION FORM

Requestor Name: Krishna Selvaraj	
Document Number Affected	Revision
Doc #3005206 (MPI0238)	BP
Deviation From:	
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.	
Deviation To:	
Doc #3005206 (Flex Commander MPI0238): OPER850.11: Using a laser micrometer at OPER900 (TMI0700-01) , 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

① UK55, 23JW 2023



DA 2484
2468 ①

Description/Objectives of Training:
DA- Inspection at final QC, Op#1050.

Group Training Record

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 MM1536-01 type correction TS12 10AUG23

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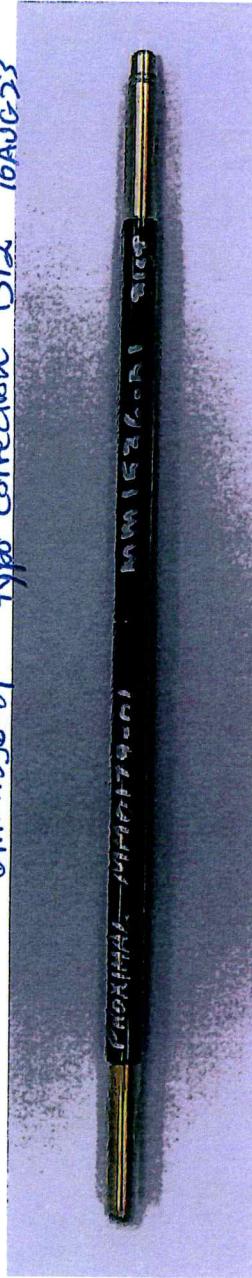


Image- 1

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)

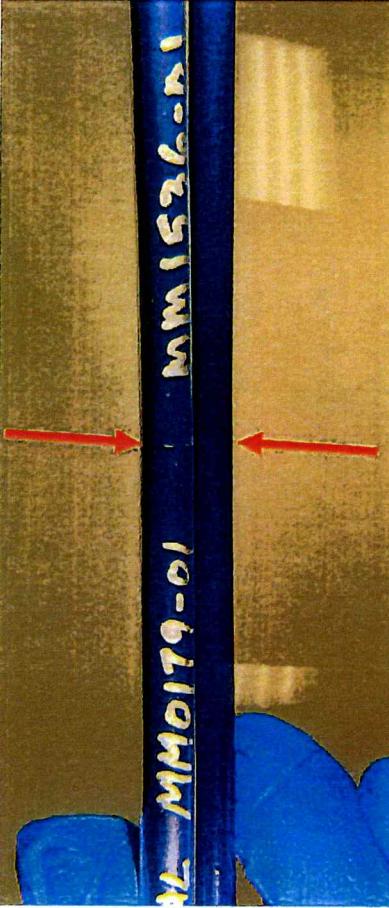
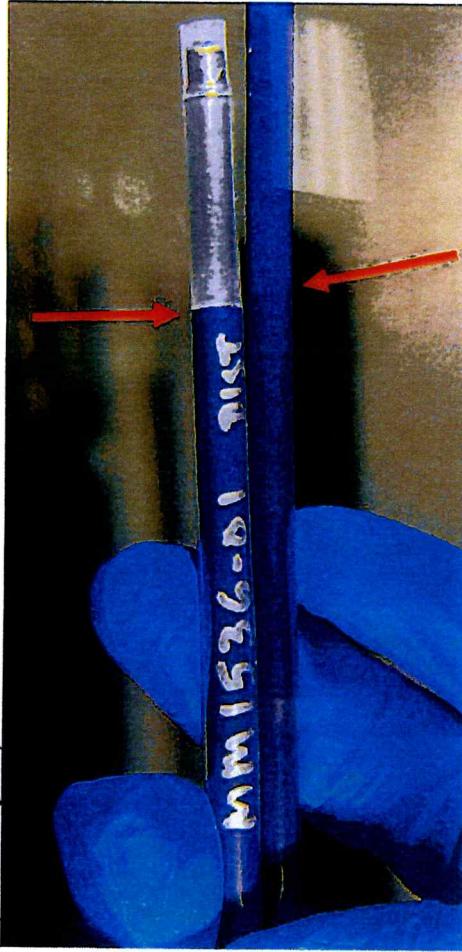


Image- 3

- 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.

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 GOOD PART	MM1536-01
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

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	25.41	27.07	28.04	32.83	31.11	24.43	30.34	33.52	29.16	24.88	28.679	3.261494	4.378	14.4001791	8.542	PASS
Seg B	70.01	76.67	72.65	70.32	80.06	69.23	80.26	74.16	73.09	72.62	73.907	3.9405246	3.981	58.2197714	8.542	PASS
Seg C	76.33	85.63	73.34	86.51	85.47	82.91	79.31	81.34	75.99	85.55	81.238	4.7623332	2.911	67.374848	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

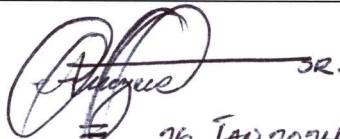
LOT #: 500000297270

Date: 26JAN2024

Inspector Name: AUGUSTINE JAH

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24



26 JAN 2024