

Production Order: 500000295738



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	Order Type: ZSTD
Production Version:	7988		Project Phase:
Plant / Business Unit:	1213 / AC5		

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>KD2 1:45pm 16 Jan 24</u> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>KD2 9:00am 17 Jan 24</u> Record Dryer Shelf #: <u>NIA</u></p> <hr/> <table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev Rev</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</td> <td>PC</td> <td>500</td> <td><u>0000278880</u></td> <td><u>500</u></td> </tr> <tr> <td>MM1537-02</td> <td>A</td> <td>PC</td> <td>500</td> <td><u>0000276175</u></td> <td><u>500</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev Rev	UOM	Qty.	Batch No.	Actual Qty Used	1000-2053-01	A	PC	500	<u>0000278880</u>	<u>500</u>	MM1537-02	A	PC	500	<u>0000276175</u>	<u>500</u>	NIA	NIA NIA NIA	16JAN24 KL27
Component Number	Req'd Rev Rev	UOM	Qty.	Batch No.	Actual Qty Used																		
1000-2053-01	A	PC	500	<u>0000278880</u>	<u>500</u>																		
MM1537-02	A	PC	500	<u>0000276175</u>	<u>500</u>																		

Notes: DA 25641, 2484.

NIA
NIA

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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	E	PC	200	N/A 58497 81054	N/A 100 37			
		TL0167-02	E	E	PC	70	N/A N/A	Bulk			
		TL0165-05	J	J	PC	5	N/A N/A	Bulk			
		TL0165-03	J	J	PC	5	N/A N/A	Bulk	N/A	N/A	N/A
		141967-01	02	D2	PC	500	85500 N/A	504 N/A			
		RM7349-02	C	C	PC	543	82854 82734	524 54			
		RM7348-01	C	C	PC	500	78688 78689	350 150 1000			

Notes:

N/A

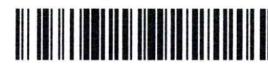
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① KPO2 18 Jan 24

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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	① 82435 N/A 82452	N/A 100			
		RM0607-01	D	<u>D</u>	PC	56	N/A 71863 ① 74663	N/A 60			
		RM0498-01	C	<u>C</u>	PC	500	0000275490 0000275489 0000287640	208 34 215			
		RM0362-01	E	<u>E</u>	PC	594	77866 78857	100 500			
		RM0009-04	I	<u>I</u>	PC	1	82971 N/A	Bulk Bulk	N/A N/A	N/A N/A	N/A
		RM0009-04	I	<u>I</u>	PC	1	82971 N/A	Bulk Bulk			
		MM1538-01	A	<u>A</u>	PC	500	0000278970 N/A	500 N/A			
		MM1537-01	A	<u>A</u>	PC	1000	0000284209	1000			

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>	<u>N/A</u>	<u>N/A</u>	
		MM0179-01	D	<u>D</u>	PC	500	<u>0000282489</u>	<u>471</u>	<u>0000275691</u>	<u>100</u>	
		MM0178-01	E	<u>E</u>	PC	500	<u>0000276172</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	
		MM0177-01	C	<u>C</u>	PC	500	<u>0000276174</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
		MM0176-01	D	<u>D</u>	PC	500	<u>0000278966</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
		MM0074-01	G	<u>G</u>	PC	500	<u>0000281411</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	
							<u>0000291638</u>	<u>30</u>			

Notes:

NIA

NIA

NIA

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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	17.Jun24	KL95
	Line Clearance					
	Confirmation Reqd(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	17.Jan24	NK62 AX05 AF54 RN27 PM96 CL30 X014
	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 Loading Braid Stock Confirmation Reqd(Milestone)	500	0	17Jan24	MY50 CY97 ST96 NY35
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	500	0	17Jan24	AL34 SX11 AS31 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 Insert Cut Hypo Tube Confirmation Reqd(Milestone)	Insert Cut Hypo Tube	500	0	17 Jun 24	LMUB CPSJ GS22
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	17 Jun 24	VY25 CLOS V078

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	17 Jan 24	NK62 AX05 AP54 pm 96 Sy47 SH85
450	CATASY01 Catheter	FEP Removal	500	0	17 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 	In-process Inspection and Rework Material Consumed: Part #: 1000-1153-01 Batch #: 87655 Qty: 15 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 Part #: N/A Batch #: N/A Qty: N/A	4680 462	OF - HII EW - HII HII HII HII T① VD - I FM - IIII DS - I WT - HII (32)① 38	17Jan24	LL61 VC09 CB81 P266 VL91 TD215
N/A	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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(1) V078 17 Jan 24

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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 . .	462	0	17 Jan 24	RS23 FB01 LG61 PPH0 mm02
600	CATASY01 Catheter Assembly 1  Distal Tip Assembly . . Distal Tip Assembly Confirmation	Distal Tip Assembly . .	449	DL-III MAH-11 III FM - 1	17 Jan 24	VA96 FB01 ML60

Notes:

NIF

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NIF

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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	449	0	17 Jan 24	VAP16 FBO) DV39 ML38
	Loading Heat Shrink					
	Confirmation Reqd(Milestone)					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: 0936A Cal Due: 31 May 24 TMI: 2038C Cal Due: 31 May 24 TMI: 0388 Cal Due: 31 May 24 TMI: 0521 Cal Due: 31 May 24 Tipping	449	0	17 Jan 24	STX48 HV36 ML38
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
750	CATASY01 Catheter Assembly 1 	Tip Inspection/ Flash Removal Material Consumed: Part #: 21N0007-01 Batch #: 71863 Qty: 5 Part #: BM4001-01 Batch #: 82435 Qty: 10 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	449	0	17 Jan 24	Hv36 STX48 SV46
	Tip Inspection/ Flash Removal					
	Confirmation Reqd(Milestone)					
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	434	ACD-HH HHH HHH	17 Jan 24	SS44 SG88 TRD AT39
Notes:						
N/A						
N/A						
N/A						

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Opn No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
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 Record DIM05 gage result for the first 5 parts at the start of operation: 1. <u>PASS</u> 2. <u>PASS</u> 3. <u>PASS</u> 4. <u>PASS</u> 5. <u>PASS</u>	433	X5 US-1 (1)	17 Jan 24	Y936
900	QUALITY1 Quality Inspection & Review	Quality Inspection and Review Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	N/A	MAR-11 EH-HHT SLR-1 #5US-1 #7DS-1 N/A	SH04 HT72 ML65	
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
	 Quality Inspection & Review Confirmation Reqd(Milestone) <i>N/A</i>	<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>31MAY24</u> TMI: <u>N/A</u> Cal Due: <u>N/A</u> TMI: <u>N/A</u> Cal Due: <u>N/A</u> Material Consumed: Part #: <u>Rm4001-01</u> Batch #: <u>82435</u> Qty: <u>6</u> Part #: <u>Rm0607-01</u> Batch #: <u>71863</u> Qty: <u>4</u> Part #: <u>Rm0158-01</u> Batch #: <u>58497</u> Qty: <u>2</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> </p>	415	#9us-11 SCR-HH(SP) #bus-1	17 Jan 24	KL67 PP40 18
950	QUALITY1 Quality Inspection & Review <i>N/A</i>	<p>Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: <u>N/A</u> Cal Due: <u>N/A</u> Record Caliper Information:</p>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>

Notes:

*N/A**N/A**N/A*

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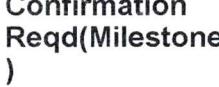


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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Quality Inspection & Review  Confirmation Reqd(Milestone)	TMI: N/A Cal Due: N/A Record DIM02 Go/No-Go Gage Information: TMI: 0691 Cal Due: 30 SEP25 TMI: 0692 Cal Due: 30 SEP25 Record DIM02 Inspection Results N = 54: Pass: 54 Fail: 0	383	DIS - UN 1H 1H 1H WK - UN 1H EW-1 MAR-11 DEL-1 STR-11 (32)	17 Jan 24	KL67
1000	QUALITY1  Quality Inspection & Review  Confirmation Reqd(Milestone)	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: 1056 Cal Due: 31 MAY 24 Record Length Gage Information: TMI: 0889 D Cal Due: 30 SEP 24 Record Calibrated Ruler Information: TMI: 0629 Cal Due: 30 SEP 24	315	LT - UN 1H (8)	17 Jan 24	KL67

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
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	341	SCR - III (IT) Del - III (IT) FM - II (IT) SKV - M1 VD - IIII EV - IIII DL - M1 Mar - 1 DIS - 1 BP - 1 GNII - 1 STN - 1 (34)	18Jan24	SV43 XN26
1100	CATASY01 Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initial/Date): <u>KP02 18Jan24</u>	N/A	N/A	18Jan24	KP02
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
1150	PACKINT1 Packing assembly  Package Confirmation Reqd(Milestone)	Package Package, Label, and Ship Finished Parts	3UL	0	19 Jan 24	AB10

Notes:

N/A AB10 19 Jan 24

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Batch Number: 0000295738

By: AP10

Date: 19 Jan 24

Reviewed By:

RB29

Date:

19 JAN 24

Notes:

N/A AP10 19 Jan 24

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PO #: 500000295738

OP #: 900 Shift #:

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

Total Parts Reworked:		81	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		1
EH	Exposed Hypotube		13
EW	Exposed Wire		2
MP	Micropores		7
SCR	Scratch		84
SKV	Skive Marks	N/A	N/A
VD	Voids		6
DIM01 US	DIM01 OD Undersized		
DIM06 US	DIM06 OD Undersized		
DIM06 OS	DIM06 OD Oversized		
DIM09 US	DIM09 OD Undersized		
Inspected By (Sign and Date):		HT 72	17 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):



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000295738 OP #: 900 Shift #: 2nd

Total Parts Reworked:		63	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube		7
EW	Exposed Wire		2
MP	Micropores	N/A	0
SCR	Scratch		43
SKV	Skive Marks	N/A	0
VD	Voids		3
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized		20
DIM06 OS	DIM06 OD Oversized		1
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		See H 17 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):



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000295738

OP #: 900 Shift #: 2nd

Total Parts Reworked:		64	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	/	1
EW	Exposed Wire	///	4
MP	Micropores	/// //	7
SCR	Scratch	N/A	N/A
SKV	Skive Marks	XXXXXXXXXXXXXX	71
VD	Voids	N/A	N/A
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized	///	3
DIM06 OS	DIM06 OD Oversized	N/A	N/A
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		PP40	17 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):



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

PO #: 500000295738 OP #: 750 Shift #: 2nd

Total Parts Reworked:		20	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		2
DIM07 US / WC	DIM07 Undersized (Window Closed)		14
EH	Exposed Hypotube		4
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		SV46 17 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):



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

PO #: 500000295738 OP #: 750 Shift #: 2nd.

Total Parts Reworked:		37	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		20
DIM07 US / WC	DIM07 Undersized (Window Closed)		3
EH	Exposed Hypotube		14
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		mm02	17 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):



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

PO #: 500000295738 OP #: 500 Shift #: 2

Total Parts Reworked:		26	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	/	0
EH	Exposed Hypotube		2
EW	Exposed Wire		5
MP	Micropores	/	0
SCR	Scratch	/	0
SKV	Skive Marks		3
VD	Voids		3
N/A	N/A	/	0
Inspected By (Sign and Date):		Caleb 11 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 #: 500000295738 OP #: 500 Shift #: 2nd

Total Parts Reworked:		<u>38</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> </u>	<u>23</u>
MP	Micropores	<u>n/a</u>	<u>n/a</u>
SCR	Scratch	<u> </u>	<u>4</u>
SKV	Skive Marks	<u> </u>	<u>7</u>
VD	Voids	<u> </u>	<u>8</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 17 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):



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

PRODUCTION ORDER# 500000295738

OP 400



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

PRODUCTION ORDER# 500000295738

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	9:48am	430	0521	17Jan24	10:00am	415	0521	17Jan24	16
Tm10942	44	10:55am	430	AX05	17Jan24	11:07am	415	AX05	17Jan24	16
Tm10942	44	11:20am	428	AX05	17Jan24	11:32am	415	AX05	17Jan24	16
Tm10942	44	11:58am	430	AX05	17Jan24	12:10pm	415	AX05	17Jan24	16
Tm10942	44	12:22PM	429	AX05	17Jan24	12:34PM	415	AX05	17Jan24	16
Tm10942	44	1:29pm	430	0521	17Jan24	1:37PM	415	0521	17Jan24	16
Tm10942	44	1:45pm	430	0521	17Jan24	1:57PM	415	0521	17Jan24	16
Tm10942	44	2:12pm	427	KL95	17Jan24	2:24pm	415	KL95	17Jan24	15
Tm10942	44	2:45pm	430	AF54	17Jan24	2:57pm	415	AF54	17Jan24	16
Tm10942	44	4:12pm	430	SH85	17Jan24	4:24PM	415	SH85	17Jan24	16
Tm10942	44	4:44pm	430	S447	17Jan24	4:56 PM	415	S447	17Jan24	16
Tm10942	44	5:14pm	429	SH85	17Jan24	① 5:26PM 5:16PM	415	SH85	17Jan24	16

① SH85 17Jan24



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

PRODUCTION ORDER# 500000295738

OP 400



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

PRODUCTION ORDER# 500000295738

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	9:55AM	430	KL95	17Jan24	10:07AM	415	AX05	17Jan24	16
Tm10745	44	11:10AM	430	AX05	17Jan24	11:22AM	415	AX05	17Jan24	16
Tm10745	44	11:34AM	428	AX05	17Jan24	11:46AM	415	AX05	17Jan24	16
Tm10745	44	12:10PM	430	AX05	17Jan24	12:22PM	415	AX05	17Jan24	16
Tm10745	44	12:37PM	430	AX05	17Jan24	12:49PM	415	AX05	17Jan24	16
Tm10745	44	1:37PM	430	PM96	17Jan24	1:49PM	415	PM96	17Jan24	16
Tm10745	44	2:00PM	430	OS21	17Jan24	2:12PM	415	OS21	17Jan24	16
Tm10745	44	2:40PM	430	AX05	17Jan24	2:52PM	415	AX05	17Jan24	16
Tm10745	44	3:00PM	427	AX05	17Jan24	3:12PM	415	AX05	17Jan24	16
Tm10745	44	3:12pm	428	NK62	17Jan24	3:24PM	415	NK62	17Jan24	7
Tm10745	44	4:25pm	430	JY90	17Jan24	4:37PM	415	JY90	17Jan24	16
Tm10745	44	4:57PM	430	JY47	17Jan24	5:09PM	415	JY47	17Jan24	16



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

PO #: 500000295738

OP #: 500 Shift #: 1st

Total Parts Reworked:		98	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		17
EW	Exposed Wire		78
MP	Micropores	N/A	N/A
SCR	Scratch	N/A	N/A
SKV	Skive Marks		4
VD	Voids		11
N/A	N/A	N/A	N/A

Inspected By (Sign and Date):

VC09, CB 81 17 Jun 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 #: 500000295738 OP #: 750 Shift #: 1st

Total Parts Reworked:		31	
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)		2
EH	Exposed Hypotube		5
N/A	Glue, Stopper		21
Inspected By (Sign and Date):		Hv36 17 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# 500D00295738

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm12036	N/A	1:30pm	190F	SSH4	17 Jan 24	2:40pm	190F	K155	17 Jan 24	28
Tm10409	N/A	2:10pm	190F	KL95	17 Jan 24	3:20pm	190F	K155	17 Jan 24	34
Tm10409	N/A	3:37pm	190F	TRN AT39 SG88	17 Jan 24	4:47pm	190F	TRN AT39 SG88	17 Jan 24	39
Tm12036	N/A	4:32pm	190F	TRN AT39 SG88	17 Jan 24	5:42pm	190F	TRN AT39 SG88	17 Jan 24	37
Tm10409	N/A	5:15pm	190F	TRN AT39 SG88	17 Jan 24	6:25pm	190F	TRN AT39 SG88	17 Jan 24	33
Tm12036	N/A	6:35pm	190F	TRN AT39 SG88	17 Jan 24	7:45pm	190F	TRN AT39 SG88	17 Jan 24	31
Tm10409	N/A	7:07pm	190F	TRN AT39 SG88	17 Jan 24	8:17pm	190F	TRN AT39 SG88	17 Jan 24	36
Tm12036	N/A	7:46pm	190F	TRN AT39 SG88	17 Jan 24	8:56pm	190F	TRN AT39 SG88	17 Jan 24	40
Tm10409	N/A	9:01pm	190F	TRN AT39 SG88	17 Jan 24	10:11pm	190F	TRN AT39 SG88	17 Jan 24	37
Tm12036	N/A	9:32pm	190F	TRN AT39 SG88	17 Jan 24	10:42pm	190F	TRN AT39 SG88	17 Jan 24	30
Tm10409	N/A	10:15pm	190F	TRN AT39 SG88	17 Jan 24	11:25pm	190F	TRN AT39 SG88	17 Jan 24	40
Tm12036	N/A	10:54pm	190F	TRN AT39 SG88	17 Jan 24	12:04am	190F	TRN AT39 SG88	① 18 Jan 24 ② 18 Jan 24	49
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

① AT39 18 Jan 24

Est. to MANDATE 5228 12/16/2023
Ex-2 to 13 Feb 2024 5228 1/9/2024

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 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 type="checkbox"/> Yes <input checked="" 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 Stanislawski		16 Nov 2023
Quality Manager	Jay Zabel		16 Nov 2023
Operations Manager	Matthew Benson		16 Nov 2023

Basis to 2024 5208 01/01/23

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MEDICAL
is part of

* See attached email extension to 24 SEP 23
1500
24 AUG 23

Extend to 22 Nov 2023 5208 10/02/23

End to 20 Oct 2023 5208 11/09/23

Requestor Name: Udhesh Kapadnis



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DE

DEVIA

TION

AUTH

ORIZATION

FORM

Other to 23 Oct 2023 5208 15/09/23

Document Number Affected

3107610

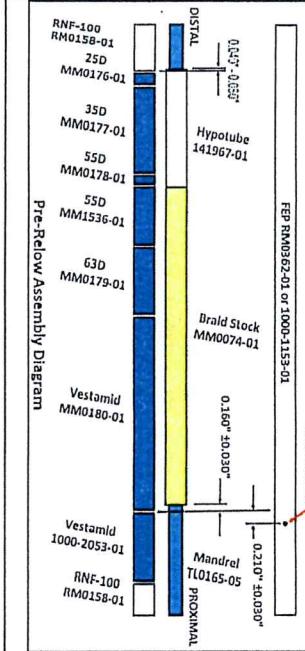
Revision

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.

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 Yes No FMEA's Yes No Validations Yes 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:	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, 23 JU 2023

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is part of



DA	2484
	2468

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 type correction TS23 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)

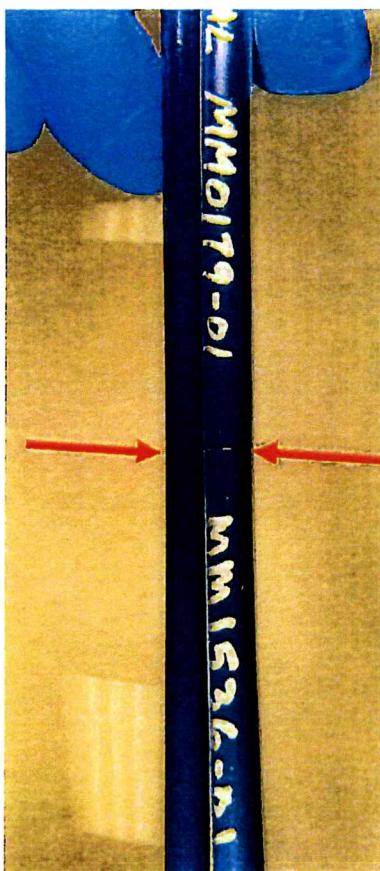


Image-3

- 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 Stanislowski		25 Jul 2023
Mgr. Operations	Matthew Benson		25 Jul 2023

FM0002.RevF

Deviation Authorization

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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	25.55	26.99	25.21	25.79	26.93	26.64	27.09	27.8	25.25	26.49	26.374	0.8792194	4.378	22.5247777	8.542	PASS
Seg B	61.15	58.86	60.86	61.34	66.77	62.12	60.12	62.38	61.63	60.8	61.603	2.0753637	3.981	53.3409772	8.542	PASS
Seg C	76.4	78.74	74.45	80.6	79.54	78.62	80.13	80.2	77.86	80.15	78.669	1.965522	2.911	72.9473655	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 #: 500000295738

Date: 18JAN24

Inspector Name: Andrew Wipf

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24


18Jan24