

Production Order: 500000296057



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

Opr No.	Planned WorkCenter Description	Operation Details						Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
50	KITTING3	Kitting Devices	Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP								
	Kitting Devices		Record Time Extrusions Enter Dryer (Initial/Time/Date):	XPO2	5:15am	17Jan24					
			Record Time Extrusions First Exit Dryer (Initial/Time/Date):	Xc31	7:20pm	18Jan24					
			Record Dryer Shelf #:	N/A							
			Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used			
			1000-2053-01	A A	PC	500	0000278880	500	N/A	N/A	162824 TPO2
			MM1537-02	A A	PC	500	0000274175	500	N/A	N/A	

Notes: DA 2484, 2564

N/A ①

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>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>85561</u>	<u>525</u>			
		RM7349-02	C	<u>C</u>	PC	543	<u>82852</u>	<u>600</u>			
		RM7348-01	C	<u>C</u>	PC	500	<u>① 78698</u> <u>78690</u> <u>78689</u> <u>N/A</u>	<u>600</u>			
								<u>N/A</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>82453</u>	<u>100</u>		
		RM0607-01	D	<u>D</u>	PC	56	<u>82454</u>	<u>100</u>		
		RM0498-01	C	<u>C</u>	PC	500	<u>74642</u>	<u>100</u>		
		RM0362-01	E	<u>2</u>	PC	594	<u>0000275491</u>	<u>500</u>		
		RM0009-04	I	<u>1</u>	PC	1	<u>82971</u>	<u>n/a</u>		
		RM0009-04	I	<u>1</u>	PC	1	<u>82971</u>	<u>Bulk</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>B</u>	PC	1000	<u>0000284209</u>	<u>1,000</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>N/A</u>	<u>N/A</u>		
		MM0180-01	E	<u>E</u>	PC	500	<u>0000281413</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>400</u>		
		MM0177-01	C	<u>C</u>	PC	500	<u>0000275691</u>	<u>100</u>		
		MM0176-01	D	<u>D</u>	PC	500	<u>0000276172</u>	<u>500</u>		
		MM0074-01	G	<u>G</u>	PC	500	<u>N/A</u>	<u>N/A</u>		

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
100	CATASY01 Catheter Assembly 1 	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	19Jan24	V078
	Line Clearance Confirmation Reqd(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	19Jan24	CL30 JY90 SY47 Y014 YK40 SD34
	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 Confirmation Reqd(Milestone)	Loading Braid Stock	500	0	19Jan24	ST96 Y014 MY50 MC11
250	CATASY01 Catheter Assembly 1  Trim Braid Wire at Proximal End		500	0	19Jan24	A531 N435 CL05 CY97 PY67

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	19Jan24	cpl2 V078 PL22 PV16
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	19Jan24	CL05 V078 CX63 BD64
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	19Jan24	S/47 ST/85 CL30 TRN/078 R/47 AL07
450	CATASY01 Catheter	FEP Removal	500	0	19Jan24	Y014 TRN/078 JY/90 AM47
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	Assembly 1 	N/A	N/A	N/A	N/A	SN67 JC92
N/A	FEP Removal					
N/A	Confirmation Reqd(Milestone)					
500	CATASY01 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	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	481	EW-HHT-HHT HHT Fm-111 FEP-+1 VD-1 WT-+1 19	19Jan24	AT39 P66 M0702 TD45 L461 L546 AR02 SX11 Trn SC10
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 Remove Heat Shrink & Mandrel Confirmation Reqd(Milestone)	481	0	19Jan24	M238 SV46 LH45 TRN MH10 CD1P TRN MH10 FBOY
600	CATASY01 Catheter Assembly 1 Distal Tip Assembly Distal Tip Assembly Confirmation	Distal Tip Assembly	476	EH - III ID - I MAS - I 5	19Jan24	ML60 MH10 FBOY

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	476	0	19Jan24	MU78 PT59 LH45 FB01
	Loading Heat Shrink					
	Confirmation Reqd(Milestone)					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: 0521 Cal Due: 31 MAY 2024 TMI: 2083C Cal Due: 31 MAY 24 TMI: 0386 Cal Due: 31 MAY 24 TMI: 0936A Cal Due: 31 MAY 24 Tipping	476	0	19Jan24	MU78 FC83
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
750	CATASY01 Catheter Assembly 1 	Tip Inspection/ Flash Removal Material Consumed: Part #: RM1001-0 Batch #: 72453 Qty: N/A Part #: RM0607-0 Batch #: 74662 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	476	0	19Jan24 B160 JL83	PP40
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	470	ACD-HH1 ⑥	19Jan24 SG88 KL45 SN67	
Notes:						
N/A						
N/A						
N/A						

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Opt 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> Cut to Length Confirmation Reqd(Milestone)	469	SKV-1 1	19Jan24	Y936 KL45
900	QUALITY1 Quality Inspection & Review	Quality Inspection and Review Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	N/A	Del-H(1) MAR-T(1) EW-C(1) N/A	N/A	Shay MLB5 DL07
Notes:						
<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
	 Quality Inspection & Review Confirmation Reqd(Milestone) Re-Inspect after re-work. 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 24</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>1000-1153-01</u> Batch #: <u>87655</u> Qty: <u>N/A</u> Part #: <u>RM4001-01</u> Batch #: <u>82453</u> Qty: <u>N/A</u> Part #: <u>RM0607-01</u> Batch #: <u>74662</u> Qty: <u>N/A</u> Part #: <u>RM0158-01</u> Batch #: <u>58497</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u>			454	19Jan24	FL67 XL91 TX54 DL-111(T) 15
950	QUALITY1 Quality Inspection & Review 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:		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
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: 30SEP25 TMI: 0692 Cal Due: 30SEP25 Record DIM02 Inspection Results N = 54: Pass: 54 Fail: 0	451 DIS-1 STR-1 MAR-1 WK+① (3)		19Jan24	KL67 XL91
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: 31MAY24 Record Length Gage Information: TMI: 0889D Cal Due: 30SEP24 Record Calibrated Ruler Information: TMI: 0629 Cal Due: 30SEP24	451	0	19Jan24	KL67 XL91 CB58

Notes:

N/A

N/A

N/A

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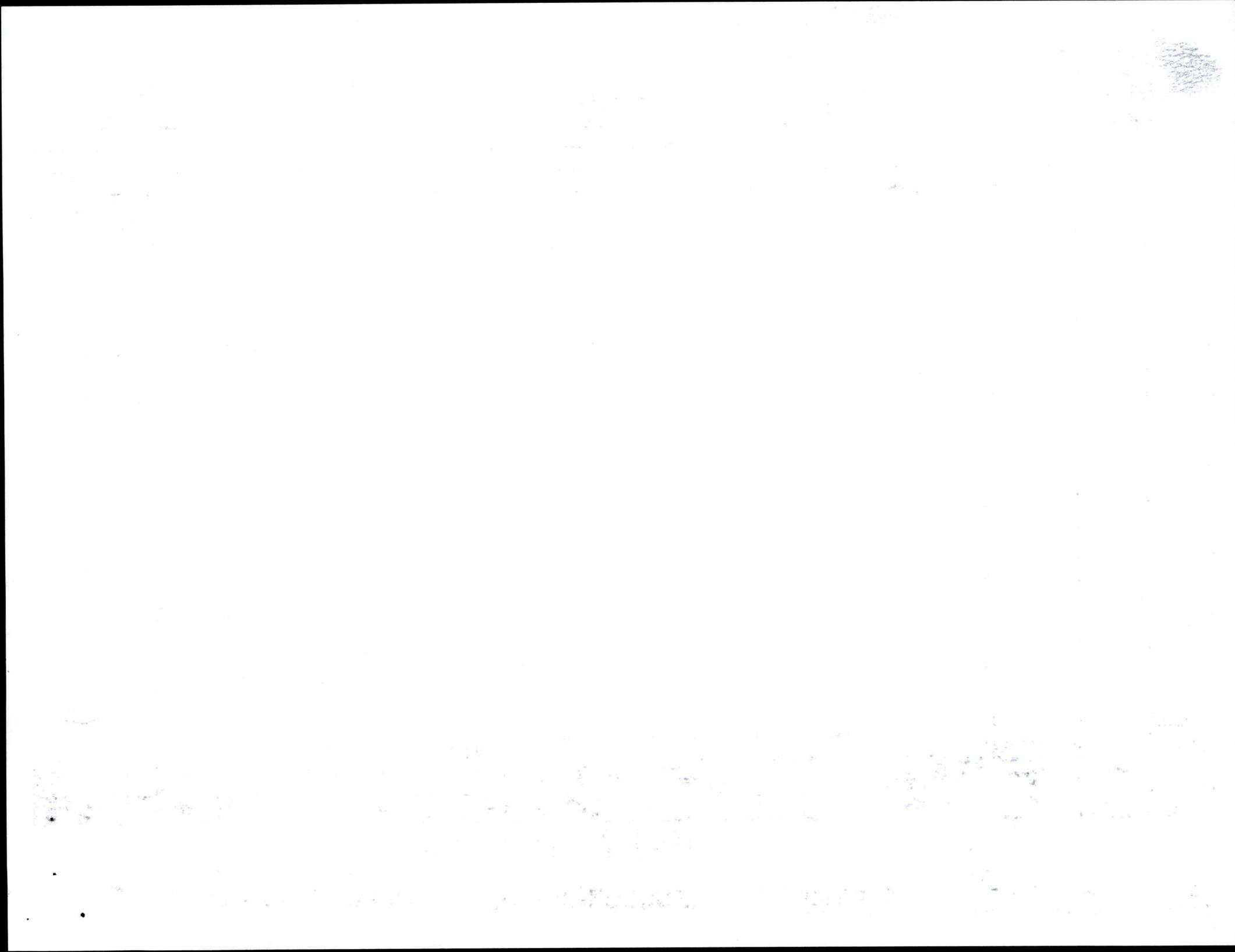
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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A	N/A	N/A	N/A	N/A
1050	QUALITY1 Quality Inspection & Review  Quality Inspection & Review Confirmation Reqd(Milestone) 	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	414	EW-HH1 SCR-III CRK-III DNT-1 SKV-III FM-II TL-1 MP-HH1 WK-1 DEL-HH DIS-II RD RDG-1 #S/us-1 (37)	19 Jan 24	YK95 SV43 XN26
1100	CATASY01 Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): <u>① AM68 19 Jan 24</u>	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
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	414	0	19 Jan 24	bft/

Notes:

N
N
N

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Batch Number: 000296057

By: BA71

Date: 19 Jan 24

Reviewed By:

RBZ9

Date:

19 JAN 24

Notes:

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OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM12036	N/A	10:10pm	190F	SG88	18 Jan 24	11:20pm	190F	SG88	18 Jan 24	40
TM10409	N/A	10:49pm	190F	SG88	18 Jan 24	11:59pm	190F	SG88	18 Jan 24	41
JM12036	N/A	12:00AM	190F	SG88	19 Jan 24	1:10AM	190F	SG88	19 Jan 24	40
TM10409	N/A	12:30AM	190F	SG88	19 Jan 24	1:40AM	190F	SG88	19 Jan 24	44
TM12036	N/A	1:15AM	190F	SG88	19 Jan 24	2:25AM	190F	SG88	19 Jan 24	35
TM10409	N/A	4:50AM	190F	KL4S	19 JAN 24	6:00 AM	190F	KL4S	19 JAN 24	24
TM10409	N/A	6:55AM	190F	SN67	19 Jan 24	8:05AM	190F	SN67	19 Jan 24	27
TM12036	N/A	7:26AM	190F	SN67	19 Jan 24	8:36AM	190F	SN67	19 Jan 24	26
TM10409	N/A	8:16AM	190F	KL4S	19 JAN 24	9:26AM	190F	KL4S	19 JAN 24	45
TM12036	N/A	8:40AM	190F	SN67	19 JAN 24	9:50AM	190F	SN67	19 JAN 24	28
TM10409	N/A	9:37AM	190F	SN67	19 Jan 24	10:47AM	190F	SN67	19 Jan 24	36
TM12036	N/A	10:10AM	190F	SN67	19 JAN 24	11:20AM	190F	SN67	19 JAN 24	42
TM10409	N/A	10:52AM	190F	KL4S	19 JAN 24	12:12 PM	190F	KL4S	19 JAN 24	42



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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	7:10 pm	430	SH85	18Jan24	7:22 pm	415	SH85	18Jan24	16
Tm10942	44	7:37 pm	428	SH85	18Jan24	7:49 pm	415	SH85	18Jan24	16
Tm10942	44	8:50 pm	430	CL30	18Jan24 7:02pm	9:02 pm	415	SH85	18Jan24	16
② Tm10942	44	9:21 pm	429	SH85	18Jan24	9:36 pm	415	CL30	18Jan24	16
Tm10942	44	9:52 pm	430	V078	18Jan24	10:04 pm	415	SH85	18Jan24	16
Tm10942	44	10:17 pm	427	SH85	18Jan24	10:29 pm	415	SH85	18Jan24	16
Tm10942	44	10:50 pm	430	CL30	18Jan24	11:02 pm	415	V078	18Jan24	16
Tm10942	44	11:55 pm	430	JY90	18Jan24	12:07 AM	415	JY90	19Jan24	16
Tm10942	44	12:35 AM	430	SH85	19Jan24	12:47 AM	415	SH85	19Jan24	16
Tm10942	44	1:30 AM	430	CL30	19Jan24	1:42 AM	415	SY47	19Jan24	16
Tm10942	44	2:00 AM	429	SY47	19Jan24	2:12 AM	415	SY47	19Jan24	16
Tm10942	44	2:26 AM	428	SY47	19Jan24	2:32 AM	415	SY47	19Jan24	5

② CB58 19Jan24

① SH85 18Jan24



Document No: 5105589
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	6:54am	430	cm99	19Jan24	7:06am	415	cm99	19Jan24	16
TM10942	44	7:56AM	430	RL47	19Jan24	8:02AM	415	RL47	19Jan24	16
TM10942	44	8:11AM	430	AL67	19Jan24	8:23AM	415	AL67	19 Jan 24	16
				N/A						



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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
Tm10745	44	6:55pm	430	SH85	18Jan24	7:07pm	415	SH85	18Jan24	16
Tm10745	44	7:24pm	429	SH85	18Jan24	7:36pm	415	SH85	18Jan24	16
Tm10745	44	7:53pm	429	SH85	18Jan24	8:05pm	415	SH85	18Jan24	16
Tm10745	44	9:08pm	430	SH85	18Jan24	9:20pm	415	SH85	18Jan24	16
Tm10745	44	9:42pm	430	CL30	18Jan24	9:54pm	415	CL30	18Jan24	16
Tm10745	44	10:10pm	430	CL30	18Jan24	10:22pm	415	SH85	18Jan24	16
Tm10745	44	10:33pm	430	CL30	18Jan24	10:45pm	415	CL30	18Jan24	16
Tm10745	44	11:08pm	429	V078	18Jan24	11:20pm	415	V078	18Jan24	16
Tm10745	44	11:44pm	430	CL30	18Jan24	11:56pm	415	CL30	18Jan24	16
Tm10745	44	12:17AM	430	CL30	19Jan24	12:29AM	415	SH85	19Jan24	16
Tm10745	44	12:50AM	428	SH85	19Jan24	1:02AM	415	SH85	19Jan24	16
Tm10745	44	1:13AM	430	CL30	19Jan24	1:25PM	415	CL30	19Jan24	16



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

PRODUCTION ORDER# 500000296057

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	1:49 AM	430	CL	19 Jan 24	1:57 AM	445	AT39	19 Jan 24	15
TM10745	44	6:39 AM	430	SD34	19 Jan 24	6:51 AM	415	SD34	19 Jan 24	16
TM10745	44	7:09 AM	430	AL67	19 Jan 24	7:21 AM	415	AL67	19 Jan 24	16
TM10745	44	7:25 AM	430	RL47	19 Jan 24	7:37 AM	415	RL47	19 Jan 24	16
TM10745	44	7:57 AM	430	RL47	19 Jan 24	8:00 AM	415	RL47	19 Jan 24	16
					AL67 19 Jan 24					
				N/A						



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

PO #: 500000296057

OP #: 500 Shift #: 2nd

Total Parts Reworked:		25	
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		15
MP	Micropores	N/A	N/A
SCR	Scratch		3
SKV	Skive Marks	N/A	N/A
VD	Voids		7
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		Vannaej Lor 18 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 #: 500008296057

OP #: 500 Shift #: 2

Total Parts Reworked:		24	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	/	1
EH	Exposed Hypotube	N/A	0
EW	Exposed Wire		24
MP	Micropores	N/A	0
SCR	Scratch	N/A	0
SKV	Skive Marks		2
VD	Voids	N/A	0
N/A	N/A	N/A	0

Inspected By (Sign and Date):

Craig 18 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 #: 500000296057 OP #: 500 Shift #: 2nd

Total Parts Reworked:		<u>31</u>	
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	-	18
MP	Micropores		1
SCR	Scratch		7
SKV	Skive Marks	N/A	N/A
VD	Voids		8
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		MM02	18Jan24

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 #: 500000296057OP #: 750 Shift #: 2nd

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

Total Parts Reworked:		46	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		11
DIM07 US / WC	DIM07 Undersized (Window Closed)		9
EH	Exposed Hypotube		26
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		PP40 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. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):

PO #: 500000296057OP #: 900 Shift #: 2nd

Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

Total Parts Reworked:		16	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	1	1
EW	Exposed Wire	N/A	N/A
MP	Micropores	N/A	N/A
SCR	Scratch		15
SKV	Skive Marks		
VD	Voids		
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):		See H	HT72 18 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 #: 505000296057 OP #: 500 Shift #: 3rd

Total Parts Reworked:		76	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		2
EH	Exposed Hypotube		5
EW	Exposed Wire		41
MP	Micropores		1
SCR	Scratch		3
SKV	Skive Marks		1
VD	Voids		5
N/A	N/A	N/A	N/A

Inspected By (Sign and Date):

Sy 11, LL61, AR02, LS46

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):



PO #: 500006296057 OP #: 750 Shift #: 3RD

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

Total Parts Reworked:		22	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		7
DIM07 US / WC	DIM07 Undersized (Window Closed)	NA	NA
EH	Exposed Hypotube		2
GD/AB	Glue Damage / Air Bubbles		13
Inspected By (Sign and Date):		BIGO 19 Jan 2023	

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 #: 580 004 246 057OP #: 750 Shift #: 3

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		18	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		5
DIM07 US / WC	DIM07 Undersized (Window Closed)		2
EH	Exposed Hypotube		3
GD	Glue Damage		3
Inspected By (Sign and Date):		IC83 19Jan24	

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 #: 500000296057 OP #: 900 Shift #: 3

Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

Total Parts Reworked:		157	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		9
EH	Exposed Hypotube		12
EW	Exposed Wire		62
MP	Micropores	N/A	N/A
SCR	Scratch		67
SKV	Skive Marks		7
VD	Voids		51
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		14
DIM06 OS	DIM06 OD Oversized		11
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		D207 KX 74 K155, KT217	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. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):

Expiry to 2024-08-16 16:23

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Extend to 2023-08-16:23
Date to 2023-08-16:23
DEVIA
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CONTROLLED COPY DEVIATION AUTHORIZATION NUMBER: 2484

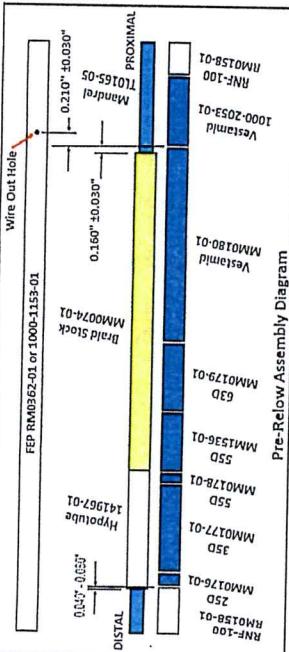
* See attached email extension to 24SEP23
TS2
24AUG23
23OCT23
24NOV23

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.

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: Yes 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 July 2023

DA | 2484
2468



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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 MM1536-01 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)

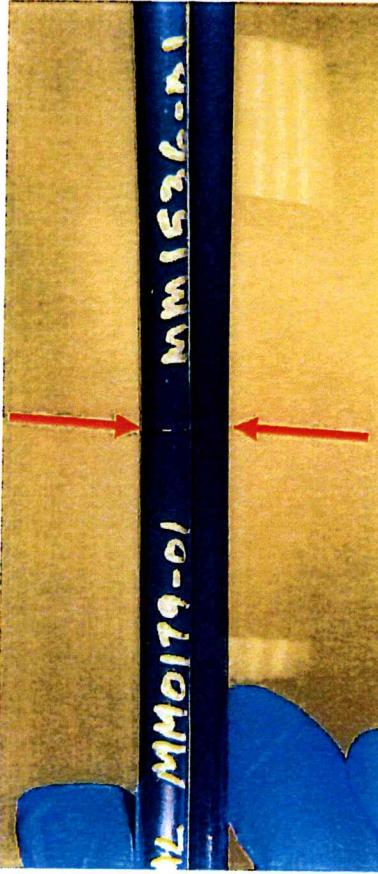


Image- 3

- 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.

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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)

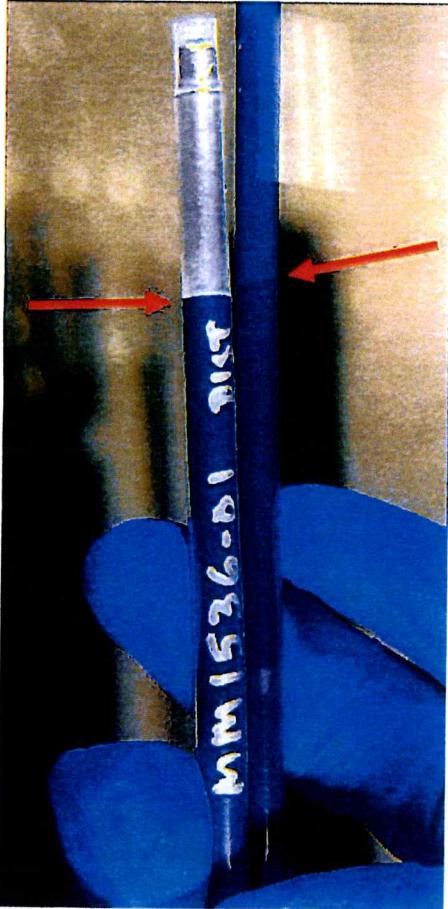
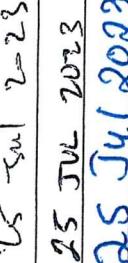


Image- 4

- 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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Entered to HINSHI 3228 1/1/2023
Entered to 13 February 3228 1/9/2024

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:
<p>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</p> <p>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.</p>	<p>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</p> <p>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.</p>

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 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	25.03	24.67	28.28	26.19	27.35	27.92	27.29	26.34	26.45	25.75	26.527	1.1888655	4.378	21.322147	8.542	PASS
Seg B	58.62	58.63	59.05	58.03	58.43	57.67	58.24	60.87	58.12	62.06	58.972	1.3953558	3.981	53.4170886	8.542	PASS
Seg C	76.98	78.33	79.51	79.6	79.1	75.56	77.43	77.39	78.03	77.41	77.934	1.2541239	2.911	74.2832454	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 #: 500000296057

Date: 19JAN24

Inspector Name: Andrew Wipf

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24

Andrew Wipf 19 Jan 24