

Production Order: 500000307847Production Order Document
Production Order Qty: 500

PC

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Material: SA0155-01 Rev FMaterial Type: ZFRT Description: Edwards Flex Shaft Commander
155885

Order Type: ZSTD

Production Version: 7987

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 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>GSE5 5:35 AM 14 Feb 24</u> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>GSE5 6:00 AM 15 Feb 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>MM0179-01</td> <td>D <u>1</u></td> <td>PC</td> <td>500</td> <td><u>0000293119</u></td> <td><u>500</u></td> </tr> <tr> <td>MM1536-01</td> <td>B <u>3</u></td> <td>PC</td> <td>500</td> <td><u>0000290560</u></td> <td><u>500</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	MM0179-01	D <u>1</u>	PC	500	<u>0000293119</u>	<u>500</u>	MM1536-01	B <u>3</u>	PC	500	<u>0000290560</u>	<u>500</u>	N/A	N/A	(13 Feb 24) TCO
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																		
MM0179-01	D <u>1</u>	PC	500	<u>0000293119</u>	<u>500</u>																		
MM1536-01	B <u>3</u>	PC	500	<u>0000290560</u>	<u>500</u>																		

Notes: DA 2564, 2484

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>81654</u>	<u>N/A</u>	<u>N/A</u>	
		1000-1153-01	A	<u>A</u>	PC	594	<u>① 88213 88347</u> <u>② 88214 88348</u> <u>③ 88215 88349</u>	<u>200</u> <u>200</u> <u>200</u>		
		1000-2053-01	A	<u>A</u>	PC	500	<u>0000297543</u>	<u>500</u>		
		MM1537-02	A	<u>A</u>	PC	500	<u>0000290571</u>	<u>500</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>	
							<u>N/A</u>	<u>Bulk</u>		

Notes:

N/A

N/A

N/A

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① 13P2624 P26
② 13P2624 P26
③ 13P2624 P26

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Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	141967-01	02	<u>O2</u>	PC	500	① 85502 85678 ① 88490 N/A	500			
		RM7349-02	C	<u>C</u>	PC	543	32265	537			
		RM7348-01	C	<u>C</u>	PC	500	88490	600			
		RM4001-01	B	<u>B</u>	PC	125	82267	N/A			
		RM0607-01	D	<u>D</u>	PC	56	82269	100	N/A	N/A	N/A
		RM0498-01	C	<u>C</u>	PC	500	2000287450	495			
		RM0009-04	I	<u>I</u>	PC	1	88492	Bulk			
		RM0009-04	I	<u>I</u>	PC	1	88492	Bulk			

Notes:

N/A

N/A

N/A

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① 13PE624TPOO

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Opr No.	Planned WorkCenter Description	Operation Details						Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	MM1538-01	A	<u>A</u>	PC	500	<u>N/A</u>	<u>Bulk</u>			
		MM1537-01	A	<u>A</u>	PC	1000	<u>0000294701</u>	<u>500</u>	<u>N/A</u>	<u>1120</u>	
		MM0177-01	C	<u>C</u>	PC	500	<u>0000294697</u>	<u>N/A</u>	<u>N/A</u>	<u>500</u>	
		MM0180-01	E	<u>E</u>	PC	500	<u>0000295774</u>	<u>N/A</u>	<u>N/A</u>	<u>400</u>	<u>N/A</u>
		MM0178-01	E	<u>E</u>	PC	500	<u>0000287541</u>	<u>100</u>		<u>N/A</u>	<u>N/A</u>
		MM0176-01	D	<u>D</u>	PC	500	<u>0000290565</u>	<u>N/A</u>	<u>N/A</u>	<u>500</u>	
		MM0074-01	G	<u>G</u>	PC	500	<u>0000288413</u>	<u>N/A</u>	<u>N/A</u>	<u>500</u>	
							<u>0000300402</u>	<u>525</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	16Feb24	AT39
	Line Clearance					
	Confirmation Reqd(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	16Feb24	AS31 Y04 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	16Feb24	SF96 CL05 VP62 MC17
250	CATASY01 Catheter Assembly 1 Trim Braid Wire at Proximal End	.	500	0	16Feb24	CL30 SA23 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	16Feb24	epic GS22 RL47 B110
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	16Feb24	NY35 GS22 CX6D 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	16Feb24	SY47 SH85 AL67 SD19 SN167
450	CATASY01 Catheter	FEP Removal	500	0	16Feb24	JY96 AM47 AT39 JC92 JS21
Notes:						
N/A						
N/A						

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Opn No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Assembly 1 FEP Removal Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
500	CATASY01 Catheter Assembly 1 In-process Inspection and Rework Confirmation Reqd(Milestone)	In-process Inspection and Rework Material Consumed: Part #: 100-1153-01 Batch #: 88348 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	EW-HH1 491 AB-1 VD-1 9	SKN-1 16Feb24	VLC91 DX55 TDL15 BI60 LS46 AK02	
N/A	N/A	N/A N/A N/A N/A	N/A	N/A	N/A	N/A
Notes:						

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Opn 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)	491	0	16Feb24	SV46 MV78 MH10 800
600	CATASY01 Catheter Assembly 1 Distal Tip Assembly Confirmation	Distal Tip Assembly	489	I0B - 1 MAH - 1 ②	16Feb24	SV46 MM02 PT09 P146

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	489	0	16Feb24	ML38 LH45
	Loading Heat Shrink					
	Confirmation Reqd(Milestone)					
700	CATASY01 Catheter Assembly 1 	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	489	0	16Feb24	ML38 IC83 AL4L TRN
	Tipping					
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 #: RM4001-01 Batch #: 82807 Qty: N/A Part #: RM0607-01 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	489	0	16Feb24	SV46 BI60 IL83
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	487	ACD-11 (2)	16Feb24	SG88 KL45 AL22 TRN

Notes:

N/A

N/A

N/A

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(1) CBS8 16Feb24

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Opr 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>pascal</u> 2. <u>pascal</u> 3. <u>pascal</u> 4. <u>pascal</u> 5. <u>pascal</u>	487	0	16Feb24	ML65 KL45 TRW PL22
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	HT72 P66 DX35 MV33 PP40
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: TMI: 0700-01 Cal Due: 31 May 24 TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A Material Consumed: Part #: 1000-1153-01 Batch #: 88348 Qty: N/A Part #: RM4001-01 Batch #: 82807 Qty: N/A Part #: RM0607-01 Batch #: 74662 Qty: N/A Part #: RM0158-01 Batch #: 81054 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A</p>	452	DIS-HH1 MAR-HH1 #9US-1 #10US-1 DEL-HHSP FM-HHTT SCR-HHTT EW-II #9OS-1 EH-I DL-II 35	16 Feb 24	K155 DL07 KX54
950	QUALITY1 Quality Inspection & Review	<p>Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: N/A Cal Due: N/A Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

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Op. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Quality Inspection & Review  Confirmation Reqd(Milestone)	TMI: <u>av/A</u> Cal Due: <u>av/A</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>30 Sep 25</u> TMI: <u>0692</u> Cal Due: <u>30 Sep 25</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	441	DIS- <u>HT</u> STR- <u>HT</u> <u>11</u>	16Feb24	Y936 0521 PL22
1000	 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>0589D</u> Cal Due: <u>30 Sep 24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30 Sep 24</u>	432	LT- <u>HT</u> <u>1111</u> <u>9</u>	16Feb24	Y936 PL22 CB58

Notes:

N/AN/AN/A

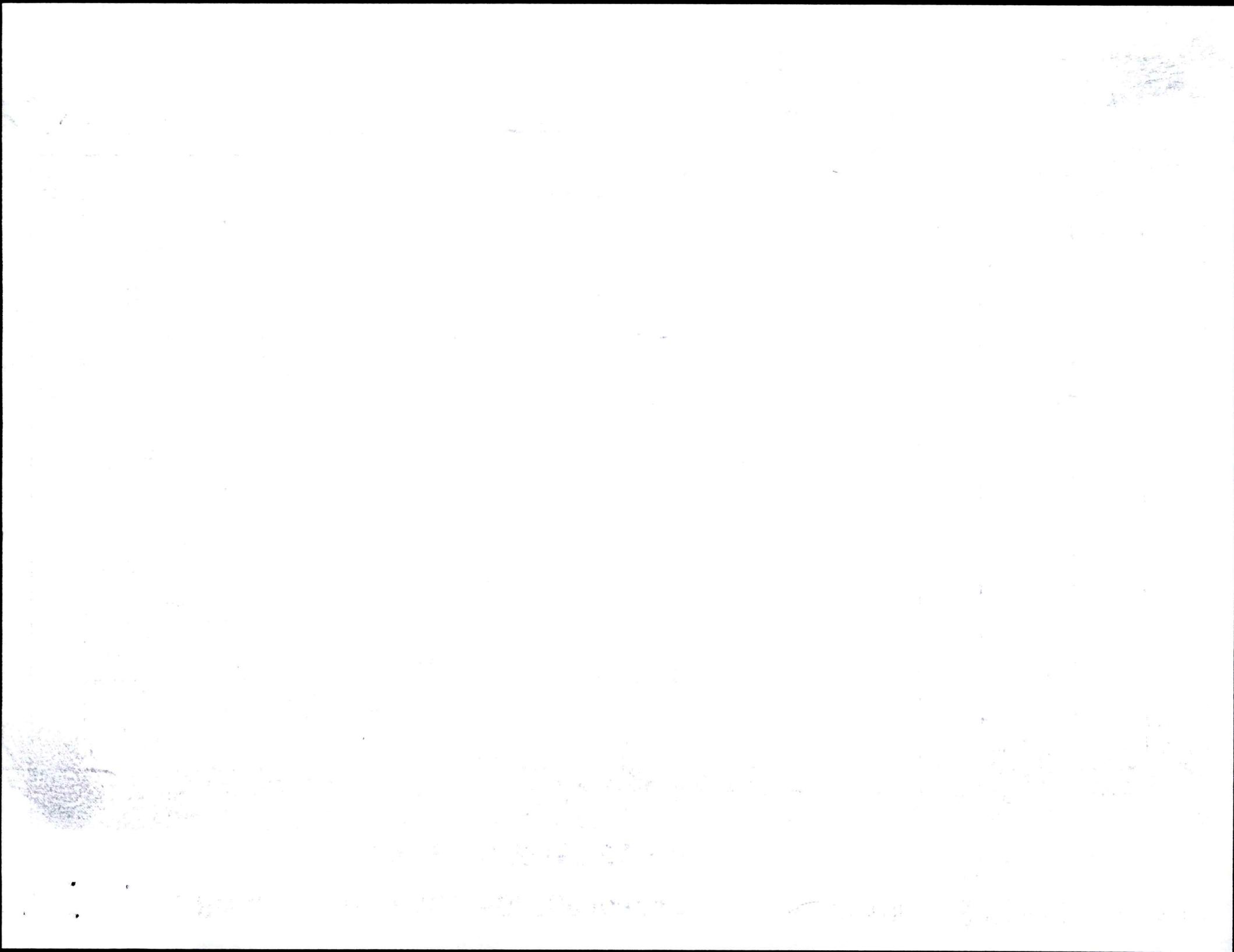
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Op ^r No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A	N/A	N/A	N/A	N/A
1050	QUALITY1 Quality Inspection & Review Quality Inspection & Review Confirmation Reqd(Milestone)	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	4/4	4-DIS 3-SCR 3-SKV 2-TA 2-DEL 1-MEX 2-EW 1-DL 18	19 Feb 24	SV43 MN26 DX52
1100	CATASY01 Catheter Assembly 1 Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): GS85 19 Feb 24	N/A	N/A	19 Feb 24 GS85	

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	014	0	19Feb24	AP10

Notes:

N/A AP10 19 Feb 24

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Batch Number: 0000307847

By: AP10

Date: 19 Feb 24

Reviewed By:

RB29

Date:

20 Feb 24

Notes:

N/A AP10 19 Feb 24

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Batches to 2024 3228 U/A/23
Expiry to 19 Feb 2024 3228 U/A/23
CREGANNA MEDICAL is part of

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REGANNA MEDICAL

Requestor Name: Udhesh Kapadnis

DEVIATION AUTHORIZATION NUMBER: 2484
* See attached email extension to 24SEP23
TS12
24AUG23
DEVIAITON FORM Extnd to 23Oct2023 3228 11/2023

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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.

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:
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:**

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

FM0002.RevF

Deviation Authorization

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① UK55, 23JW 2023



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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 TS12 10AUG-23



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)

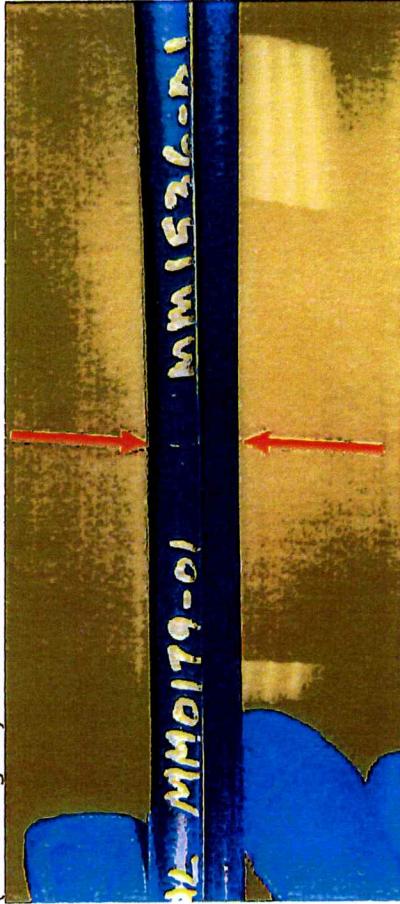


Image- 3

- 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)

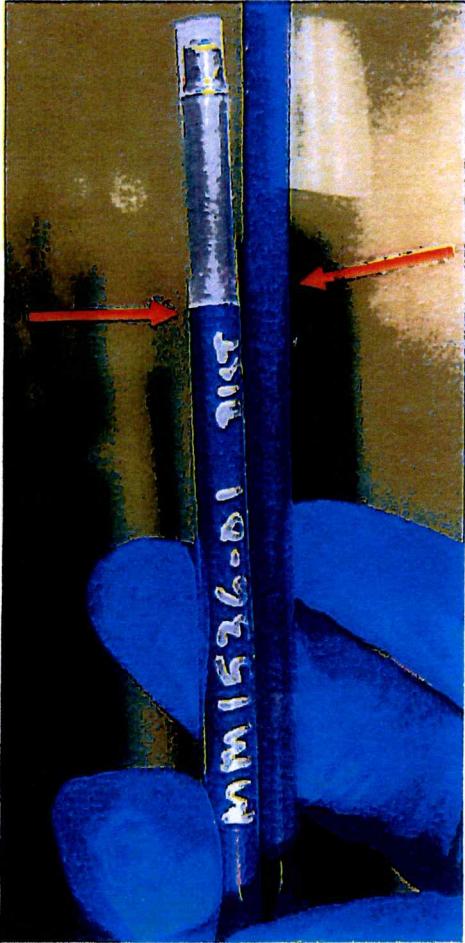


Image- 4
Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.

- 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	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

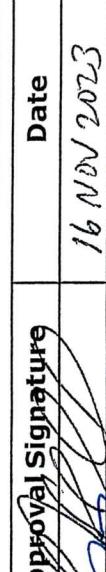
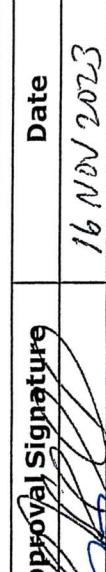
DEVIATION AUTHORIZATION FORM

Requestor Name: Krishna Selvaraj			
Document Number Affected	Revision		
Doc #3005206 (MPI0238)	BP		
Deviation From:	Deviation To:		
Doc #3005206 (Flex Commander MPI0238): OPER850.11:	Doc #3005206 (Flex Commander MPI0238): OPER850.11:		
<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>			

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 FMEAs <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



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

PRODUCTION ORDER#: 500000307847

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	7:15pm	428	SH85	15 Feb 24	7:27pm	415	Sy47	15 Feb 24	16
Tm10942	44	7:42pm	428	Sy47	15 Feb 24	7:54pm	415	Sy47	15 Feb 24	16
Tm10942	44	9:12pm	430	Sy47	15 Feb 24	9:24pm	415	Sy47	15 Feb 24	16
Tm10942	44	9:50pm	430	Sy47	15 Feb 24	10:02pm	415	Sy47	15 Feb 24	16
Tm10942	44	10:23pm	429	Sy47	15 Feb 24	10:35pm	415	Sy47	15 Feb 24	16
Tm10942	44	10:55pm	428	Sy47	15 Feb 24	11:07pm	415	SH85	15 Feb 24	16
Tm10942	421	11:37pm	430	SH85	15 Feb 24	11:49pm	415	SH85	15 Feb 24	16
Tm10942	44	12:12AM	429	SH85	16 Feb 24	12:24AM	415	SH85	16 Feb 24	16
Tm10942	44	12:47AM	430	JY90	16 Feb 24	12:59AM	415	JY90	16 Feb 24	16
Tm10942	44	1:21AM	430	SH85	16 Feb 24	1:33AM	415	SH85	16 Feb 24	16
Tm10942	44	1:55AM	429	JY90	16 Feb 24	2:07AM	415	SA07	16 Feb 24	16
Tm10942	44	6:33AM	430	SN607	16 Feb 24	6:45AM	415	SN607	16 Feb 24	16

① SH85 16 Feb 24
② CB58 16 Feb 24



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 560000307847

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	7:05Am	430	SNL67	16 Feb 24	7:17Am	415	SNL67	16 Feb 24	16
Tm10942	44	7:35Am	430	SNL67	16 Feb 24	7:47Am	415	SNL67	16 Feb 24	16
Tm10942	44	7:56Am	430	SNL67	16 Feb 24	8:08Am	415	SNL67	16 Feb 24	16
Tm10942	44	8:23Am	430	SNL67	16 Feb 24	8:35Am	415	SNL67	16 Feb 24	16
				N/A						
				SNL67	16 Feb 24					



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

PRODUCTION ORDER# 500000307847

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	7:00pm	429	JY90	15Feb24	7:12pm	415	JY90	15Feb24	16
Tm10745	44	7:30pm	429	Sy47	15 Feb 24	7:42pm	415	Sy47	15 Feb 24	16
Tm10745	44	7:58pm	438	SH85	15Feb24	8:11pm	415	SH85	15Feb24	16
Tm10745	44	8:52pm	430	CL30	15 Feb 24	9:04pm	415	CL30	15 Feb 24	16
Tm10745	44	9:26pm	429	Sy47	15 Feb 24	9:38pm	415	Sy47	15 Feb 24	16
Tm10745	44	10:06pm	430	CL30	15 Feb 24	10:18pm	415	CL30	15 Feb 24	16
Tm10745	44	10:40pm	430	Sy47	15 Feb 24	10:52pm	415	Sy47	15 Feb 24	16
Tm10745	44	11:55pm	430	Sy47	15 Feb 24	12:07Am	415	Sy47	16 Feb 24	16
Tm10745	44	12:27Am	429	SH85	16 Feb 24	12:39Am	415	SH85	16 Feb 24	16
Tm10745	44	1:00Am	428	SH85	16 Feb 24	1:12Am	415	SH85	16 Feb 24	16
Tm10745	44	1:34Am	429	SH85	16 Feb 24	1:46Am	415	SH85	16 Feb 24	16
Tm10745	44	6:56Am	430	Sy467	16 Feb 24	7:02Am	415	Sy467	16 Feb 24	16

DSH85 15Feb24



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

PRODUCTION ORDER# 500000307847

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	7:20AM	430	SN67	16Feb24	7:32AM	415	SN67	16Feb24	16
Tm10745	44	7:45AM	430	SN67	16Feb24	7:57AM	415	SN67	16Feb24	16
Tm10745	44	8:10AM	430	SN67	16Feb24	8:22AM	415	SN67	16Feb24	16
Tm10745	44	8:27AM	430	SN67	16Feb24	8:39AM	415	SN67	16Feb24	4
				N/A						
				SN67	16Feb24					



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

PO #: 50000307847

OP #: 500 Shift #: 2nd

Total Parts Reworked:		34	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		2
EH	Exposed Hypotube	N/A	N/A
EW	Exposed Wire	/ /	24
MP	Micropores	N/A	N/A
SCR	Scratch	/	8
SKV	Skive Marks	N/A	N/A
VD	Voids	N/A	N/A
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		DX35.CLO5 15 feb 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 #: 500000307847 OP #: 500 Shift #: 2nd

Total Parts Reworked:		41	
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	/ / /	23
MP	Micropores	N/A	N/A
SCR	Scratch	///	3
SKV	Skive Marks		4
VD	Voids	/	13
N/A	N/A	N/A	N/A

Inspected By (Sign and Date):

Vannmeij Lor 15 Feb 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 #: 500000 307847

OP #: 500 Shift #: 3

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):

):

BIGO, LS46 D429 AB

~~+6 fed 24~~

parts only.
py46 19 Feb 24
correction for B160

- CONFIDENTIAL -

Page 1 of 1

PO #: 50000307847OP #: 750 Shift #: 2nd

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		14	
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)		4
EH	Exposed Hypotube		8
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		SVH6 15 Feb 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 #: 500000307847 OP #: 750 Shift #: 3

Total Parts Reworked:		29	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)	NA	NA
DIM07 US / WC	DIM07 Undersized (Window Closed)	NA	NA
EH	Exposed Hypotube		11
GD / AB	glue damage / Air Bubbles		18
Inspected By (Sign and Date):		B160 16 FEB 2024	

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

Data Uploaded for Engineering Review (Check):



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

PO #: 500 000 307 847 OP #: 750 Shift #: 3

Total Parts Reworked:		28	
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)		3
EH	Exposed Hypotube		11
GD	Glue Damage		7
Inspected By (Sign and Date):		ICB3	16 FEB 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# 500000307847

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM12036	N/A	10:20 PM	190F	SG88	15 Feb 24	11:30 PM	190F	SG88	15 Feb 24	42
TM10409	N/A	11:35PM	190F	SG88	15 Feb 24	12:45AM	190F	SG88	16 Feb 24	30
TM12036	N/A	12:23 AM	190F	SG88	16 Feb 24	1:33AM	190F	SG88	16 Feb 24	31
TM10409	N/A	1:03AM	190F	SG88	16 Feb 24	2:13AM	190F	SG88	16 Feb 24	31
TM10409	N/A	5:05AM	190F	KL45	16 FEB 24	6:15 AM	190F	KL45	16 FEB 24	36
TM10409	N/A	7:10AM	190F	AL42	16 FEB 24	8:20AM	190F	AL42	16 FEB 24	21
TM12036	N/A	8:03AM	190F	AL42	16 FEB 24	9:13 AM	190F	AL42	16 FEB 24	41
TM10409	N/A	8:30AM	190F	AL42	16 Feb 24	9:40AM	190F	AL42	16 Feb 24	23
TM12036	N/A	9:20 AM	190F	AL42	16 Feb 24	10:30AM	190F	AL42	16 Feb 24	22
TM10409	N/A	9:42 AM	190F	AL42	16 Feb 24	10:52AM	190F	AL42	16 Feb 24	40
TM12036	N/A	10:31 AM	190F	AL42	16 Feb 24	11:41 AM	190F	AL42	16 Feb 24	61
TM10409	N/A	10:55AM	190F	AL42	16 Feb 24	12:05 PM	190F	AL42	16 Feb 24	36
TM12036	N/A	11:43AM	190F	AL42	16 Feb 24	12:53PM	190F	AL42	16 Feb 24	73



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 50000307847

OP #: 900 Shift #: 2

Total Parts Reworked:		18	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	/	1
EW	Exposed Wire	HH 1	6
MP	Micropores	N/A	0
SCR	Scratch	HHH HHH HHH IIII	19
SKV	Skive Marks	N/A	0
VD	Voids	/	1
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):		HT72, <i>Andy</i>	15 Feb 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 #: 500000307847OP #: 900 Shift #: 3

Total Parts Reworked:		126	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		12
EH	Exposed Hypotube		14
EW	Exposed Wire		73
MP	Micropores	N/A	N/A
SCR	Scratch		56
SKV	Skive Marks		3
VD	Voids		32
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		9
DIM06 OS	DIM06 OD Oversized		7
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		DL07 KX54	16 Feb 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):

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	33.65	27.44	33.49	24.37	29.81	22.85	26.8	26.6	26.8	27.57	27.938	3.5013991	4.378	12.6088748	8.542	PASS
Seg B	69.77	80.75	73.54	77.14	69.09	68.88	75.64	75.33	71.85	74.92	73.691	3.8416098	3.981	58.3975515	8.542	PASS
Seg C	87.7	87.6	88.17	89.98	88.26	81.88	83.47	88.44	85.07	87.29	86.786	2.5119014	2.911	79.4738549	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 #: 500000307847

Date: 19FEB2024

Inspector Name: AUGUSTINE JAH

Equipment ID: TMIO311B

Cal Due Date: 27 OCT 24



19 FEB 2024

