

Production Order: 500000066053

Production Order Document
Production Order Qty: 500
PC Sheet: 1 of 1



Material: SA0254-06 Rev G

Material Type: ZFRT Description: Printed Shaft 144C Prox End Color B CMDR
Production Version: 8000
Plant / Business Unit: 1213 / AC5

Order Type: ZSTD

Project Phase:

Planned WorkCenter Description		Operation Details			
Opn No.	WorkCenter Description	Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initiat
50	CATASY04 Catheter Assembly 4 Count: Yes	500	0	11 Jan 2021	11 Jan 2021
	By: CL Date: 11 Jan 21				
	Prepare Materials				
	Confirmation Rreqd(Milestone)				
100	CATASY04 Catheter	Straighten First Jacket	MPI0398 Rev. U	U/A	11 Feb 2021

Notes: DA : 1738 DA1787

DA

Date Printed: 11.01.2021 / 07:13:56



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19 Feb 2021



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Opn No.	Planned Workcenter Description	Operation Details					
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials		
200	CATASY04 Catheter Assembly 4 	312	0	11Jan21	AN		
	Strain Relief Reflow MPI0398 Rev. <u>L</u> Temp = 420°F 5°F Air Flow = 60 SCFH			11Jan21			
	Strain Relief Reflow	Component Number	Req'd Rev	UOM	Qty.	Batch No.	Actual Qty Used
	Confirmation Reqd(Milestone)	MM0527-01	B	PC	500	<u>0000058674</u>	<u>500</u>
		RM0096-01	F	PC	125	<u>27976</u>	<u>191</u>
						<u>N/A</u>	<u>N/A</u>
250	CATASY04 Catheter Assembly 4 	270	0	11Jan21	SC SP WT BK VMG		
	Position Tubing For Reflow MPI0398 Rev. <u>L</u>	Component	Req'd Rev	UOM	Qty.	Batch	Actual
						230	0
							11Jan21
	Notes:	<u>11/11</u>					

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Opn No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		Number	Rev	Used	No.	Qty Used					
	Position Tubing for Reflow	MM0186-00	D	D	PC	500	P08-06-11C1	350			
		MM0523-03	C	C	PC	500	0000059871	150			
		MM0524-01	B	B	PC	500	0000058676	500	N/A		
		MM0530-01	B	B	PC	500	0000059064	500	N/A		
		RM7586-02	D	D	PC	500	0000059064	70	N/A		
		RM8745-01	B	B	PC	500	25632	465	TPL4459	35	
		MM0185-01	I	I	PC	500	27440	200	27613	135	
							27613	165			
							0000058372	465			
							P01-090901	35			

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Op. No.	Planned WorkCenter Description	Operation Details			
		Comp. Qty.	Scrap Qty. & Desc.	Date Comp.	Initials
400	Skive Heat Shrink				NJA
400	CATASY04 Catheter Assembly 4 Count: Yes In Process Inspection	In-Process Inspection (Visual Inspection) MPI0398 Rev. U FM5104693 (Rework if needed. Use FM5104983)	490 6EW 2DF 2DS	12 Jun 21	YK TrnCL JKH
450	CATASY04 Catheter Assembly 4 Anneal Shaft	Anneal Shaft MPI0398 Rev. U FM5104692 Anneal Shaft	490 O	12 Jun 21	YK

Notes:

10/14

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Opn No.	Planned WorkCenter Description	Operation Details			
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initiator
500	CATASY04 Catheter Assembly 4	Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. <u>U</u>	175 14	12 Jan 21 CKY 12 Apr 21 NYL	Hoffert
	Leak Test/Prox Cut/Ring Gage-Dim 13/21	FM5104694 FM5104695	289	12 Jan 21 NYL	OPTEC
550	CATASY04 Catheter Assembly 4	Distal Cut MPI0398 Rev. <u>U</u> Line Closure MPI0230 Rev. <u>E</u> By: <u>JKL</u> Date: <u>12 Jun 21</u>	175 289	12 Jan 21 CKY 12 Jun 21 NYL	O
	Distal Cut				
600	PADPRIN1 Pad Print Count: Yes	Pad Print Set Up MPI0276 Rev. <u>D</u> Line Clearance MPI0230 Rev. <u>E</u>	464	13 Jan 21 PK	(TAN) (DK)
	Notes:	N/A			

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CKY 12 Jan 21

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Opr No.	Planned Work Center Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Pad Print Setup	<p>By: <u>PK (TEN) Date: 13 Jan 21</u></p> <p>TM10503 (circle TMI used) Cliché - TL0525 Ink # RM7407-01 Thinner - RM7408-01 Hardener - RM7409-01 Customized Measuring Equipment - Caliper Inspection Gauge TMI0843 Setup Rod # TL0815 Program - #10 Ink Viscosity (REF) -5 to 6 Pad - TL0545 or equivalent Fence - TL0538 Drying Oven - TMI0643 Drying Racks-TL0531, TL0532</p> <p><u>TMI0735</u> Cliché - TL0567 Ink - RM7407-01 Thinner - RM7408-01 Hardener - RM7409-01 Customized Measuring Equipment - Caliper Inspection Gauge TMI0843 Setup Rod # TL0815 Program - #10 Ink Viscosity (REF) -5 to 6 Pad - TL0545 or equivalent Fence - TL0569 Drying Oven - TMI0643 Drying Racks-TL0531, TL0532</p>				N/A

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Opr No.	Planned WorkCenter Description	Operation Details				Initials (TEN D)
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.		
650	PADPRIN1 Pad Print 	Verification MPI0276 Rev. <u>D</u> Section 15.0		464	0	PK (TEN D) 13 Jan 21
RM7407-01	B	Rev Used <u>B</u>	UOM L	Qty. 0.050	Batch No. 25658	Actual Qty Used 0.040 N/A

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Opn No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initiator
		B	L	0.005	TP53072	0.005	N/A				
700	PADPRIN1 Pad Print 	RM7408-01	B	<u>B</u>	L	0.005	TP53072	0.005	N/A	13 Jan 21	PK (TPN)
700	PADPRIN1 Pad Print 	RM7409-01	B	<u>B</u>	L	0.010	26764	0.010	N/A	13 Jan 21	PK (TPN)
750	PADPRIN1 Pad Print 						464	0		13 Jan 21	PK (TPN)

Notes:
N/A

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Op No.	Planned Work Center Description	Operation Details					
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials		
800	PADPRIN1 Pad Print 	In-Process Inspection and Rework MP10276 Rev. <u>D</u> Section 30.0 Polynit Wipes 99% IPA Mag Light	464	0	13 Jan 21	PK (TPN) (PA)	
850	PADPRIN1 Pad Print 	Curing Oven MP10340 Rev. <u>B</u> Section 35.0	464	0	13 Jan 21	PK (TPN) (PA)	
		Curing oven for 120 +30/-15 minutes Parts sit for 8 hours minimum after curing oven					
		Lot Completion time: <u>2:55 PM</u> By: <u>PK</u> Date: <u>13 Jan 21</u>					
900	PADPRIN1 Pad Print 	Confirmation Reqd(Milestone)	464	0	14 Jan 21	PK	
		Transfer Parts to Production MP10276 Rev. <u>D</u> Section 40.0					

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Job No.	Planned Work Center Description	Operation Details			
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Transfer Parts to Line Time: <u>5:30 AM</u> By: <u>PK</u> Date: <u>14 Jan 21</u>				
950	Transfer parts to Production Confirmation Rreq(Milestone) N/A				
950	PADPRIN1 Pad Print Count: Yes Cleaning Confirmation Rreq(Milestone) N/A	Cleaning MP10276 Rev. <u>D</u> Section 50.0 Line Clearance MP10230 Rev. <u>E</u> By: <u>PK</u> (<u>PK</u>) Date: <u>13 Jan 21</u>	464 0	13 Jan 21 PK (PK)	
1000	CATASY04	In-Process Dimensional Inspection		N/A	

Notes:	<u>N/A</u>

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Opn No.	Planned WorkCenter Description	Operation Details					
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials		
	Catheter Assembly 4	MP10398 Rev. <u>U</u> FM5104662 FM5104696	(No Rework can be done at this OP)				
	In-Process Dimensional Inspection	Line Closure MP10230 Rev. <u>E</u>	By: <u>Pny</u> Date: <u>23 Jan 21</u>				
1050	QUALITY1	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan		(60) 43.00/050018 1-54/over	372 2-WT 1-PRT 1-DISC 1-VD 10-TT	19 Feb 21 DX	
	Quality Inspection & Review						
	Quality Inspection & Review						
	Confirmation Reqd(Milestone)						

Notes:

14 10 Feb 21

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Opn No.	Planned WorkCenter Description	Operation Details					
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials		
1070	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1070	CATASY04	Rework MPI0398 Rev. 1.5	1 SL	19 Feb 21	VC		
		Material consumed Material 0M8745-01	371				
		Material					
		Material					
		Material					
		Material					
		Confirmation Reqd(Milestone)					
1090	QUALITY1	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	371	19 Feb 21	DR		
	Quality Inspection & Review						
	Quality Inspection & Review						
	Notes:						

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Ord No.	Planned Work Center Description	Operation Details			
		Comp. City.	Scrap Qty & Desc.	Date Comp.	Initials
	Confirmation Rqrd(Milestone)	N/A	N/A	N/A	N/A
1100	PACKINT1 Packing assembly	371	0 19 Feb 2021 APP	19 Feb 2021 APP	

Notes:

N/A

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Batch Number: 0000006053

By: AP

Date: 19 Feb 21

Reviewed By:

Date: 19 Feb 21

Notes:

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Document No: FM5104983

Rev. B

Rev. B Document Type: Manufacturing Form
Title: SA0254 Cause of Rework Form

PRODUCTION ORDER# 50000066053

Attachment B: Cause of Rework.

OPER 400.0

Date	Initial	AB (Prox)	AB (Distal)	DF	DS	EW	FM	Disc	SCR	SKV	VD
12 Jan 21	√c yk	o	58	o	o	/	19	o	9	/	o

Attachment B: Cause of Rework

OPER 500.0

Date	Initial	Dim 13 (Go Gauge)	Dim 21 (Go gauge)
11 Jan 21	VL	0	6
12 Jan 21	MCL	0	97

PRODUCTION ORDER# 50000000 66053

OPER 500.0

▲13 & ▲21 Max OD Gauge Check for the manufacturing lot PRIOR TO AND AFTER Inspection

Before & After Inspecting Parts	Dimension ## Gauge Check	TMI###XX (Ex. TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13				
Before	Dimension 21	TMI 0748 AN CL	12 Jan 21	10:50 AM	
After	Dimension 13	TMI 0747 u CL	12 Jan 21	10:50 AM	
After	Dimension 21	TMI 0748AN LY	12 Jan 21	9:00 PM	
		TMI 0747u LY	12 Jan 21	9:00PM	

PRODUCTION ORDER# 500000660653 66053

OPER 500.0							Pressure Decay Testing			
Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date			
Air Leak Test GN 15	N/A	100%	Issac Pressure Decay Tester	TM10791 U9D	0	0	MUL 12 Jan 21			
Outer Diameter ▲ 13 MAX OD at Pad Printed Area	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TM10748 U6U	11612	26		MUL 12 Jan 21			
Outer Diameter ▲ 21 MAX OD	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TM10747	164	0	0	MUL 12 Jan 21			



Document No: FM5104662

Rev: B

Document Type: Manufacturing Form

Title: SA0254 Max OD Form

PRODUCTION ORDER# 500000066053

OP 1000.0 ▲13, ▲21 Max OD Gauge Check for the manufacturing lot PRIOR TO AND AFTER Inspection

Before & After Inspecting Parts	Dimension ## Gauge Check	TMI##XX (Ex. TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13	TMI 0748 AM KJL		25 Jan 21	5:10 A.M
Before	Dimension 21	TMI 0747 T KJL		25 Jan 21	5:10 A.M
After	Dimension 13	TMI 0748 AM MV		23 Jan 21	7:30 P.m
After	Dimension 21	TMI 0747 T MV		23 Jan 21	7:30 P.m

PRODUCTION ORDER# 50000066053

OP 1000.0

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Outer Diameter ▲13 MAX OD at Pad Printed Area Drop Go Gauge from proximal end of shaft. Pass if ring stops at stop sleeve shoulder. Fail if gauge stops above or falls past stop sleeve shoulder.	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TMI0748 or equivalent	TMI 0748 459	459	5	xx 23 Jan 21
Outer Diameter ▲21 MAX OD Drop Go Gauge from stop sleeve shoulder. Pass if ring does not stop. Fail if ring stops less than 4" distal above stop sleeve shoulder.	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI 0747 or equivalent	TMI 0747 444	444	15	xx 23 Jan 21
Outer Diameter ▲2 MAX OD Go-gauge: Measure from distal end to minimum 1.7" from tip. Gravity force only.	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0967, or equivalent	TMI 0967 427	432	12	xx 23 Jan 21
Outer Diameter ▲2 MIN OD No-go gauge: End must not pass through	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0968, or equivalent	TMI 0968 427	432	0	xx 23 Jan 21
Outer Diameter ▲8 MAX OD Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049 427	432	0	pm/ 23 Jan 21
Outer Diameter ▲8 MIN OD Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049 427	432	0	pm/ 23 Jan 21

pm/ 23 Jan 21
L4 10 Feb 21
L4 10 Feb 21
L4 10 Feb 21

PRODUCTION ORDER# 500000046053

Document No: FM5104696

Rev: B

Document Type: Manufacturing Form
Title: SA0254 In-Process Inspection Form

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Outer Diameter ▲13 AVG OD at Pad Printed Area Measure from distal end of material transition to stop sleeve shoulder NOTE: Measure AVG OD and record results	0.145 +0.002/-0.004" (0.141"-0.147")	100%	Two Axis Laser Micrometer	TMI50049 427 432	0	0	Puy 23 Jan 21
Outer Diameter ▲21 AVG OD Measure from stop sleeve shoulder to 4" distal of stop sleeve shoulder. NOTE: Measure AVG OD and record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer	TMI50049 427 432	0	0	Puy 23 Jan 21
Outer Diameter ▲17 AVG OD Measure 4" distal the stop sleeve shoulder to the braid termination. NOTE: Measure and Record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer	TMI50049 427 432	0	0	Puy 23 Jan 21
Outer Diameter ▲12 MAX OD Measure distally from the braid termination to the all the way distal end of the shaft.	0.142" ± 0.002" (0.140"-0.144")	100%	Two Axis Laser Micrometer	TMI50049 427 432	0	0	Puy 23 Jan 21
Outer Diameter ▲12 MIN OD Measure distally from the braid termination to the all the way distal end of the shaft.	0.142" ± 0.002" (0.140"-0.144")	100%	Two Axis Laser Micrometer	TMI50049 427 432	0	0	Puy 23 Jan 21

L4 10 Feb 21
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Document No: FM5104983

Rev: B

Document Type: Manufacturing Form

Title: SA0254 Cause of Rework Form

PRODUCTION ORDER# 5000006053

OPER 1050.0

Date	Initial	AB	DISC	DF	DS	EW	FM	OD	SCR	SKV	VD	OTHER
19 Feb 21	DR	O	O	O	O	O	O	O	10	O	O	4-DSU
					N/A							

Record total quantity reworked:

14

Quantity Passed after Rework:

13

Rework Performed by: VC Date: 19 Feb 21 Rework Performed by: NIA Date: NIA

Re-Inspection Performed by: DR Date: 19 Feb 21

#53 09DEC2020

Status/Initials

Signature

Mfg Engineering manager	Renata Holahan	APPROVAL SIGNATURE	Date
Quality Manager Ops mgmt	Steve Julie Michelin	APPROVAL SIGNATURE	Date
Operations Manager	Mike Opatz	APPROVAL SIGNATURE	Date

Training Required:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If no, explain: N/A
--------------------	---	---------------------

If no, explain:	Deviation talks about recording the variable data at a operation where we are already checking for the dimension.
Corrective Action Required:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

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

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
--	---	--	-----------------------

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

Risk Assessment:	At Risk
Start Date:	12/9/2020
End Date:	1/9/2021
Lot Number:	N/A

Part Number Affected	SA0254 - 04/05/06
Revision	5

Justification:	As per the customer requirement we are starting to record the variable data for dimension 12 and 13 at "inline dimensional inspection operation".
----------------	---

Deviation From:	Currently at "inline dimensional inspection operation" operators record the variable dimension using laser mic and ring gauges and do not record any variable data.
Deviation To:	Record the variable data for Dim 12 and Dim 13. 10 samples from each lot. Variable data record form to be filled by ops department. ops lead to add to the excel file to monitor variable data behavior.

Document Number Affected	MP10398
Revision	U

Requestor Name:	Govind Sharma
-----------------	---------------

DEVIATION AUTHORIZATION FORM

DEVIATION AUTHORIZATION NUMBER: DA1738



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TEST DATA SHEET

Sample	Dim 12 (Max) 0.142" +/- 0.002	Dim 12 min 0.142" +/- 0.002	Dim 13 Avg N/A	Dim 13 Max 0.145" +0.002" -0.004"	Dim 13 Max 0.145" +0.002" -0.004"	Comments: N/A
1	0.1432	0.1424	N/A	0.1449	0.1456	
2	0.1439	0.1436	N/A	0.1444	0.1460	
3	0.1427	0.1424	N/A	0.1452	0.1462	
4	0.1434	0.1428	N/A	0.1438	0.1477	
5	0.1430	0.1427	N/A	0.1445	0.1454	
6	0.1431	0.1426	N/A	0.1446	0.1453	
7	0.1430	0.1423	N/A	0.1449	0.1456	
8	0.1427	0.1418	N/A	0.1450	0.1459	
9	0.1426	0.1420	N/A	0.1442	0.1447	
10	0.1431	0.1429	N/A	0.1445	0.1454	
11						
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30						

Test Description: Dim 12 and 13 variable data recording

Tested by: Puy

Lot Number: 500000066053

Part Number: SA0254-xx 06

Date: 23 Jan 21

Maximum Force Reached During Tensile Test
 (10 samples accepted from final inspection for each lot shall be randomly 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 1	29.12	27.44	26.49	28.14	26.56	27.87	26.64	27.08	25.82	26.29	27.145	1.0011355	4.378	22.76202893	8.542	PASS
Seg B	23.5	23.02	21.14	22.82	21.75	22.17	22.18	22.51	23.08	23.03	22.52	0.715666	4.378	19.38681439	8.542	PASS
Seg C	48.62	65.44	46.98	65.56	59.94	48.24	53.4	66.14	48.9	52.44	55.566	7.9081733	4.378	20.94401743	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 not being required for DA acceptance.

Kochhy Lee

19 Feb 21



DEVIATION AUTHORIZATION FORM

Requestor Name: Saroeun Chhum

Document Number Affected	Revision
2100586	B

Deviation From:

100% Inspections at Final Inspection (Do not Require SmartSolve Notification to be issued).

The following rules apply to these product families: If there is a characteristic that is 100% inspected at Final Inspection, and this product is an Edwards product line there is a 35% allowance to scrap at final inspection.

Deviation To:

100% Inspections at Final Inspection (Do not Require SmartSolve Notification to be issued).

For products listed below, Smartsolve Notification is not required for any sum of scraps at final inspection:
SA0286-01 & -02; SA0254-04, -05 & -06; SA0155-01

Justification:

All lots undergo 100% visual inspection; therefore, there is no risk to the customer for lots released without documenting in the Smartsolve notification.

Part Number Affected	Revision
SA0286-01	07
SA0286-02	07
SA0254-04	G
SA0254-05	G
SA0254-06	G
SA0155-01	F

Start Date:	End Date:	Lot Number:
15Jan2021	22Jan2021	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):

If yes to any of the above, what controls are being put in place to mitigate the risk: N/A

Corrective Action Required: Yes No

If no, explain:

No correction is required, SAP will address all lot manufactured in the new system.

Training Required: Yes No **If no, explain:**

Title	Approval Name	Approval Signature	Date
Quality Director	Jeff Pumper		15 JAN 2021
OPS Manager	Zach Nelson		15 JAN 2021
Staff Engineer	Vivek Rangaswami PETZL 15 JAN 2021		15 JAN 2021