



Monthly Technical Review (Jul 2018 Data)

Flex CFT

15 Aug 2018

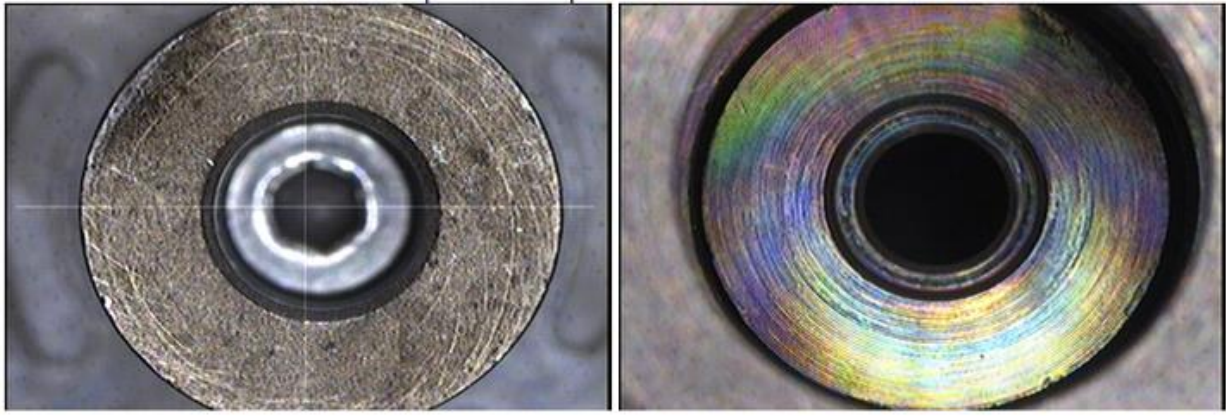
Agenda

1. Review of last MTR minutes & action items
2. First Pass Yield
 - Overall Results & individual instrument results
 - Instrument > targets (does not meet Waters targets or having downtrend)
 - Improvement actions & effectiveness (if any)
3. Manufacturing readiness
 - Training review and competencies updates (na for this session)
 - Manufacturing Engineering Issues / Updates
 - Test Engineering Issues / Updates
 - TMD Updates
4. Quality (trending, analysis of issues (repeated case), updates / actions taken)
 - Suppliers
 - LAR
 - SCAR
 - Audit (schedules, audit results, findings and closure etc)
 - In Process
 - NCR
 - CAPA
 - Quality alerts
 - Customers & field complaints
 - QMS updates (na for this session)
5. Others
 - AOB

Review Of Last MTR Minutes

Description	Responsible	Due Date
<u>1) Quality Plan update</u> • 11Nov: Quality Plan to include the Arc Detectors. • 21Dec: update is in progress by WPPL. • 21Dec: Flex would like to propose to exclude “ISO 9001” from the Quality Plan. Flex QMS to send explanation why Flex proposes so. • 17 Feb: Flex to review Waters draft and get back to Waters. • 15 Jun: draft was sent back to WPPL • 21 Jul: WPPL and Flex will discuss the Draft Quality Plan comments on 27th Jul. • 15 Sep: Flex sent proposed draft Quality Plan on 10 Aug 2017 . Pend WPPL review. • 18 Dec: Flex reviewing the updated draft Quality Plan received on 14 Dec 2017. • 20 Mar: Quality plan pending update on DHR content requirement and adding new model (QSM Plus)	Flex	23 Mar 2018

Review Of Last MTR Minutes

Description	Responsible	Due Date
2) GPV (WAT270524) 15 Sep: after using the corrected lot, 1 failed out of more than 500u tested. 20 Sep: Parker's FA report- no indication of metallic fragments from the screw thread cutting process in the armature was found. (Refer to below photo cut from Prelim FA). The part will be returned to Flex for control build.  21 Nov: pend Parke to return GPV after FA to Flex. 18 Dec: 3 x RMA, Pend update from Parker 15 Jan: Request Flex stop checking with Parker until further notice as Parker is relocating the factory 20 Feb: Flex can start to peruse outstanding issues with Parker 20 Mar: RMA#14671 (01pc) - produced after corrective action. Flex is query Idex on the findings reported by Idex's FA report. 20 Mar: pursuing the other outstanding's reports 16 Apr: see next slide on the response from Parker on FA sent on 03 Apr 2018 17 Apr: WPPL informed the triggering is 15000ppm. 14 Aug: Jan to Jul PPM – see next slide.	Parker / Flex	On-going

Review Of Last MTR Minutes

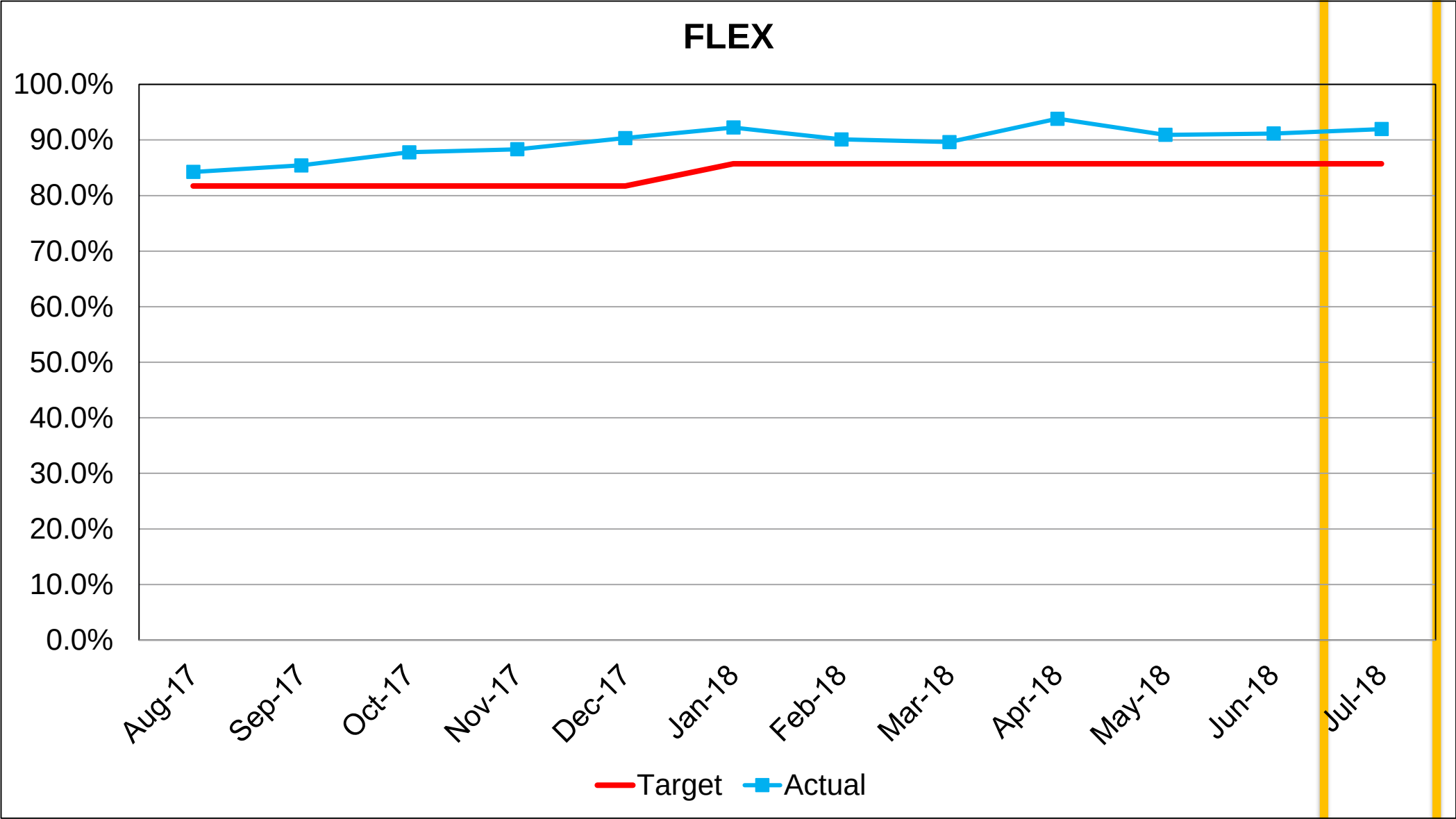
PPM for Alliance GPV (PN WAT270524) (Jan to Jul 2018)

Month	Qty Build	Qty GPV Failure	% Failed	PPM	GPV SN	Instrument SN	Remarks
Jan-18	462	1	0.22%	2,165	(1) 131069	(1) A18SM4243A	(1) Jan 2018 : Solvent Inlet Plumbing Verification, Solvent A no water flow
Feb-18	361	3	0.83%	8,310	(1) 141457 (2) 141632 (3) 141671	(1) B18SM4522A (2) B18SM7778A (3) B18SM4588A	(1) Feb 2018 : Solvent Inlet Plumbing Verification, Solvent D no water flow (2) Feb 2018 : Solvent Inlet Plumbing Verification, Solvent C & Solvent D water flow in reverse direction (3) Feb 2018 : Solvent Inlet Plumbing Verification, Solvent B no water flow
Mar-18	400	5	1.25%	12,500	(1) 141980 (2) 142062 (3) 142045 (4) 141795 (5) 142078	(1) C18SM7836A (2) C18SM4732A (3) C18SM7877A (4) C18SM4682A (5) C18SM4839A	(1) Mar 2018 : Solvent Inlet Plumbing Verification, Solvent A no water flow (2) Mar 2018 : Chemistry Test, AC chemistry test failed (3) Mar 2018 : Solvent Inlet Plumbing Verification, Solvent B no water flow (4) Mar 2018 : Chemistry Test, BD chemistry test failed (5) Mar 2018 : BD Presicion Test, Failed at final test
Apr-18	352	7	1.99%	19,886	(1) 142173 (2) 142169 (3) 142168 (4) 142161 (5) 142167 (6) 142241 (7) 142303	(1) C18SM4947A (2) C18SM4902A (3) C18SM7906A (4) C18SM7915A (5) C18SM7913A (6) D18SM4994A (7) D18SM4021A	(1) Apr 2018 : Solvent Inlet Plumbing Verification, Solvent C & Solvent D water flow in reverse direction (2) Apr 2018 : Solvent Inlet Plumbing Verification, Solvent C & Solvent D water flow in reverse direction (3) Apr 2018 : Solvent Inlet Plumbing Verification, Solvent C & Solvent D water flow in reverse direction (4) Apr 2018 : Solvent Inlet Plumbing Verification, Solvent C & Solvent D water flow in reverse direction (5) Apr 2018 : Solvent Inlet Plumbing Verification, Solvent C & Solvent D water flow in reverse direction (6) Apr 2018 : BD Presicion Test, Failed at final test (7) Apr 2018 : Carryover test failed, No reading
May-18	394	5	1.27%	12,690	(1) 142823 (2) 143126 (3) 143191 (4) 143286 (5) 143201	(1) E18SM4309A (2) E18SM7010A (3) E18SM4387A (4) E18SM7035A (5) E18SM4424A	(1) May 2018 : Solvent C & Solvent D water flow in reverse direction (2) May 2018 : Solvent C no water flow (3) May 2018 : Solvent C no water flow (4) May 2018 : Solvent B no water flow (5) May 2018 : Solvent C no water flow
Jun-18	488	6	1.23%	12,295	(1) 143365 (2) 143367 (3) 143352 (4) 143393 (5) 143569 (6) 143501	(1) E18SM4518A (2) E18SM4535A (3) E18SM4524A (4) E18SM7065A (5) F18SM7089A (6) F18SM4689A	(1) June 2018 : Solvent A, B & D no water flow (2) June 2018 : Solvent B no water flow (3) June 2018 : Solvent D no water flow (4) June 2018 : BD precision test failed at final test (5) June 2018 : AC precision test failed at final test (6) June 2018 : Solvent Inlet Plumbing Verification, Leak
Jul-18	558	8	1.43%	14,337	(1) 144272 (2) 143865 (3) 144079 (4) 141795 (5) 141457 (6) 142062 (7) 144685 (8) 144791	(1) F18SM7194A (2) F18SM7204A (3) F18SM7241A (4) G18SM4889A (5) G18SM4965A (6) G18SM4975A (7) G18SM7297A (8) G18SM4226A	(1) Jul 2018 : Chemistry test BD test failed (2) Jul 2018 : Solvent D no water flow (3) Jul 2018 : Solvent Inlet Plumbing Verification failed (4) Jul 2018 : BD Precision Test failed (5) Jul 2018 : Solvent D no water flow (6) Jul 2018 : AC Precision Test failed (7) Jul 2018 : BD precision test failed (8) Jul 2018 : Solvent A no water flow

Note: Apr 2018 PPM exceed 15000

First Pass Yield (without Alliance Carry over test failure)

Overall



NOTE : FPY target is revised upward to 85.7% from 81.7% wef Jan 2018.

FLEX		
Period	Target	Actual
Aug-17	81.7%	84.3%
Sep-17	81.7%	85.4%
Oct-17	81.7%	87.8%
Nov-17	81.7%	88.3%
Dec-17	81.7%	90.3%
Jan-18	85.7%	92.2%
Feb-18	85.7%	90.1%
Mar-18	85.7%	89.6%
Apr-18	85.7%	93.8%
May-18	85.7%	90.9%
Jun-18	85.7%	91.2%
Jul-18	85.7%	92.0%

First Pass Yield (without Alliance Carry over test failure)

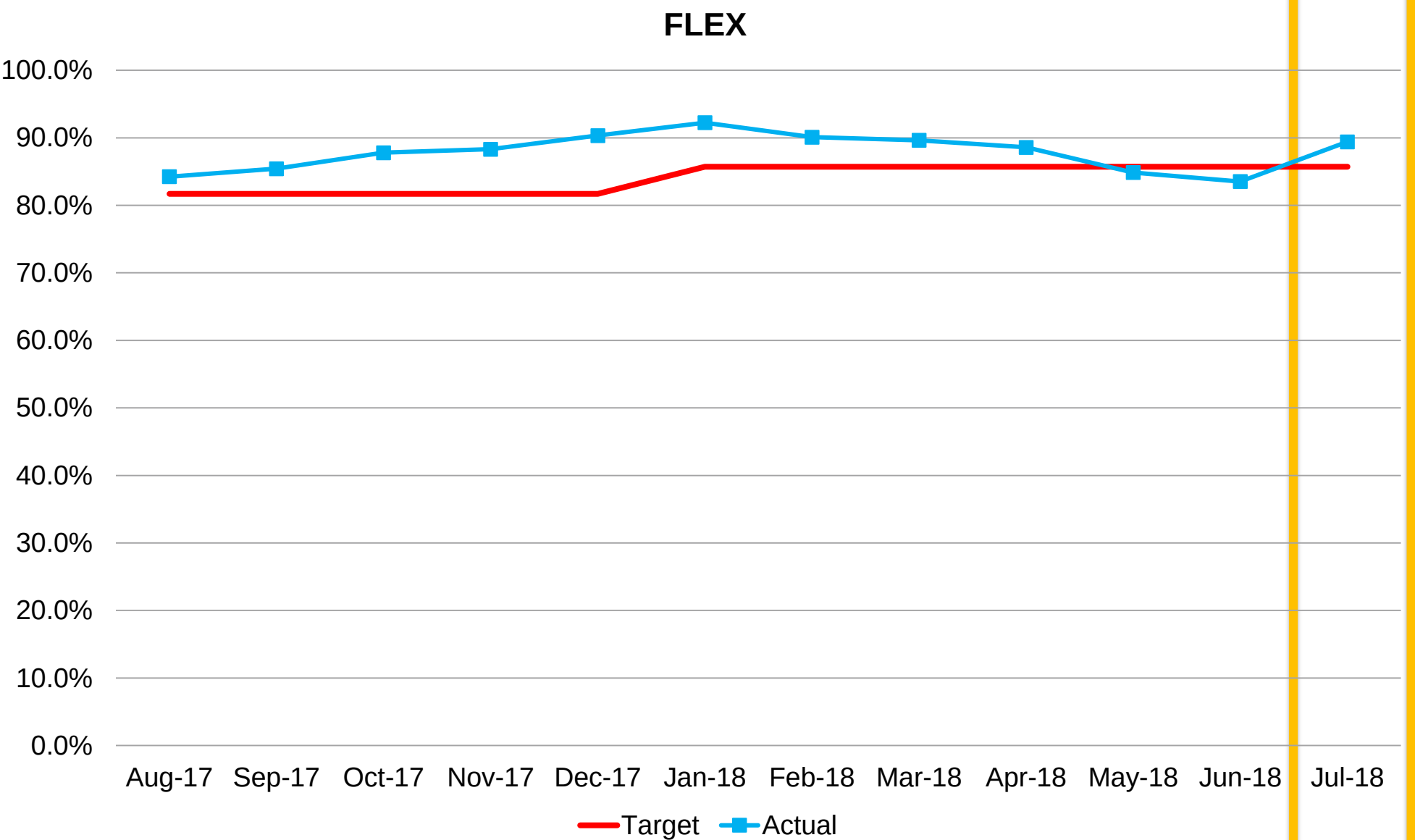
By Instruments

Material Number	Instrument Description	Product Group	Product Class	Target	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
186002487	2489 UV/Visible Detector	Detector	HPLC	92%	92.5%	92.9%	97.8%	92.3%	92.6%	100.0%	100.0%	100.0%	97.0%	100.0%	100.0%	98.1%
186002998	2998 Photodiode Array Detector	Detector	HPLC	79%	60.7%	85.7%	86.1%	77.8%	80.0%	63.0%	50.0%	88.9%	89.3%	72.2%	69.0%	83.3%
186248900	2489 UV/Visible Detector	Detector	HPLC	94%	94.7%	94.5%	95.1%	95.8%	97.4%	98.8%	97.2%	98.7%	98.5%	96.9%	95.4%	98.1%
186299800	2998 Photodiode Array Detector	Detector	HPLC	81%	73.2%	80.9%	85.5%	85.5%	70.0%	86.0%	58.3%	80.5%	87.3%	85.2%	91.5%	88.7%
186015031	ACQUITY TUV (with TC)	Detector	UPLC	91%	61.8%	87.5%	93.7%	96.9%	99.0%	95.7%	98.8%	98.6%	92.9%	94.1%	98.4%	98.0%
186015032	ACQUITY PDA (with TC)	Detector	UPLC	83%	76.9%	80.0%	81.7%	91.3%	82.8%	78.8%	70.4%	83.9%	85.7%	84.1%	84.2%	83.9%
186015033	ACQUITY eλ PDA (with TC)	Detector	UPLC	80%	80.0%	81.7%	88.9%	75.0%	84.4%	78.3%	74.1%	84.7%	87.2%	91.4%	76.6%	81.8%
186015034	ACQUITY UPC2 PDA Detector	Detector	UPLC	88%	87.5%	0.0%	100.0%	100.0%	0.0%	88.9%	0.0%	66.7%	100.0%	83.3%	75.0%	87.5%
186015053	ACQUITY PDA Detector w/TaperSlit	Detector	UPLC	89%	75.0%	0.0%	90.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	80.0%	0.0%	100.0%
186017002	ACQUITY Arc 2489 UV/Vis Detector	Detector	UPLC	94%	97.7%	93.8%	96.9%	96.0%	100.0%	97.9%	97.5%	95.6%	100.0%	100.0%	96.4%	100.0%
186017003	ACQUITY Arc 2998 PDA Detector	Detector	UPLC	79%	67.2%	86.4%	75.0%	82.8%	77.3%	88.7%	0.0%	73.5%	97.4%	89.6%	95.1%	88.2%
WAT207000	ASSY, HPLC PUMP, M515	Pump	HPLC	97%	100.0%	94.4%	97.2%	94.4%	100.0%	97.3%	100.0%	100.0%	95.8%	100.0%	100.0%	100.0%
186001515	1515 ISOCRATIC HPLC PUMP	Pump	HPLC	99%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
186001525	1525 BINARY HPLC PUMP	Pump	HPLC	98%	95.2%	100.0%	93.8%	100.0%	100.0%	100.0%	94.7%	100.0%	100.0%	100.0%	100.0%	100.0%
186001825	1525 MICRO W/DEGASSER	Pump	HPLC	100%	0.0%	0.0%	0.0%	90.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
186269505	e2695 Separations Module w/o HC	eAlliance	HPLC	86%	90.1%	80.0%	84.1%	85.5%	91.2%	93.2%	89.5%	86.0%	91.8%	86.3%	88.5%	88.0%
186269506	e2695 Separations Module w/HC	eAlliance	HPLC	86%	86.6%	85.5%	84.1%	88.9%	90.6%	88.1%	86.2%	87.5%	91.8%	85.7%	88.0%	88.7%
186015001	ACQUITY Binary Solvent Manager	BSM	UPLC	67%	61.2%	61.8%	83.9%	65.4%	90.5%	100.0%	100.0%	100.0%	96.7%	100.0%	100.0%	90.6%
186015018	ACQUITY QSM	QSM	UPLC	75%	72.8%	73.9%	78.7%	77.1%	91.6%	95.8%	95.7%	97.4%	98.0%	100.0%	98.0%	96.8%
186017012	ACQUITY Arc Bio 2489 UV/Vis Detector	Detector	UPLC	85.7	0.0%	0.0%	0.0%	0.0%	100.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%
186017013	ACQUITY Arc Bio 2998 PDA Detector	Detector	UPLC	85.7	0.0%	0.0%	0.0%	0.0%	100.0%	76.5%	0.0%	0.0%	0.0%	100.0%	0.0%	83.3%

New Product - Monitor FPY for at least 6 months (Recommend to follow final FPY target as a start)

First Pass Yield (with Alliance Carry over test failure)

Overall



NOTE : FPY target is revised upward to 85.7% from 81.7% wef Jan 2018.

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Feb-18	85.7%	90.1%
Mar-18	85.7%	89.6%
Apr-18	85.7%	88.6%
May-18	85.7%	84.9%
Jun-18	85.7%	83.5%
Jul-18	85.7%	89.4%

First Pass Yield (with Alliance Carry over test failure)

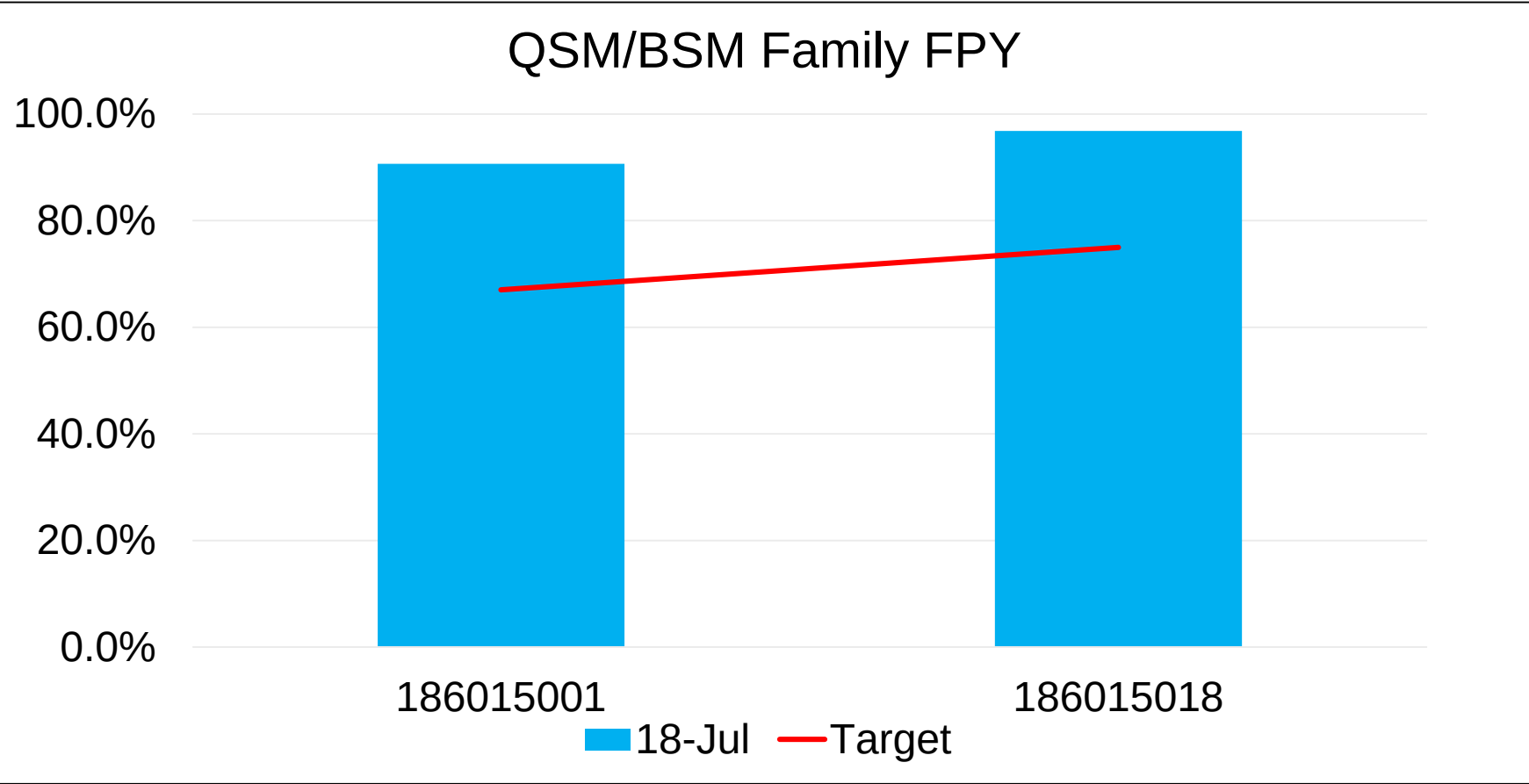
By Instruments

Material Number	Instrument Description	Product Group	Product Class	Target	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
186002487	2489 UV/Visible Detector	Detector	HPLC	92%	92.5%	92.9%	97.8%	92.3%	92.6%	100.0%	100.0%	100.0%	97.0%	100.0%	100.0%	98.1%
186002998	2998 Photodiode Array Detector	Detector	HPLC	79%	60.7%	85.7%	86.1%	77.8%	80.0%	63.0%	50.0%	88.9%	89.3%	72.2%	69.0%	83.3%
186248900	2489 UV/Visible Detector	Detector	HPLC	94%	94.7%	94.5%	95.1%	95.8%	97.4%	98.8%	97.2%	98.7%	98.5%	96.9%	95.4%	98.1%
186299800	2998 Photodiode Array Detector	Detector	HPLC	81%	73.2%	80.9%	85.5%	85.5%	70.0%	86.0%	58.3%	80.5%	87.3%	85.2%	91.5%	88.7%
186015031	ACQUITY TUV (with TC)	Detector	UPLC	91%	61.8%	87.5%	93.7%	96.9%	99.0%	95.7%	98.8%	98.6%	92.9%	94.1%	98.4%	98.0%
186015032	ACQUITY PDA (with TC)	Detector	UPLC	83%	76.9%	80.0%	81.7%	91.3%	82.8%	78.8%	70.4%	83.9%	85.7%	84.1%	84.2%	83.9%
186015033	ACQUITY eλ PDA (with TC)	Detector	UPLC	80%	80.0%	81.7%	88.9%	75.0%	84.4%	78.3%	74.1%	84.7%	87.2%	91.4%	76.6%	81.8%
186015034	ACQUITY UPC2 PDA Detector	Detector	UPLC	88%	87.5%	0.0%	100.0%	100.0%	0.0%	88.9%	0.0%	66.7%	100.0%	83.3%	75.0%	87.5%
186015053	ACQUITY PDA Detector w/TaperSlit	Detector	UPLC	89%	75.0%	0.0%	90.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	80.0%	0.0%	100.0%
186017002	ACQUITY Arc 2489 UV/Vis Detector	Detector	UPLC	94%	97.7%	93.8%	96.9%	96.0%	100.0%	97.9%	97.5%	95.6%	100.0%	100.0%	96.4%	100.0%
186017003	ACQUITY Arc 2998 PDA Detector	Detector	UPLC	79%	67.2%	86.4%	75.0%	82.8%	77.3%	88.7%	0.0%	73.5%	97.4%	89.6%	95.1%	88.2%
WAT207000	ASSY, HPLC PUMP, M515	Pump	HPLC	97%	100.0%	94.4%	97.2%	94.4%	100.0%	97.3%	100.0%	100.0%	95.8%	100.0%	100.0%	100.0%
186001515	1515 ISOCRATIC HPLC PUMP	Pump	HPLC	99%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
186001525	1525 BINARY HPLC PUMP	Pump	HPLC	98%	95.2%	100.0%	93.8%	100.0%	100.0%	100.0%	94.7%	100.0%	100.0%	100.0%	100.0%	100.0%
186001825	1525 MICRO W/DEGASSER	Pump	HPLC	100%	0.0%	0.0%	0.0%	90.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
186269505	e2695 Separations Module w/o HC	eAlliance	HPLC	86%	90.1%	80.0%	84.1%	85.5%	91.2%	93.2%	89.5%	86.0%	50.7%	43.8%	58.3%	80.5%
186269506	e2695 Separations Module w/HC	eAlliance	HPLC	86%	86.6%	85.5%	84.1%	88.9%	90.6%	88.1%	86.2%	87.5%	58.1%	45.2%	49.1%	78.1%
186015001	ACQUITY Binary Solvent Manager	BSM	UPLC	67%	61.2%	61.8%	83.9%	65.4%	90.5%	100.0%	100.0%	100.0%	96.7%	100.0%	100.0%	90.6%
186015018	ACQUITY QSM	QSM	UPLC	75%	72.8%	73.9%	78.7%	77.1%	91.6%	95.8%	95.7%	97.4%	98.0%	100.0%	98.0%	96.8%
186017012	ACQUITY Arc Bio 2489 UV/Vis Detector	Detector	UPLC	85.7	0.0%	0.0%	0.0%	0.0%	100.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%
186017013	ACQUITY Arc Bio 2998 PDA Detector	Detector	UPLC	85.7	0.0%	0.0%	0.0%	0.0%	100.0%	76.5%	0.0%	0.0%	0.0%	100.0%	0.0%	83.3%

New Product - Monitor FPY for at least 6 months (Recommend to follow final FPY target as a start)

First Pass Yield

QSM/BSM Family FPY (Jul 2018 data)

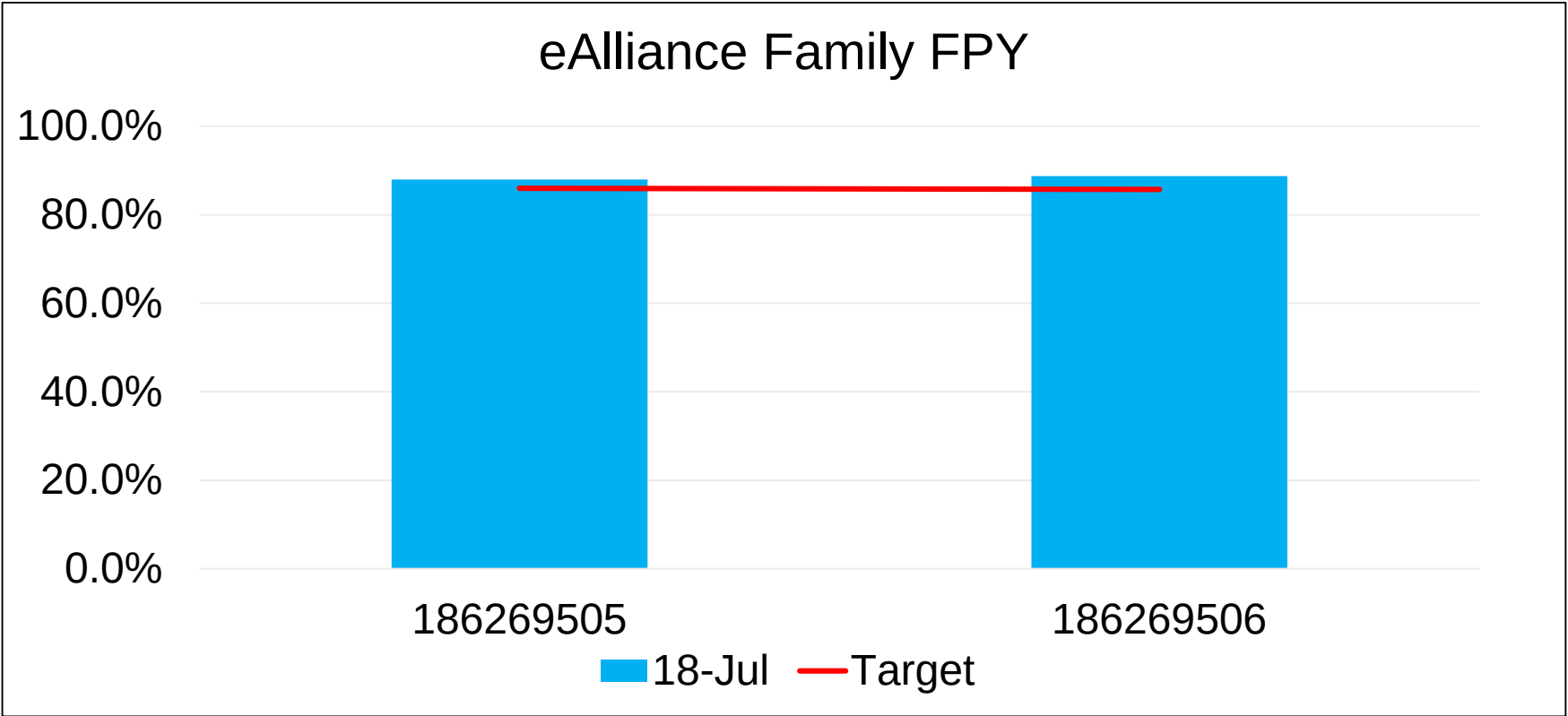


**All meet
target**

Material Number	Instrument Description	Product Group	Product Class	Target	Jul 18 Qty Tested	Jul 18 Qty Failed	Jul 18 Qty Passed	Jul 18 Yield
186015001	ACQUITY Binary Solvent Manager	BSM	UPLC	67%	32	3	29	90.6%
186015018	ACQUITY QSM	QSM	UPLC	75%	126	4	122	96.8%

First Pass Yield (without Alliance Carryover test failure)

eAlliance Family FPY (Jul 2018 data)

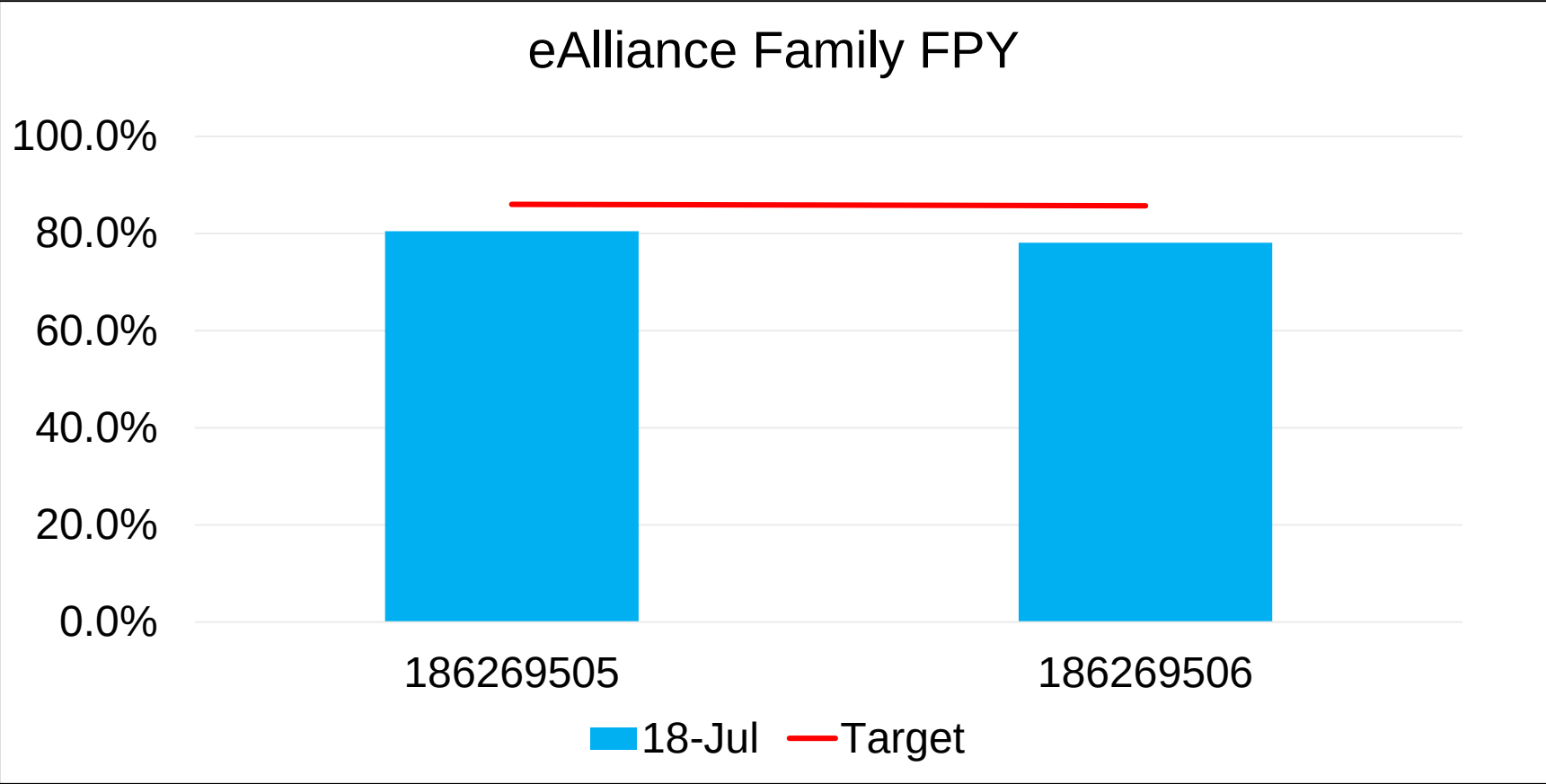


All meet target

Material Number	Instrument Description	Product Group	Product Class	Target	Jul 18 Qty Tested	Jul 18 Qty Failed	Jul 18 Qty Passed	Jul 18 Yield
186269505	e2695 Separations Module w/o HC	eAlliance	HPLC	86%	133	16	117	88.0%
186269506	e2695 Separations Module w/HC	eAlliance	HPLC	86%	425	48	377	88.7%

First Pass Yield (with Alliance Carryover test failure)

eAlliance Family FPY (Jul 2018 data)
with Alliance Carryover test failure



Both model
did not
meet target

Material Number	Instrument Description	Product Group	Product Class	Target	Jul 18 Qty Tested	Jul 18 Qty Failed	Jul 18 Qty Passed	Jul 18 Yield
186269505	e2695 Separations Module w/o HC	eAlliance	HPLC	86%	133	26	107	80.5%
186269506	e2695 Separations Module w/HC	eAlliance	HPLC	86%	425	93	332	78.1%

First Pass Yield

Alliance 186269505– Top Failure Trends (Jul 2018 data)

		Top 1			Top 2			Top 3			
		Carry over test failed (High Blank)			Leak Detection Procedure			Injector Adjustment Test			
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed		
Feb '18	86	0	0.0%		3	3.5%		3	3.5%		
Mar '18	104	0	0.0%		5	4.8%		5	4.8%		
Apr '18	73	21	28.8%		3	4.1%		3	4.1%		
May '18	73	17	23.3%		4	5.5%		3	4.1%		
Jun '18	156	19	12.2%		7	4.5%		6	3.8%		
Jul '18	133	7	5.3%		5	3.8%		4	3.0%		
			Debug Breakdown / Finding		Jul '18	Debug Breakdown / Finding		Jul '18	Debug Breakdown / Finding		Jul '18
			Replaced blank(9)		6	Tighten WAT270409		2	Fine Tune Screw of Sensor Bracket		4
			Replaced blank(9) and cap		1	Tighten 430001194		2			
					Tighten WAT078565		1				

First Pass Yield

Alliance 186269505– Top Failure Trends (Jul 2018 data)

	Top 1	Top 2	Top 3
	Carry over test failed (High Blank)	Leak Detection Procedure	Injector Adjustment Test
Analysis / Comment	- Evaluation is in progress and cover as per Engineering discussion and action items. - Trouble shooting as per agreed advise \ approach with WPPL and Flex Eng'g.	- High Pressure points.	- At Injector sub assy already set at higher side of Spec but still needs fine adjustment during the Final Testing.
Root Cause / Possible Root Cause	- On going evaluation (2 units of Injector has been sent to Milford for Failure Analysis 07 Jun 2018)	- Low priority to work on this issue.	- This issue is discussed during “Engineering discussion and action items”.
Corrective Action	NA	NA	NA
Effectiveness	NA	NA	NA

First Pass Yield

Alliance 186269506– Top Failure Trends (Jul 2018 data)

		Top 1			Top 2			Top 3		
		Carry over test failed (High Blank)			Carry over test failed (High Carryover %)			Injector Adjustment test		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
Jan '18	329	0	0.0%		0	0.0%		18	5.5%	
Feb '18	275	0	0.0%		0	0.0%		13	4.7%	
Mar '18	296	0	0.0%		0	0.0%		13	4.4%	
Apr'18	279	60	21.5%		2	0.7%		10	3.6%	
May'18	321	67	20.9%		49	15.3%		12	3.7%	
Jun'18	332	50	15.1%		37	11.1%		40	12.0%	
Jul'18	425	23	5.4%		21	4.9%		18	4.2%	
		Debug Breakdown / Finding		Jun'18	Debug Breakdown / Finding		Jun'18	Debug Breakdown / Finding		Jun'18
		Replaced blank(9)		15	Replaced blank(9)		13	Fine Tune Screw of Sensor Bracket		18
		Replaced blank(9) and cap		8	Replaced blank(9) and cap		8			

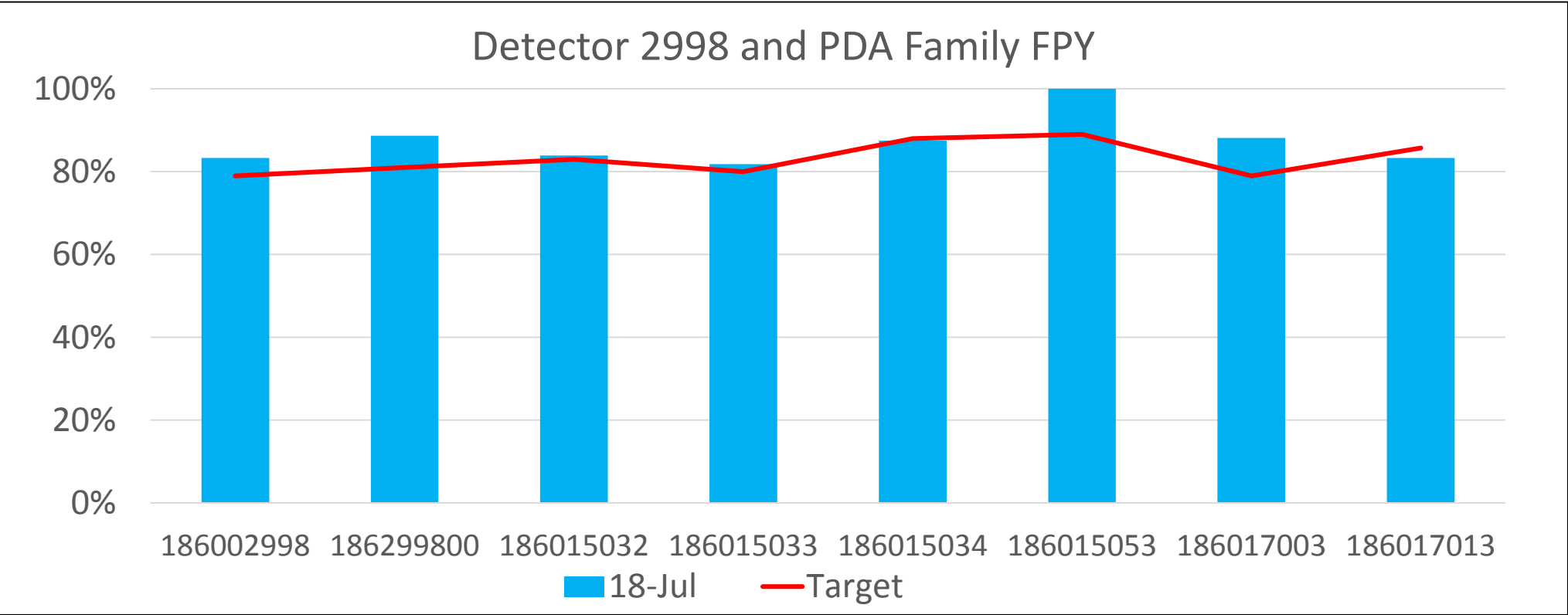
First Pass Yield

Alliance 186269506– Top Failure Trends (Jul 2018 data)

	Top 1	Top 2	Top 3
	Carry over test failed (High Blank)	Carry over test failed (High Carryover %)	Injector Adjustment test
Analysis / Comment	- Evaluation is in progress and cover as per Engineering discussion and action items. - Trouble shooting as per agreed advise \ approach with WPPL and Flex Eng'g.		- At Injector sub assy already set at higher side of Spec but still needs fine adjustment during the Final Testing.
Root Cause / Possible Root Cause	- On going evaluation (2 units of Injector has been sent to Milford for Failure Analysis 07 Jun 2018)		- This issue is discussed during “Engineering discussion and action items”.
Corrective Action	NA		NA
Effectiveness	NA		NA

First Pass Yield

Detector 2998 and PDA Family FPY (Jul 2018 data)



All meet target, except
186015034 and
186017013

Material Number	Instrument Description	Product Group	Product Class	Target	Jul 18 Qty Tested	Jul 18 Qty Failed	Jul 18 Qty Passed	Jul 18 Yield
186002998	2998 Photodiode Array Detector	2998 and PDA Detector	HPLC	79%	30	5	25	83.3%
186299800	2998 Photodiode Array Detector	2998 and PDA Detector	HPLC	81%	203	23	180	88.7%
186015032	ACQUITY PDA	2998 and PDA Detector	UPLC	83%	112	18	94	83.9%
186015033	ACQUITY eλ PDA	2998 and PDA Detector	UPLC	80%	88	16	72	81.8%
186015034	ACQUITY UPC2 PDA Detector	2998 and PDA Detector	UPLC	88%	8	1	7	87.5%
186015053	ACQUITY PDA Detector w/TaperSlit	2998 and PDA Detector	UPLC	89%	5	0	5	100.0%
186017003	ACQUITY Arc 2998 PDA Detector	2998 and PDA Detector	UPLC	79%	76	9	67	88.2%
186017013	ACQUITY Arc Bio 2998 PDA Detector	2998 and PDA Detector	UPLC	85.7%	12	2	10	83.3%

First Pass Yield

Detector 186015034– Top Failure Trends (Jul 2018 data)

		Top 1			Top 2		Top 3	
		Noise			NA		NA	
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed	Qty Failed	% Failed
Feb'18	0	0	#DIV/0!	—	NA		NA	
Mar'18	9	0	0.0%	—				
Apr'18	6	0	0.0%	—				
May'18	6	0	0.0%	—				
Jun'18	8	1	12.5%	▲				
Jul'18	8	1	12.5%	▲				

Debug Breakdown / Finding	Jul'18	Debug Breakdown / Finding	Jul'18	Debug Breakdown / Finding	Jul'18
Retest without doing anything	1	NA		NA	

First Pass Yield

Detector 186015034– Top Failure Trends (Jul 2018 data)

	Top 1	Top 2	Top 3
	Noise	NA	NA
Analysis / Comment	Retest and pass	NA	NA
Root Cause / Possible Root Cause	Random failure. Low priority to work on this failure.	NA	NA
Corrective Action	NA	NA	NA
Effectiveness	NA	NA	NA

First Pass Yield

Detector 186017013– Top Failure Trends (Jul 2018 data)

		Top 1				Top 2			Top 3	
		Communication				Drift			NA	
Mth	Qty Tested	Qty Failed	% Failed			Qty Failed	% Failed		Qty Failed	% Failed
Feb'18	0	0	#DIV/0!			0	#DIV/0!		NA	
Mar'18	0	0	#DIV/0!			0	#DIV/0!			
Apr'18	0	0	#DIV/0!			0	#DIV/0!			
May'18	10	0	0.0%			0	0.0%			
Jun'18	0	0	#DIV/0!			0	#DIV/0!			
Jul'18	12	1	8.3%			1	8.3%			

Debug Breakdown / Finding	Jul'18	Debug Breakdown / Finding	Jul'18	Debug Breakdown / Finding	Jul'18
Retest without doing anything	1	Retest without doing anything	1	NA	

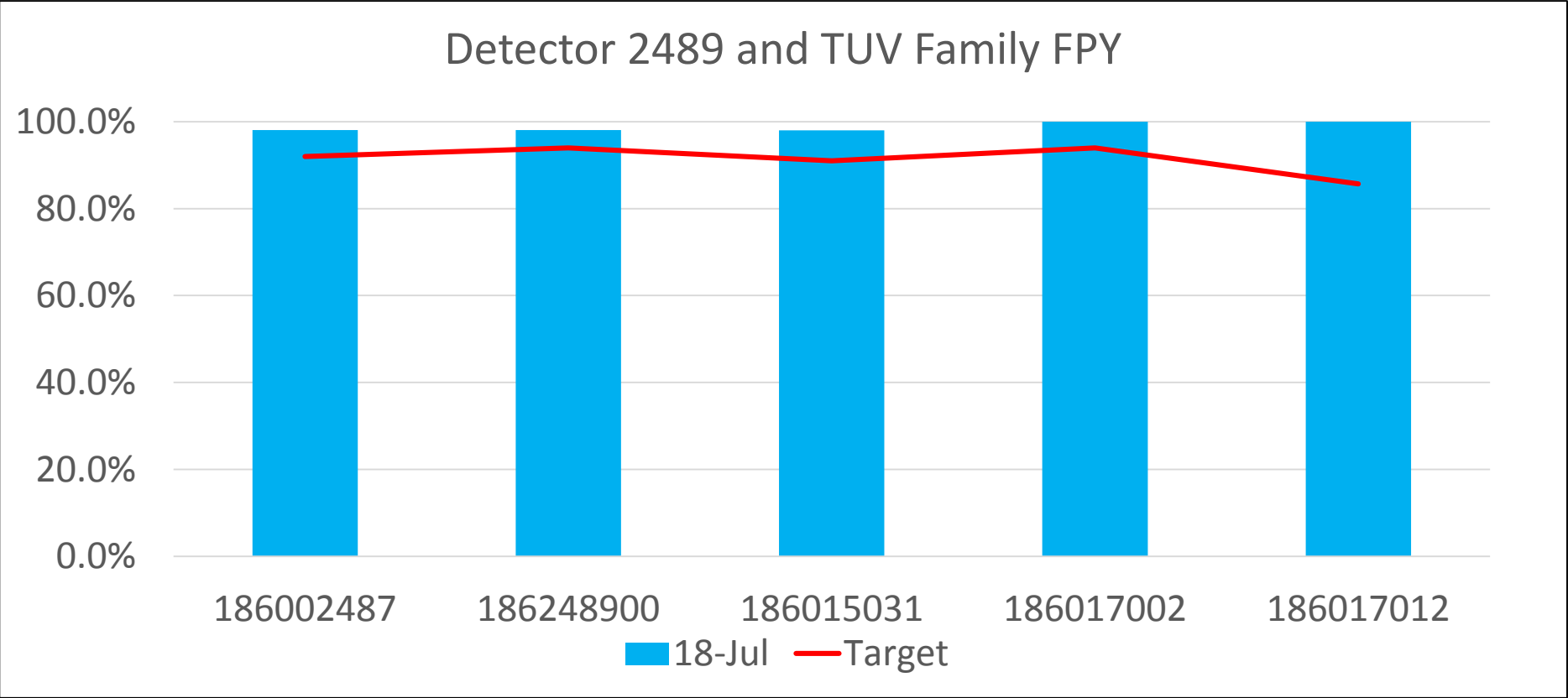
First Pass Yield

Detector 186017013– Top Failure Trends (Jul 2018 data)

	Top 1	Top 2	Top 3
	Communication	Drift	NA
Analysis / Comment	-Clear the DHCP server -Restart test program -Retest UUT	Drift Test is allowed to loop and perform drift test without iteration 24X.	NA
Root Cause / Possible Root Cause	Random failure. Low priority to work on this failure.	Random failure. Low priority to work on this failure.	NA
Corrective Action	NA	NA	NA
Effectiveness	NA	NA	NA

First Pass Yield

Detector 2489 and TUV Family FPY (Jul 2018 data)



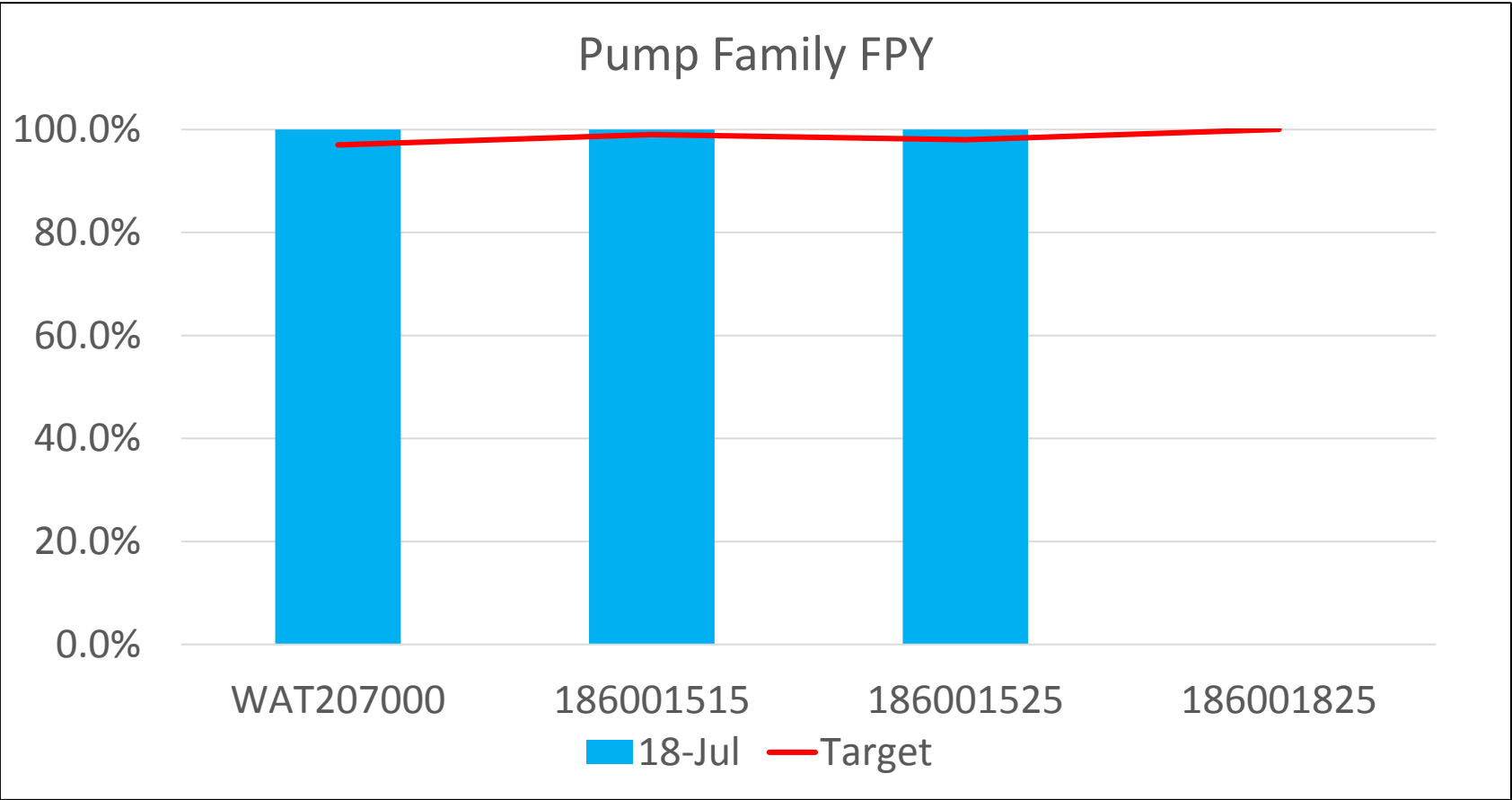
All meet target

Material Number	Instrument Description	Product Group	Product Class	Target	Jul 18 Qty Tested	Jul 18 Qty Failed	Jul 18 Qty Passed	Jul 18 Yield
186002487	2489 UV/Visible Detector	2489 and TUV Detector	HPLC	92%	52	1	51	98.1%
186248900	2489 UV/Visible Detector	2489 and TUV Detector	HPLC	94%	310	6	304	98.1%
186015031	ACQUITY TUV	2489 and TUV Detector	UPLC	91%	102	2	100	98.0%
186017002	ACQUITY Arc 2489 UV/Vis Detector	2489 and TUV Detector	UPLC	94%	56	0	56	100.0%
186017012	ACQUITY Arc Bio 2489 UV/Vis Detector	2489 and TUV Detector	UPLC	85.7%	10	0	10	100.0%



First Pass Yield

Pump Family FPY (Jul 2018 data)



**All meet
target**

Material Number	Instrument Description	Product Group	Product Class	Target	Jul 18 Qty Tested	Jul 18 Qty Failed	Jul 18 Qty Passed	Jul 18 Yield
WAT207000	ASSY, HPLC PUMP, M515	Pump	HPLC	97%	24	0	24	100.0%
186001515	1515 ISOCRATIC HPLC PUMP	Pump	HPLC	99%	10	0	10	100.0%
186001525	1525 BINARY HPLC PUMP	Pump	HPLC	98%	22	0	22	100.0%
186001825	1525 MICRO W/DEGASSER	Pump	HPLC	100%	NA	NA	#VALUE!	#VALUE!

TMD Updates

TMD summary

TMD Tracker 2018		
Total TMD Received	No of TMD closed	No of TMD Active
16	11	5

TMD Updates

TMD – OPEN:

Originator: Roland Poisson	Date: 30-May-2018	TMD #: TMD010475	v 01
Lab Office: SP1	Notify: Eugene Tan	Requester: Roland Poisson	
P/N(s): WAT270389		P/N Desc.: Clip, Mounting, Column, Out	
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: August 30, 2018	Expiration Detail: N/A	
Risk Assessor: Roland Poisson	TMD Category: Nonconforming Part		
Reason for Deviation (<i>describe why deviation is needed</i>): It was discovered upon inspection that P/N WAT270389 Clip, Mounting, Column, was out of tolerance for the following dimensions: 0.25, 38° and 76°. The part is used to snap a column into the holder and hold a column in place when used in the Alliance Front Bezel. This TMD is being extended to allow for additional time for assessment of mitigation plan for this part and impliment an ECR for the non-critical dimensions.			

Status : Current Rev F parts will deplete around Oct 2018.

New Rev G parts will be delivered from next order, qty 1.8k

TMD Updates

TMD – OPEN:

Originator: Joe Gately	Date: 30-May-2018	TMD #: TMD010508	v 00
Lab Office: AKX	Notify: Kris Bujold, Monica Collins,	Requester: Ken Voisine	
P/N(s): See below		P/N See Below Desc.:	
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: 30-Sep-2018	Expiration Detail: N/A	
Risk Assessor: Joe Gately	TMD Category: Nonconforming Part		
Reason for Deviation (<i>describe why deviation is needed</i>): The drawings for the following list of materials contains a requirement that the packaging of the part to contain verbiage "WATERS CRITICAL CLEAN per 735001035" be on their label to assist in identification' per design spec 735001035 Section 7.2. Currently these parts do not comply to this labeling requirement. This TMD will allow the receipt of these parts until such time as the labeling can be added to the packaging. This TMD supersedes TMD010043 V02.			

Status : active

TMD Updates

TMD – OPEN:

Originator: Matt Franklin	Date: 02-Jul-2018	TMD #: TMD010367	v 04
Lab Office: AKT	Notify: Tom Chase, Eugene Tan	Requester: Tom Chase	
P/N(s): 415002619; 415002125 415002122	P/N COVER, FLOW CELL, ID; COVER, FLOWCELL, BLUE Desc.: COVER, FLOWCELL, BLUE		
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: 30-Dec-2018	Expiration Detail: N/A	
Risk Assessor: Matt Franklin	TMD Category: Nonconforming Part		
Reason for Deviation (<i>describe why deviation is needed</i>): - Flow Cell Covers (415002619, 415002122 and 415002125) are secured to the Flow Cell using 4 Screws (WAT270393). The Flow Cell Cover has 4 boss features with holes, in which the screws are installed into. - One of these features has been cracking when installing the screw. The feature closest to the opening in the cover is always the feature to crack (see attachment B for location). The 3 other features seem to accept the screw without cracking. - Both the hole feature and the screw measure within specification. This TMD is needed to use a smaller screw in this one feature while root cause is determined.			

Status : active. 500pcs of 'smaller' screws received from WPPL for TMD implementation

TMD Updates

TMD – OPEN:

Originator: Bryan Deguire	Date: 13-Jun-2018	TMD #: TMD010511	v 01
Lab Office: E31	Notify: Dave Reed	Requester: Bryan Deguire	
P/N(s): 210000444	P/N ASSY, PCB, 2690 H/C Desc.:		
Expiration Type: ☐ Date or ☒ Qty/Lot	Expiration Date: N/A	Expiration Detail: see implementation plan	
Risk Assessor: Bryan Deguire	TMD Category: Pilot Run		
Reason for Deviation <i>(describe why deviation is needed)</i> : To determine if there are any issues with the new 210000444 Rev D pcb in the production process.			

Status : pending boards to delivered to Flex Kallang from Flex Senai

TMD Updates

TMD – OPEN:

Originator: Randy Ryder	Date: 23-Jul-2018	TMD #: TMD010532	v 00
Lab Office: AKU	Notify: See Implementation Plan	Requester: Randy Ryder	
P/N(s): WAT270524, 279001810, 279003338,	P/N Gradient Proportioning Valve assemblies Desc.:		
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: 31-Dec-2018	Expiration Detail: N/A	
Risk Assessor: Randy Ryder	TMD Category: Other		
Reason for Deviation <i>(describe why deviation is needed)</i> : This deviation would allow use of pre qualified material associated with Part #s WAT270524 revision 02, 279001810 revision L and 279003338 revision E for production builds where the GPV's contain threadless armatures.			

Status : expect to phase in WAT270524 around 17 Aug 2018

Manufacturing Engineering Issues / Updates

ECO Update for 2017 / 2018

ECO Tracker 2017			
Total ECO Received	No. of ECO closed	No. of ECO Open	Remarks
133	126	03	Raw Material effective date 1) 03 ECO Child Part Uprev

ECO Tracker 2018			
Total ECO Received	No. of ECO closed	No. of ECO Open	Remarks
126	60	66	Raw Material effective date 1) 06 ASP Uprev 2) 45 ECO Child Part Uprev 3) 14 ERC State 4) 01 FA

ASP / TSP Check and Changes Implementation

In Progress
 Complete

Overall ASP/ TSP compliance check Status

Compliance check

122/
124

Redlining documents
(*Only applicable docs)

122/
124

Changes Implementation

81/
124

ASP/ TSP Compliance Check status :

Product Family	ASP/ TSP	ASP/TSP Compliance Check			ASP/TSP Changes Implementation			
		Total	Completed Review	% Status	Complete Implementation	Pending Implementation	% Status	Remarks
eAlliance	ASP	26	26	100%	26	0	100%	- 3 ECO completed.
	TSP	10	10	100%	10	0	100%	- 2 Flex ECO completed
BSM/QSM	ASP	12	12	100%	5	7	42%	- 7 Redlining sent to WPPL.
	TSP	3	3	100%	2	1	67%	- 1 OESR submitted to WPPL.
TUV Detectors	ASP	21	21	100%	13	8	58%	- 8 Redlining submitted to WPPL.
	TSP	6	6	100%	6	0	100%	
PDA Detectors	ASP	28	28	100%	9	19	27%	- 19 Redlining submitted to WPPL,
	TSP	1	1	100%	1	0	100%	- 1 ECO Complete
Pump	ASP	16	14	100%	6	8	43%	- 3 X Redline on Word format - 5 X Redline on PDF format
	TSP	3	3	100%	3	0	100%	- Complete

- Submitted the compliance check findings to Waters.

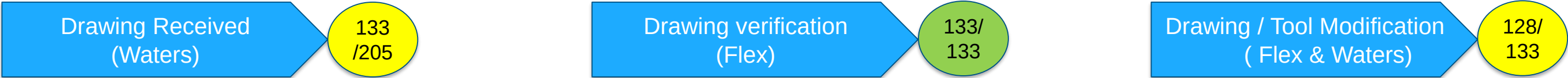
- All redlining documents completed and submitted to Waters.

- 2 ASP (Pump Family) awaiting for Production Run in order to review ASP. No Production run in Yr 2018

Drawing Verification Activity for Jigs/Fixtures/Tooling

In Progress
Complete

Overall Status for Drawing Verification Activity



Drawing Verification status :

No	Category of Tooling	Total number of Tools identified	Total number of Tools (with Drawings) Received from Waters	% of Drawings received	Total number of Tools (with Drawings) completed Review by Flex	% Reviewed of received drawings	Total number of Tools (with Drawings) Pending Drawing/ Tool Modification	Remarks
1	Customized tool	205	133	65%	133	100%	2	- Drawing verification complete. for 9 new drawings received. - 5 no changes required. - 2 tooling modification – Complete. - 2 drawing to be updated – Submitted OESR.
2	Off the Shelf tool	26	NA	NA	NA	NA	NA	No action required
3	Obsoleted	4	NA	NA	NA	NA	NA	No action required.
	Total	235						

Training review and competencies updates

- NA -

Test Engineering Issues / Updates

TESTER DASH BOARD

Downtime Summary from 18 Jul 2018 to 15 Aug 2018 .

(Refer to attached Dashboard)



Date	Tester	Problem	Root Cause	Action Taken	Status
19 Jun 2018	Pump Tray Tester 2 (TE82526)	Ripple Test Failed	1. Rheodyne vent valve leaking.	1. Pin Plug FV2 during Ripple Test - Test Result PASS 2. Pin Plug FV2 during Flow Test - Test Result PASS 3. Removed the Pin Plug during Ripple Test - Test Result FAIL and observed small amount of leak solvent during test. 4. Removed the Pin Plug during Flow Test - Test Result FAIL and observed small amount of leak solvent during test. 5. Therefore I conclude that the root cause is leaky ASFVO Flow Valve. 6. Replaced ASFVO Valve 7. Replaced Vent Valve (01 Aug 2018) still failed Ripple test 8. Running but unstable – monitoring in progress	Open

Test Engineering Issues / Updates

Date	Tester	Problem	Root Cause	Action Taken	Status
09 Jul 2018	BSM / QSM Final Tester (TE82943-13)	Electronic Weigh Balance s/n: 12326184 – Display showing Error 1	Electronic weigh balance faulty (Unable to get a stable reading)	1. Ensure that the bubble spirit level is okay. 2. Re-Zero the weighing balance but to no avail. 3. Ensure that balance stability is not influence by breeze or vibration. 4. Remove weighing pan, Re insert the pan and Re- zero but no avail. 5. Press and hold the Re-Zero key until balance display CAL. Release the RE-Zero Key. Display shows "Error 1". 7. Repair In-progress	Open
09 Jul 2018	BSM / QSM Final Tester (TE82943-17)	Electronic Weigh Balance s/n: 12326279 – Repaired 18 Jul 2018	Reschedule calibration	Calibration – PO raised Jul 2018 PO released 28 Jul 2018 Schedule Calibration : 06 Aug 2018 Calibration Completed – awaiting for calibration report	Open
20 Jul 2018	BSM / QSM Final Tester (TE82943-11)	Electronic Weigh Balance s/n: 12326300 –	Reschedule calibration	Calibration – PO raised Jul 2018 PO released 28 Jul 2018 Schedule Calibration : 06 Aug 2018 Calibration Completed – awaiting for calibration report	Open
27 Jul 2018	Waters Server PSU 1 is absent	PowerEdge T320 PSU 1 is absent	Unknown – Investigation is progress	Unknown – Investigation is progress 1. David Moss Power OFF the server and swap the PSU. PUS1 is not detected the display is Blue. 03 Aug 2018 7:PM	Close

Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – LAR

S/N	LAR / Month	Commodity	Target	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
1	BAITENG	Sheet Metal	96%	99%	98%	99%	100%	100%	99%	100%	100%	100%	100%	100%	100%
2	CMTI	Cable & Harnesses	96%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	88%
3	JCC	Machining	96%	80%	100%	78%	100%	100%	100%	100%	100%	50%	82%	100%	100%
4	Technimetal		96%	77%	100%	100%	100%	83%	81%	100%	100%	100%	95%	96%	100%
5	WPC		96%	100%	96%	100%	100%	100%	94%	100%	100%	100%	100%	95%	100%
6	B&E		96%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	99%
7	Fuyu	Plastics	96%	100%	100%	100%	100%	100%	96%	100%	100%	93%	100%	100%	100%
8	MRPC		96%	100%	100%	97%	100%	98%	100%	100%	100%	100%	100%	100%	100%
9	FLEXTRONICS SHAH ALAM SDN BHD	PCBA	96%	100%	99%	100%	95%	97%	100%	99%	98%	100%	100%	100%	97%
10	CEI		96%	NA	100%	100%	NA	NA	NA	NA	NA	NA	NA	NA	100%

Remarks:

- 1) CMTI found 2 out of 16 lots due to wrong label rev on part and wrong rev in COC document.
- 2) B & E found 1 out of 69 lots fail go thread gauge.
- 3) Flextronics Shah Alam found 2 out of 77 lots component damage and missing component.

Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – LAR

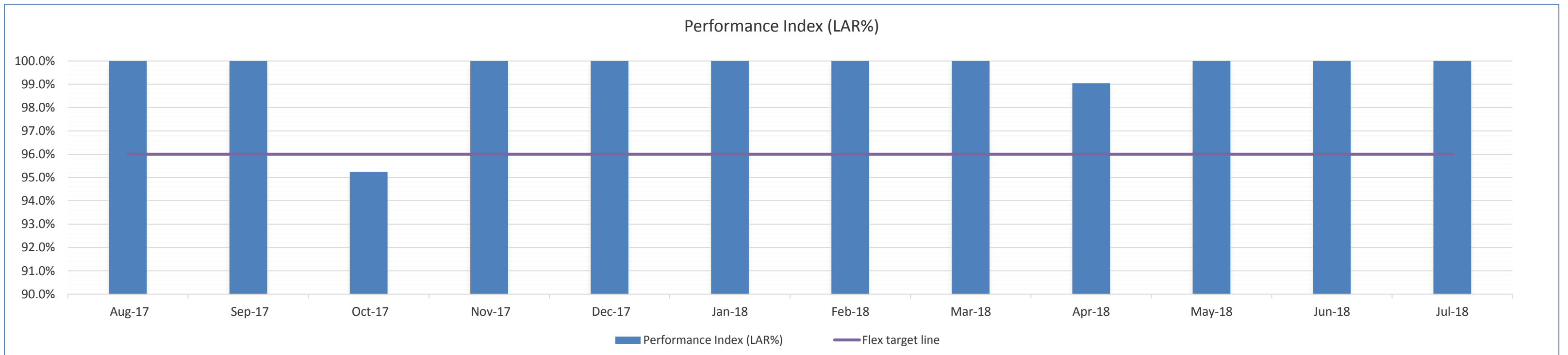
Vendor score below 96% LAR target

No	Supplier	Rejected Lot / Total Lot Received	LAR (%)	Part Number	Part Description	Defect Description	Disposition
1	CMTI PTE LTD	2/16	88%	WATH-441000481-F	ASSY,CABLE,SUPPLY,INHIBIT	Wrong Rev on Label-13/13	RTV
				WATH-WAT270354-02	CABLE ASSY ,OPTION CONTROL	Wrong Rev on Label-50/50 (Wrong Rev Receive COC)	RTV

2. Data Analysis – Lot Acceptance Rate (LAR)

WATERS Machine shop Quality performance

Month	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
Performance Index (LAR%)	100.0%	100.0%	95.2%	100.0%	100.0%	100.0%	100.0%	100.0%	99.0%	100.0%	100.0%	100.0%
No of lot inspected	86	62	63	88	69	78	65	68	105	81	89	80
No of lot accepted	86	62	60	88	69	78	65	68	104	81	89	80
Flex target line	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%



Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – dPPM

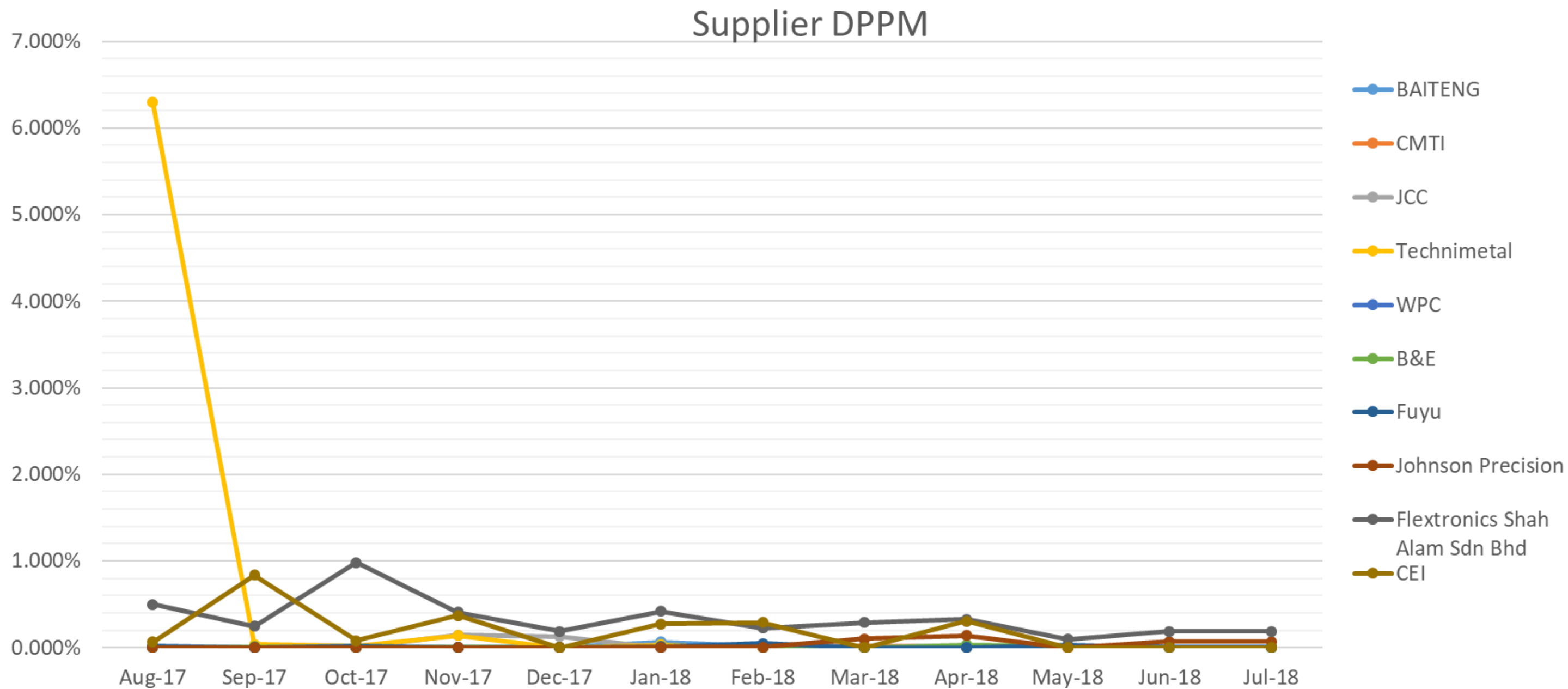
S/N	DPPM / Month	Target	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	'Apr-18	'May-18	Jun-18	Jul-18
			%	%	%	%	%	%	%	%	%	%	%	%
1	BAITENG	0.500%	0.004%	0.000%	0.000%	0.004%	0.005%	0.068%	0.015%	0.004%	0.016%	0.000%	0.000%	0.000%
2	CMTI	0.500%	0.002%	0.002%	0.001%	0.001%	0.000%	0.000%	0.008%	0.021%	0.004%	0.001%	0.000%	0.013%
3	JCC	1.000%	0.000%	0.000%	0.000%	0.147%	0.128%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
4	Technimetal	1.000%	6.296%	0.037%	0.017%	0.137%	0.000%	0.032%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
5	WPC	1.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.019%	0.007%	0.000%
6	B&E	1.000%	0.000%	0.009%	0.000%	0.008%	0.000%	0.013%	0.008%	0.000%	0.035%	0.024%	0.000%	0.000%
7	Fuyu	1.000%	0.017%	0.000%	0.015%	0.000%	0.000%	0.013%	0.051%	0.000%	0.000%	0.029%	0.000%	0.000%
8	Johnson Precision (MRPC)	1.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.004%	0.004%	0.102%	0.139%	0.000%	0.072%	0.000%
9	Flextronics Shah Alam Sdn Bhd	0.500%	0.500%	0.245%	0.984%	0.409%	0.191%	0.417%	0.223%	0.288%	0.327%	0.095%	0.190%	0.245%
10	CEI	1.000%	0.062%	0.835%	0.081%	0.372%	0.000%	0.274%	0.289%	0.000%	0.305%	0.000%	0.000%	0.166%

Remarks:

NA – No receipt of delivery

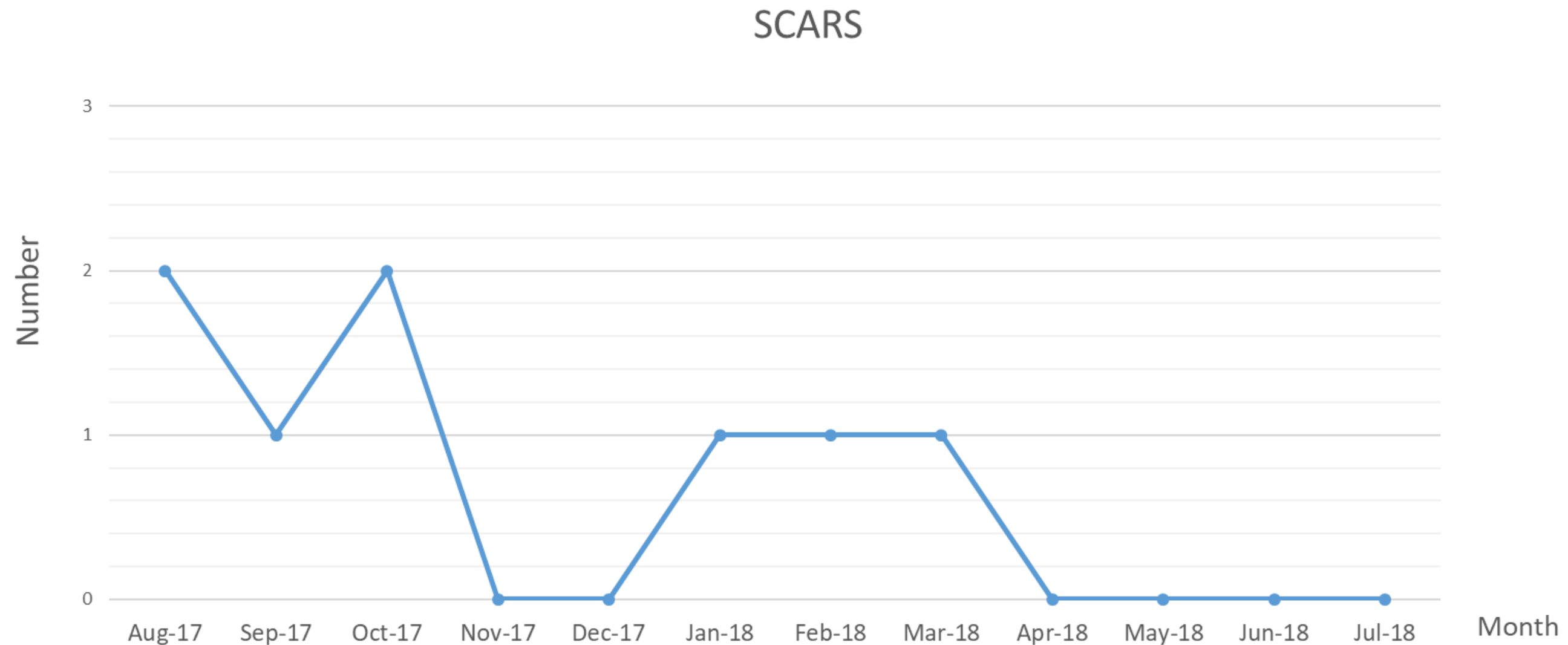
Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – dPPM



Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – SCARS



Data Analysis – Quality Issues

Quality Issues (Supplier) – SCAR Update / Action Taken on Supplier

Mar '17 – Angle out of specification

No	Supplier	Failure Mode / Issues	Action Plan	Owner	Target Date	Status
1	SHENZHEN BAITENG TECHNOLOGY DEVELOP CO LTD	CA Number: CA-RW002658 CA issued date: 28-Mar-17 Part No: WAT-205001016 Product: WAT-186269505, WAT-186269506, WAT-186269507, WAT-186269508 Part Description: KIT, SHEET METAL, ALLIANCE X Defect: A purge notice WAT-0030 was created due to customer complaint on the angle out of specification. Reject Qty: 26 / 1435 pcs Root Cause: Based on Flex feedback on the affected PO number (J12K22022 and J12K22399) , Baiteng has traced back the affected bracket was produced between 3rd week of Sep to 2nd week of Oct'16. Baiteng performed further investigation with chemical conversion supplier that there was operator from other stations assigned to perform jigging process at the time instead of "old workers" due to National Holiday. The changes of operator, resulted jigged on the affected area that impacted on the angle dimension. Whereby, there is no work instruction define on which jigging fixture to be used during chemical conversion process. The jigging location (circle with red) at lower holes will cause the bracket angle out of spec during removal of the bracket when complete the chemical conversation process	1. Use calibrated filler gauge 0.023" as no go to perform 100% check on flatness (WIP-bracket) before assembly. 2. Develop a work instruction how method of measuring the flatness & conduct a training. 3. Use CMM for 100% sorting on current finish good (191pcs). 4. Chemical conversion supplier to update the work instruction for operator to follow the correct method to hang the part during chemical conversion process. 5. Baiteng added flatness at in-process check in stamping process and IQC when receive from chemical conversation supplier. 6. 100% inspection using CMM at outgoing inspection for 5 months (Mar'17 until Jul'17). 7. To use fixture to perform 100% inspection check on the bracket. 1st set of fixture has been completed on 13th Sep and review with Waters Quality. Baiteng is in progress of fabricate more fixtures for inspection and target completion TBA. 8. Baiteng fabricated 2 fixtures and is in-progress verifying and thereafter perform the GR&R. 9. Baiteng to re-fabricate fixture due to dimension found out of spec after reworking 10. Baiteng unable to correct it so Flex will fabricate 1 gauge for BAITENG. Estimated 2 months to complete. 11. Fixture sent to Baiteng. GR& R completed. Fixture verification implemented. 12. Monitor 3 months (Sept – Nov) NCMR trending for effectiveness.	Flex	15-Nov-18	Open

Data Analysis – Quality Issues

Quality Issues (Supplier) – SCAR Update / Action Taken on Supplier

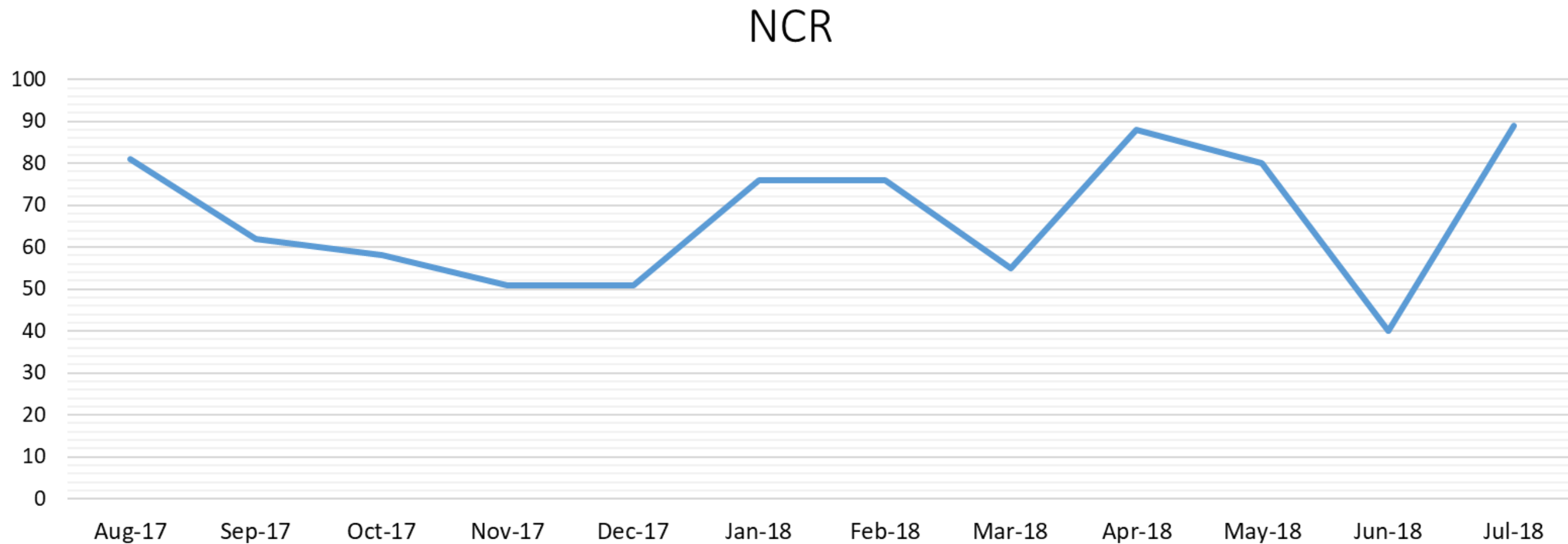
Mar '18 – Richport send mix part

No	Supplier	Failure Mode / Issues	Action Plan	Owner	Target Date	Status
1	Richport Technology Pte Ltd	CA Number: CAR-SKW-00000006 CA issued date: 16-Mar-18 Part No: WAT-289001892-E Product:, WAT-S-700002597 Part Description: ASSY, BARBED SEAL WASH HOUSING Defect: Richport has reported that there was mixture of parts sent to Flex Kallang. The total quantity that was mixed up was reported to be 73pcs.The mix up was delivered to Flex Kallang Reject Qty: 73 / 280 pcs Root Cause: Richport inhouse inspection found surplus 289001892 parts (73pcs) and further verification found other Waters part XXXXX0698 shortage of quantity (73pcs) , which concluded XXXXX0698 parts mixed to 289001892 and shipped to Flextronics customer. Affected lots are 288 pcs & 290pcs of 289001892 shipped to Flextronics shipment on 22nd Feb. Richport: Outgoing QC did not phase out the similar part as per procedure. There were more than 1 cleaned basket with different part inside the cleanroom and outgoing QC picked the wrong part from other basket after inspection and proceed plastic bag sealing.	<u>Richport (Immediate)</u> – Completed on 16 Mar 18 1. Train production, QC & Planner on the mix part prevention method, phase in – phase out method 2. Display comparison of 3 models at incoming & outgoing inspection station 3. Implement QC leader verification & signature for each similar part model phase out. 4. Planner verification on ERP system to ensure no similar part models at the line & cleanroom before release similar part to the line. <u>Richport (Long Term)</u> – To be completed by Q2 2018 1. Verify all other Flextronics critical clean parts and identify any other models with similar shapes for possible mix - Target by 16 Apr 18. 2. Identify the Critical Cleaning Basket with number and record in process traveler . There are 5 baskets exists and all identified with number and only 1 basket can load 1 time . 3. Make fool proof Process Traveler system for 3 similar part models in the ERP system - Unable to create new process traveler if there is any other model (among 3 similar part models) exists in the system without QC check out. – Target by Q2 2018 Verification – To be completed by Aug 18 1. To conduct audit at Richport for 3 months, prior to this part can be shipped. Completed. 2. Monitor 3 months(May-Jul) NCMR Trending for effectiveness.	Flex	30 Aug 18	Closed

Data Analysis – Quality Issues

Quality Issues (Process - Material) – NCR (running 12 months)

	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
NCR	81	62	58	51	51	76	76	55	88	80	40	89



Data Analysis – Quality Issues

Quality Issues (Process - Material) – Repeated NCR / NCR Update

Supplier	Part No.	Part Description	Non-conformance	Defect Category	Non-Conformance Repeated		Rejected Qty	Out of Control Limit	Action Taken	Remark	Target Date
MK Fluidic Systems LLC	WATH-WAT073109-14	SYRINGE, 250 ML . WISP	Non conformance Description: Failed no value during compression test	Test Failure	Jun'18	Jul'18	1	No	Under monitoring with P-chart	Jun 18 rej, 4pc	NA
PARKER HANNIFIN,PRECISION FLUIDICS DIVISION	WAT-WAT270524-02	GPV ASSEMBLY	Non conformance Description: - Inlet D no flow - no flow for all four channels proceeding from D to C to B to A - BD precision test failed during complete test - AC precision test failed during complete test	Test Failure	Jun'18	Jul'18	7	No	Under monitoring with P-chart	June 18 rej, 4 pcs	NA
FLEXTRONICS SHAH ALAM SDN BHD	WATH-210000411-F	ASSY, PCB EALLIANCE CPU RoHS	Non Conformance Description: - Display distorted after UUT restart - Speaker no sound when press button during rear panel test - Connector J8 found damaged upon received	Test Failure Visual Defect	Jun'18	Jul'18	3	No	Under monitoring with P-chart	June 18 rej, 4 pcs	NA
WATERS TECHNOLOGIES CORP.	WAT-405001338-B	\$NEEDLE,INJECTOR, MP35N	Non Conformance Description: - Fail decay test	Test Failure	Jun'18	Jul'18	47	Yes	Parts will be return for FA	June 18 rej, 3 pcs	NA
FLEXTRONICS SHAH ALAM SDN BHD	WATH-210000444-C	ASSY, PCB ALLIANCE H/C	Non Conformance Description: Sample temperature h/w fault (4) during heater cooler test	Test Failure	Jun'18	Jul'18	1	No	Under monitoring with P-chart	June 18 rej, 3 pcs	NA
FLEXTRONICS SHAH ALAM SDN BHD	WATH-210000425-E	ASSY, PCB, PUMP DRIVER, ROHS	Non Conformance Description: - GPV no function during Solvent Inlet Plumbing Verification - Connector J7 wrong part	Test Failure Visual Defect	Jun'18	Jul'18	2	No	Under monitoring with P-chart	June 18 rej, 2 pcs	NA

Data Analysis – Quality Issues

Quality Issues (Process - Material) – Repeated NCR / NCR Update

PARKER HANNIFIN,PRECISION FLUIDICS DIVISION	WAT- 279001810-L	ASSY, GPV, DUAL CHANNEL, QSM	Non Conformance Description: - Test Input line A Prime with MeOH Failed - Test Input line C Prime with MeOH Failed	Test Failure	Jun'18	Jul'18	3	No	Under monitoring with P-chart	June 18 rej, 1 pc	NA
HAMAMATSU CORPORATION	WATH- 279001105-F	POWER SUPPLY, HB LAMP HAMAMATS	Non Conformance Description: - Display malfunction - Communication with DSP Failed	Test Failure	Jun'18	Jul'18	2	No	Under monitoring with P-chart	June 18 rej, 1 pc	NA
NIDEC MOTOR CORP DBA HURST MFG	WATH- WAT270279-05	ASSY,MOTOR CARRIAGE DRIVE	Non Conformance Description: - Unable to home carrier motor alignment - Assy motor carrier drive found stain mark	Test Failure Visual Defect	Jun'18	Jul'18	29	Yes	Parts return for FA	June 18 rej, 1 pc	NA
FLEXTRONICS SHAH ALAM SDN BHD	WAT- 210000355-D	ASSY, PCB, 2489 TUV PERSONALIT	Non Conformance Description: Lamp Power Indicator Malfunction	Test Failure	Jun'18	Jul'18	1	No	Under monitoring with P-chart	June 18 rej, 1 pc	NA
IDEX HEALTH AND SCIENCE LLC	WATH- 289000144-F	ASSY, CARTRIDGE, CHECK VALVE	Non Conformance Description: Unable to Ramp Up 5000PSI	Test Failure	Jun'18	Jul'18	14	No	Under monitoring with P-chart	June 18 rej, 1 pc	NA
FLEXTRONICS SHAH ALAM SDN BHD	WAT- 210000345-L	ASSY, PCB ANALYTICAL PUMP	Non Conformance Description: Failed Alarm type 52, Degasser no vacuum (14.80)	Test Failure	Jun'18	Jul'18	1	No	Under monitoring with P-chart	June 18 rej, 1 pc	NA
DJ INSTRUMENTS	WAT- WAT270172-05	PRESSURE TRANSDUCER	Non Conformance Description: Failed sample transducer range	Test Failure	Jun'18	Jul'18	4	No	Under monitoring with P-chart	Jun 18 rej, 1 pc	NA

Data Analysis – Quality Issues

Audit Schedules

Supplier Audit Schedule 2018											
JAN		FEB		MAR		APR		MAY		JUN	
Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
*ALIGENT	Aligent	N/A	N/A	N/A	N/A	*EPE	EPE	Fu Yu	Fu Yu	+Key Point	+Key Point
Supplier Audit Schedule 2018											
JUL		AUG		SEP		OCT		NOV		DEC	
Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
N/A	N/A	N/A	N/A	+Season Malaysia		*Greenpac		N/A	N/A	Armstrong Industrial	

Remarks:

* – Common supplier

+ - Process Audit

Data Analysis – Quality Issues

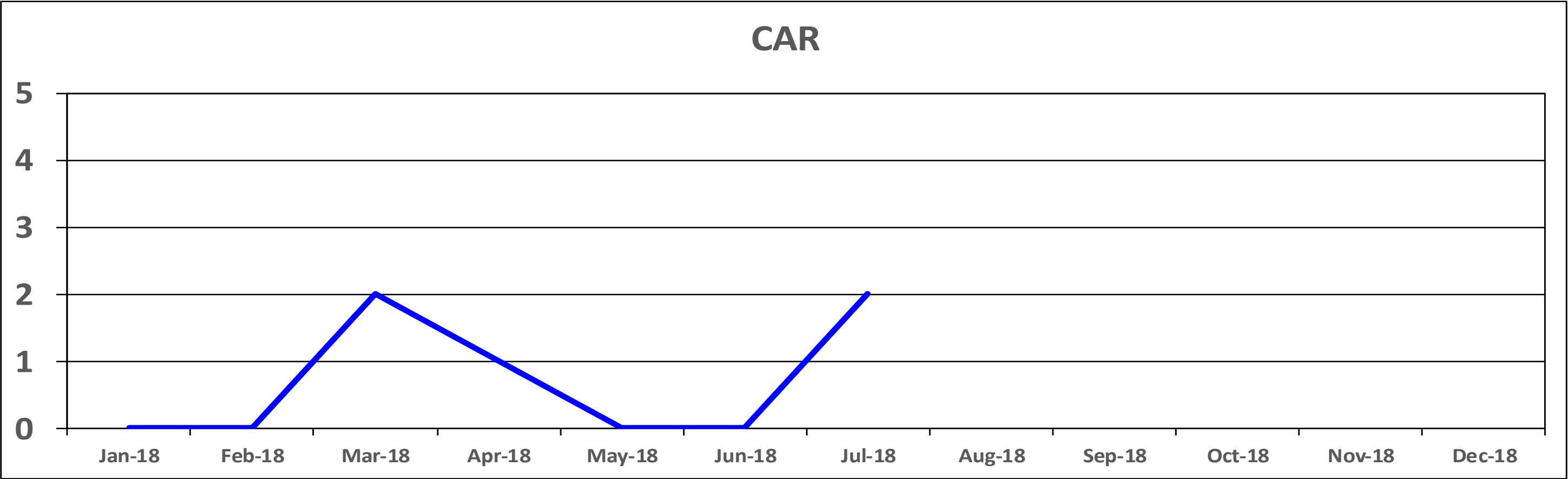
Audit Results, Findings and Closures

Fu Yu Corporation Limited					
Category	Findings	Open	Close	Target to Close by	Status Update
NC	7	7	0	Aug-18	Open

In Process - CAPA

CAR Trending

Month	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
CAR	0	0	2	1	0	0	2					
Open	0	0	0	0	0	0	2					
Closed	0	0	2	1	0	0	0					



Customer & Field Complaints

CAR Update

Mar '18

- CAR 18-003 – PN: 700001219 (2695 DEGASSER TRAY) - closed
- CAR 18-004 – PN: WAT-S-700002597 (Seal Wash Housing, UPLC Pump) closed

Apr'18

- CAR 18-007- Collapse tubing of the red tube 430000922 – closed

Jul'18

- CAR 18-014 - QSM Plus chassis spill gasket found to be torn off - open
- CAR 18-015 – Detector (TMD) Power Supply part number wrongly recorded manually in one DHR .
(Recorded Part number: 279003765; Correct part number 279003675)

QSM Plus (186015080) Chassis Gasket Torn

Problem Statement	Investigation/ Possible Root Cause	Corrective Action/ Improvement															
Reported Date: 11 Jul 2018 Product: PN 186015080 (QSM Plus) SN: G18QSP659A, G18QSP665A Qty: 2u Problem: Chassis Spill Gasket found torn during the DTS inspection  Manufacturing Date: Jul 2018 Chassis supplier: Baiteng <u>Note:</u> DTS sampling inspection, Lot 1 to Lot 6, no issue was found (total 89u were inspected by WPPL) This problem happened on the 7th lot of inspection.	<u>Containment Actions:</u> 1) Flex CFT members proposed and demonstrated to WPPL (Eugene Tan) the method to replace the torn Spill Gasket. After review the reworked Spill Gasket, the method was agreed upon. Completed by CK Tan (ME) on 11 Jul 2018 2) Q-Alert raised to create awareness of IQA, FQA and Production personnel's of this issue. Completed by Ivy Marges (PQE) on 12 Jul 2018 3) Briefing conducted to Production for Step by Step on replacing the Spill Gasket and the technique of closing the Top cover to Chassis assembly to avoid damaging the Spill Gasket. Completed by CK Tan (ME) on 12 Jul 2018 4) There is no WIP for QSM (PN: 186015018). QSM Plus (PN: 186015080) and Raw Chassis level (PN: 289005258) screened. Result: <table><tr><th>Level</th><th>Qty screened</th><th>Qty rejected</th></tr><tr><td>Instrument level (Model: QSM Plus PN: 186015080)</td><td>54</td><td>4</td></tr><tr><td>Raw part (PN: 289005258) at Supermart</td><td>12</td><td>8</td></tr><tr><td>Raw part (PN: 289005258) at Store Hub at Changi</td><td>153</td><td>0</td></tr><tr><td>TOTAL</td><td>219</td><td>12</td></tr></table> Completed by ST Wong (Production), Gary Lai Yam Bee (ME) on 13 Jul 2018 and Melody Yu (SQE) on 14 Jul 2018 <u>Investigation:</u> Investigation by supplier is still on-going. <u>Root Cause</u> TBA	Level	Qty screened	Qty rejected	Instrument level (Model: QSM Plus PN: 186015080)	54	4	Raw part (PN: 289005258) at Supermart	12	8	Raw part (PN: 289005258) at Store Hub at Changi	153	0	TOTAL	219	12	<u>Corrective Action at Flex:</u> 1. FQA checklist updated. Included the checking of spill gasket condition. Completed by Ivy Marges on 13 Jul 2018 2. FVMI checklist updated. Included the checking of spill gasket condition. Completed by CK Tan on 18 Jul 2018 <u>Corrective Action at Supplier:</u> Investigation is in progress. To be advise.
Level	Qty screened	Qty rejected															
Instrument level (Model: QSM Plus PN: 186015080)	54	4															
Raw part (PN: 289005258) at Supermart	12	8															
Raw part (PN: 289005258) at Store Hub at Changi	153	0															
TOTAL	219	12															

Delta Power Supply part number was wrongly recorded

Problem Statement	Investigation/ Possible Root Cause	Corrective Action/ Improvement																				
Reported Date: 12 Jul 2018 Product: PN 279003675 (Power Supply) SN: G1887E142A Qty: 1u Problem: During TMD010490 buy-off for Delta Power Supply evaluation by WPPL at Flex on 12 July 2018, found the new Delta Power Supply part number was wrongly recorded inside the DHR. Part number recorded: 279003765 Correct part number should be 279003675 Manufacturing Date: Jul 2018	Containment Actions: 1) Immediately corrected the affected DHR page (Instrument SN: G1887E142A) with wrong part number written, to changed PN from 279003765 to 279003675. Completed by Koh Huan Leng on 12 Jul 2018 2) This issue only impacts the DHR under TMD numbers TMD010480 V00, TMD010481 V00 and TMD010490 V00. This 3 TMD's covers the assembly of new Delta Power Supply (PN 279003675) in 15units each of instrument part numbers 186015031, 186299800 and 186248900. As all the TMD DHR were scanned and sent to Waters Milford on 05/Jul, 09/Jul and 13/Jul 2018, these DHR soft copy were reviewed again. Result: no issue found. Completed by Ivy Marges on 13 Jul 2018 Verification Result: <table><tr><th>No</th><th>TMD Number</th><th>Qty</th><th>Remarrks</th></tr><tr><td>1</td><td>TMD010480 V00</td><td>15</td><td>>15units instrument PN 186015031 buyoff on 05/Jul. >Result: All OK.</td></tr><tr><td>2</td><td>TMD010481 V00</td><td>15</td><td>>15units instrument PN 186299800 buyoff on 06/Jul. >Result: All OK.</td></tr><tr><td>3</td><td>TMD010490 V00</td><td>3</td><td>>3units instrument PN 186248900 buyoff on 06/Jul. >Result: All OK.</td></tr><tr><td>4</td><td>TMD010490 V00</td><td>12</td><td>>12units instrument PN 186248900 buyfoff on 12/July >Result: All OK.</td></tr></table> Investigation and Root Cause: Still on-going.	No	TMD Number	Qty	Remarrks	1	TMD010480 V00	15	>15units instrument PN 186015031 buyoff on 05/Jul. >Result: All OK.	2	TMD010481 V00	15	>15units instrument PN 186299800 buyoff on 06/Jul. >Result: All OK.	3	TMD010490 V00	3	>3units instrument PN 186248900 buyoff on 06/Jul. >Result: All OK.	4	TMD010490 V00	12	>12units instrument PN 186248900 buyfoff on 12/July >Result: All OK.	Corrective Action To be advised
No	TMD Number	Qty	Remarrks																			
1	TMD010480 V00	15	>15units instrument PN 186015031 buyoff on 05/Jul. >Result: All OK.																			
2	TMD010481 V00	15	>15units instrument PN 186299800 buyoff on 06/Jul. >Result: All OK.																			
3	TMD010490 V00	3	>3units instrument PN 186248900 buyoff on 06/Jul. >Result: All OK.																			
4	TMD010490 V00	12	>12units instrument PN 186248900 buyfoff on 12/July >Result: All OK.																			

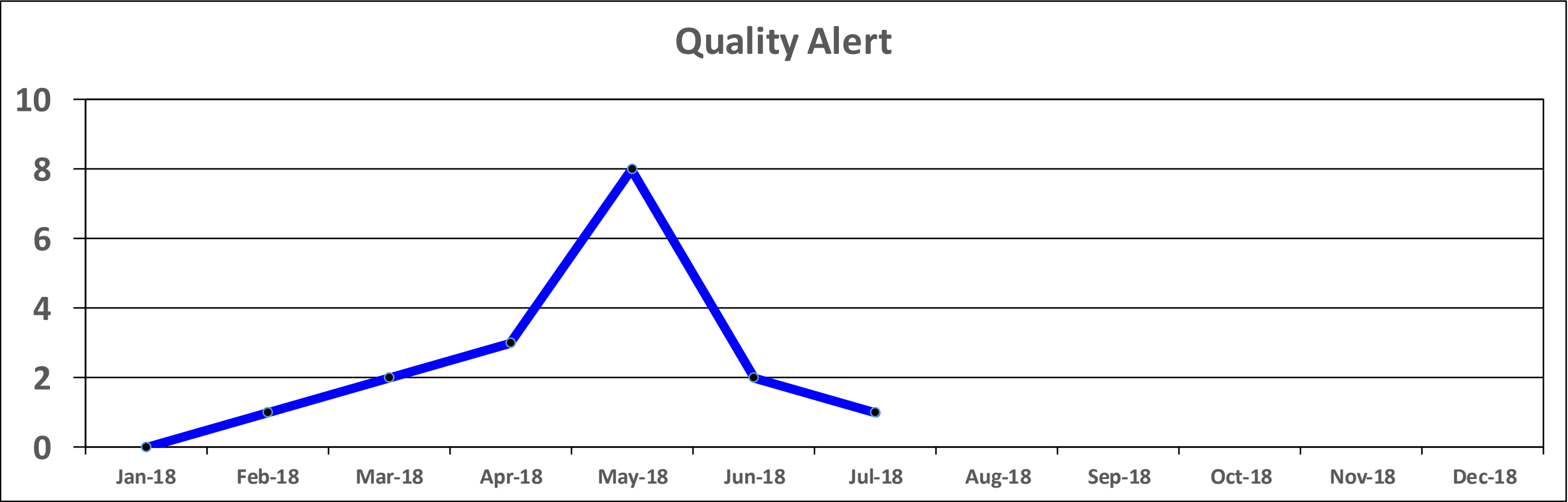
51

flex

In Process - Quality Alert

Quality Alert

Month	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
Quality Alert	0	1	2	3	8	2	1					
Open	0	0	0	1	1	0	1					
Closed	0	1	2	2	7	2	0					



In Process - Quality Alert

Quality Alert Update

Apr'18:

Q-Alert Notice raised for IQA of WAT-WAT270389 to inspect part dimension as per TMD010475 v01.

Part Description: Clip Mounting Column Out
Part: Supplier: MPRC

Q-Alert Notice		It is the Area/department representatives to retain Q-Alert Notice.	
EFFECTIVE DATE : FlexQ - On File			
Date	: 19 June 2018	Document No	: WAT-RW-SKI04700
Customer	: Waters Corporation	Document Rev	: B
Project Part Number	: 186269505, 186269506	☐ New	☐ In House Originated
Affected Part Number	: WAT-WAT270389	☒ Customer/Supplier Feedback	
Initiated by	: Ivy Marges		
Description / Sketches/Diagram :			
To inspect below dimensions. Acceptance of the dimensions listed below:			
This TMD will allow the use and acceptance of the dimensions listed below to have the adjusted tolerance. - Angle 76° +8.5° - 1° - Angle 38° +8.5° - 1° - .25+- 0.01 to .25 + 0.010 - 0.024			
Refer to TMD010475 v01 for more details.			

In Process - Quality Alert

Quality Alert Update

May'18:

Q-Alert Notice raised for IQA and Production for PN: WAT025531 to inspect the parts for any sign of rust.

Part Description: ASSY,SOLVENT FILTER

Part: Supplier: Keypoint

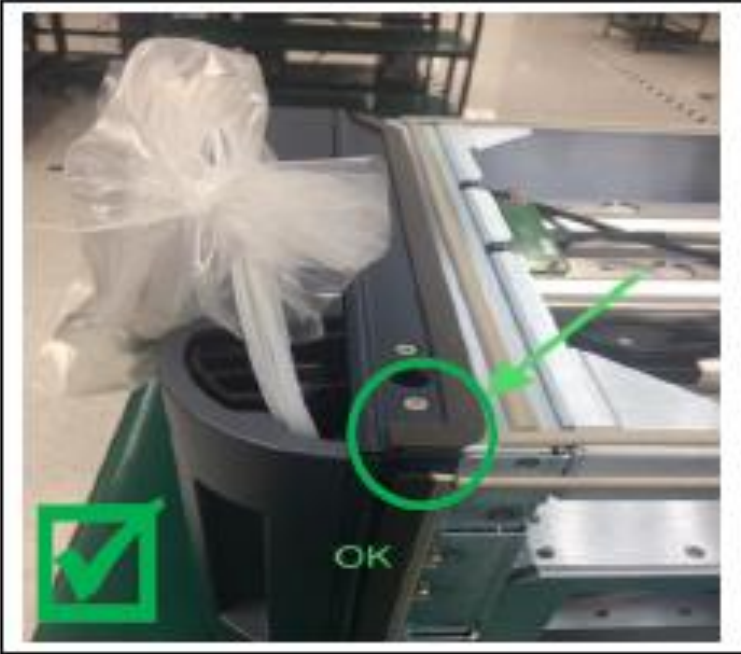
Q-Alert Notice		It is the Area/department representatives to retain Q-Alert Notice.	
EFFECTIVE DATE : FlexQ - On File			
Date : <u>29 Jun 2018</u>		Document No : <u>WAT-RW-SKI04794</u>	
Customer : <u>Waters Corporation</u>		Document Rev : <u>B</u>	
Project Part Number : <u>186269505, 186269506, WAT207000</u>		☐ New ☐ In House Originated	
<u>186001515, 186001525, 186001825</u>		☒ Customer/Supplier Feedback	
Affected Part Number : <u>WAT-WAT025531-05</u>			
Initiated by : <u>Ivy Marges</u>			
Description / Sketches/Diagram : 1. Customer has feedback that the Solvent Filter has rusting issue. 2. PN: WAT-WAT025531-05, to inspect the Solvent Filter for "sign of rust".			
			

In Process - Quality Alert

Quality Alert Update

Jul'18:

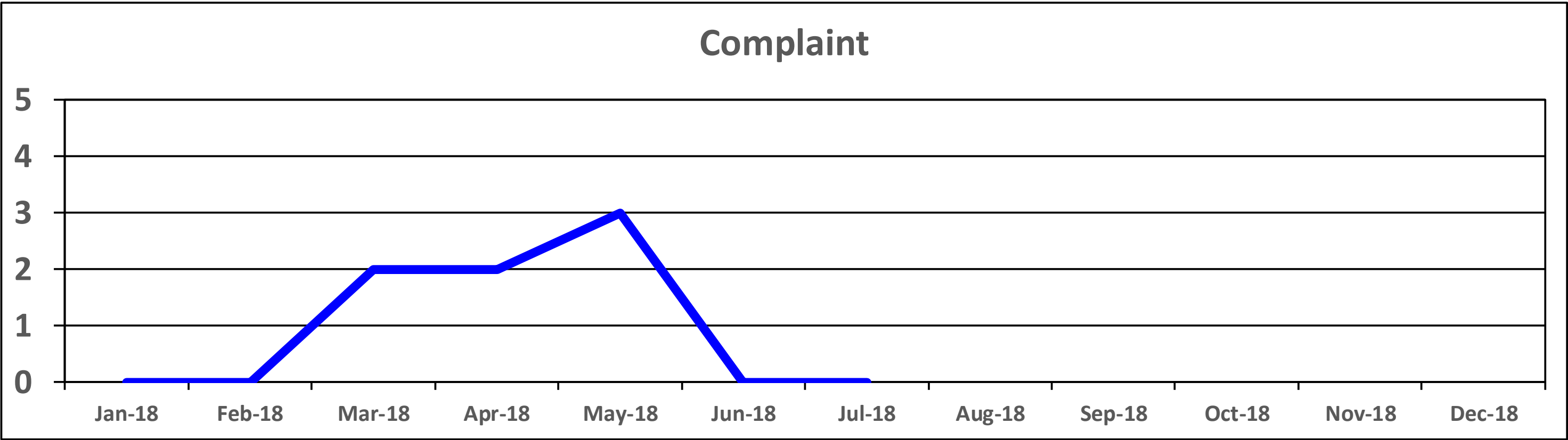
Q-Alert Notice raised for IQA, Sub assy, Main line assy, Final test station, FVMI and FQA to check the top surface of QSM Chassis spill gasket

Q-Alert Notice		It is the Area/department representatives to retain Q-Alert Notice.	
EFFECTIVE DATE : FlexQ - On File			
Date : <u>12 July 2018</u>		Document No : <u>WAT-RW-SKI04878</u>	
Customer : <u>Waters Corporation</u>		Document Rev : <u>A</u>	
Project Part Number : <u>186015018, 186015080</u>		☐ New ☐ In House Originated	
Affected Part Number : <u>WAT-289005258-F</u>		☒ Customer/Supplier Feedback	
Initiated by : <u>Ivy Marges</u>			
Description / Sketches/Diagram :			
Issue: During Dock-to-stock inspection of Customer for QSM Plus (Part Number: 186015080) found chassis spill gasket torn.			
To check top surface of chassis spill gasket is not torn.			
			

Customer & Field Complaints

Customer & Field Complaints Trending

Month	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
Complaint	0	0	2	2	3	0	0					
Open	0	0	0	0	0	0	0					
Closed	0	0	2	2	3	0	0					



Customer & Field Complaints (status - open in Year 2017)

Customer & Field Complaints Update

Nov'17 Feedback:

- 14a) 3 x RMA from India (Alliance) received in 06 Nov 2017 -open
- 14b) 4thRMA unit received on 08Mar2018 –open

Mar'18 Feedback:

- 1)Solaris Pharma Corporation 2695EB Alliance SN K17SM4227A & M17SM4930A: start up failures -closed
- 2)Solvent Filter (WAT025531) rusty issue -closed

Apr'18 Feedback:

- 3) 2695 Red Tube OFI -430000922 -poor cut issue summary –closed
- 4) Missing Info Set (reported by Japan) –closed

May'18 Feedback:

- 5) Alliance -Injector Needle not assemble properly –closed
- 6) Detector -4 x units reported Missing Flow Cell –closed
- 7) Missing Functional Test Certificate (reported by Turkey) -closed

Customer & Field Complaints (Year 2017)

Customer & Field Complaints Update

14a) Complaints: 3 x RMA from India (Alliance)

Reject/Feedback/Complaint	Root Cause	Action Plan : Analysis/Containment /Corrective/Preventive		Owner	Target Date for Closure	Status				
Reported Date: 17 Oct 2017 RMA Received: 06 Nov 2017 Product: 186269506 (Alliance) Affected Qty: 3u Unit 1) SN L16SM4371A: Carryover Test Failures on 22-Feb'17 and 16-Mar'17, Sample Temp not attaining 5 degree on 22-Feb'17, and Vial missing on 12-Jun'17. Unit 2) SN L16SM4368A: missing vial and carry over on 20-Mar'17 and 9-Jun'17. Unit 3) SN L16SM4356A: Vial Missing error on 2-May'17, Carryover failing in customer method on 3-May'17 and 11-May'17.	pend. Joint investigation (WPPL and Flex) is still on-going	Investigation: pend. Joint investigation (WPPL and Flex) is still on-going Below update as of 14 Aug 2018: (yellow - pend execution)		WPPL / Flex	TBA	Open (On-going)				
			Stage / Activity				Unit 1	Unit 2	Unit 3	
			Serial Number				Unit 1) SN L16SM4371A:	Unit 2) SN L16SM4368A:	Unit 3) SN L16SM4356A	
		1	Visual				Scratches on Chassis, wire connections removed, inner compartment dirty etc.			
		6a	Run Full Vial Test				Pass	Pass	FAIL (39 out of 120 position failed)	
		6b	Run Carry Over Test				Pass	Pass	Fail vial Sensor. Not able to proceed.	
		6c	Verify the Bracket bending angle with Go-NoGo Fixture				Pass	Pass	Fail - "GO"	
		7	Rework the Bracket of the Chassis and check with Fixture				NA	NA	Pass	
		8	Run Final Test				Pass	Pass	pend	
		9	Run Full Vial Test and Carry Over Test				Pass	Pass	pend	
		10	SQT				Completed. Need to re run	Completed. Need to re-run	pend	

Customer & Field Complaints (Year 2017)

Customer & Field Complaints Update

14b) Complaints: 4th RMA from India (Alliance)

Reject/Feedback/Complaint	Root Cause	Action Plan : Analysis/Containment /Corrective/Preventive	Owner	Target Date for Closure	Status
Reported Date: 17 Oct 2017 RMA Received: 08 Mar 2017 Product: 186269506 (Alliance) Affected Qty: 1u Unit 4) SN C17SM4376A. Gradient test failed on 26 Jun 2017. Black particles deposited)Pressure fluctuations) on 18-Jul-2017 and Drift and Noise test results not meeting on 07 Aug 2017. Date of Manufactured: Mar 2017	still under investigation	Investigation: Joint investigation (WPPL and Flex) is still on-going Visual inspection completed - some scratches and damaged found. Final test failed for Static Leak Test. After replaced a non Flex installed tubing, still fail. Observed Pump tray tubeing dressing not normal. REmoved Pump tray for sub assy testing - Failed. But managed to passed after replaced 2 tubings and a check valve.Install pump tray back to Instrument, the Instrumentn now passed Final Test. Pend to run SQT	WPPL / Flex	TBA	Open (On-going)

QMS Update

NA

AOB

NA

