ELIMINATION OF MIXED DEVICE ON OPERATOR-DEPENDENT PROCESSES AT FINAL TEST P1

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ABSTRACT

This paper presents an analysis of Mixed Device (MD), one of the challenging quality issues at onsemi Carmona. MD can occur in various Test processes, and its complexity is increased by its administrative nature and dependence on human intervention.

Within the top 4 defects in FT P1 (Final Test Plant 1), MD constituted the highest occurrences between January 2019 and December 2020, totaling Y1 (42% of all defects). This adversely affected overall FT cost and delivery performance, requiring actions like rescreening, reinspection or retesting for affected lots.

The study outlines the approach undertaken to identify potential causes of mixing during operator-dependent steps at FT P1. Techniques such as simulation through designed experiments and Gemba Walk were employed to identify all the risks. While many proposed solutions are proactive and not reliant on human actions, certain controls face limitations due to process constraints. To overcome this, an environment enforcing compliance with identified controls was established.

Significantly, the results demonstrate considerable impact on both internal and external quality metrics recording zero incidents of MD for over a year after full implementation of controls in 2022. This resulted to an annualized cost reduction of $4,349 and cost avoidance of $16,801.

1. 0 INTRODUCTION

Mixed Device (MD) is any unit/s shipped to a customer that is/are of different type (including same device with different seal code) from what the customer ordered. This alien unit can be a single unit in a reel/tube/tray of correct units, or a whole reel/batch of wrong units (Figure 1).

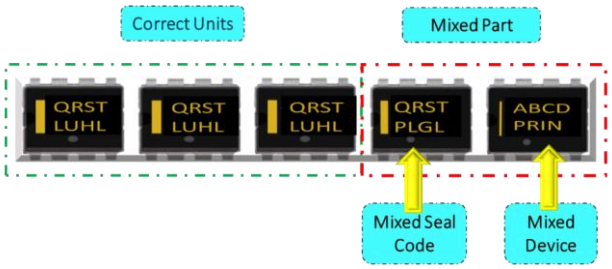


Figure 1. Illustration of Mixed Device. This shows the different scenarios of mixed device incidents.

MD can happen at various stages of the production, from Final Test to Final Packaging, especially when the process is too manual and very human-dependent.

During the 2019-2020 period, MD was identified as the most prevalent defect monitored by FT P1. On average, there were Y2 GMRB/MPE incidents related to mixing per month during this time. As a result, the high level of rejection led to significant delays in cycle time and scrap due to the need for 100% reinspection and potential rework and re-testing of the affected products.

Figure 2 displays a notable rise in MD, a 76% increase in incidents in 2020. This was observed across all areas, types of packages, and machine technology as shown in Appendix A.

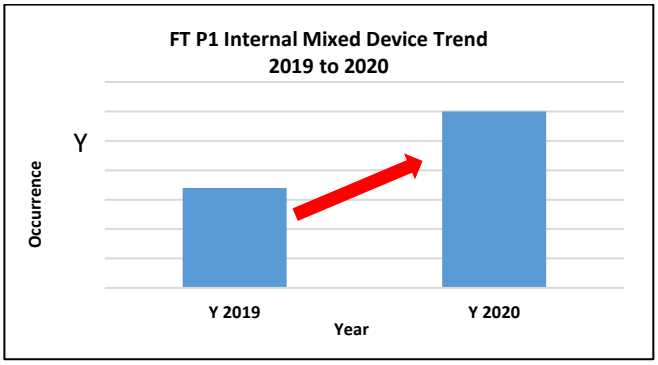


Figure 2. FT P1 Yearly Internal Mixed Device Trend 2019-202. This shows the significant increase of MD incidents in 2020 versus 2019.

To effectively address this issue, this paper presents a comprehensive assessment of all areas in FT P1 using SIPOC (Figure 3), a tool that maps the suppliers, inputs, processes, outputs, and customers of a system. Critical processes that are prone to the risk of mixing were identified, namely Final Test, Tape and Reel (TnR), PreGate, QA, and Final Packaging.

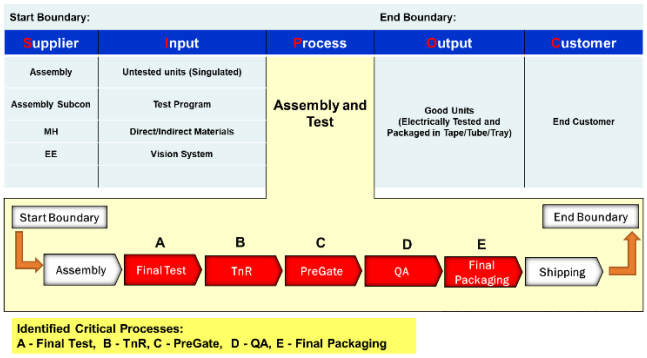


Figure 3. Illustration of SIPOC. This shows the critical processes to focus.

A systematic method is proposed to prevent MD by analyzing and controlling the risks in these processes using various tools and techniques. It demonstrates how this method can eliminate MD at every stage of production, from Test to Final Packaging, and improve the performance and efficiency of the semiconductor industry.

With this, the goal is to eliminate (1) GMRB/MPE on Mixed Device resulting to reinspection and retest of affected units, and (2) Reworked and Scrapped lots due to Mixed Device at FT P1.

2. 0 REVIEW OF RELATED WORK

Refer to 1.0 Introduction.

3.0 METHODOLOGY

The methodology employed in this study involves the systematic application of the DMAIC problem-solving framework to tackle the challenge of Mixed Device occurrences within operator-dependent processes at FT P1. DMAIC, which stands for Define, Measure, Analyze, Improve, and Control, is a well-established approach within the Lean Six Sigma methodology. This structured approach is aimed at enhancing process performance and quality by identifying and addressing issues, thereby promoting operational excellence.

3.1 Define

In the Define phase, the primary focus is on outlining and clarifying the scope and objectives of the project. This lays the foundation for the entire DMAIC process by providing a clear understanding of what needs improvement and why. It ensures that the project team and stakeholders are aligned on the project's purpose, goals, and scope before proceeding to data collection and analysis in the subsequent phases.

3.2 Measure

In the Measure phase, the primary focus is on gathering and analyzing data to gain an accurate and comprehensive understanding of the current state of the process or system being studied. This aims to provide a clear and data-driven understanding of the current state of the process, identifying areas that require improvement. The insights gained during this phase serve as a foundation for the subsequent Analyze phase, where the root causes of problems are explored in greater detail, leading to the formulation of targeted improvement strategies.

3.3 Analyze

In the Analyze phase, the primary focus is on systematically investigating and understanding the root causes of problems or inefficiencies identified in the previous stages. This aims to provide a deep understanding of the underlying reasons for the identified issues. By identifying root causes, the project team gains insights into the most effective ways to address the problems and implement targeted improvements. The outcomes of the Analyze phase serve as a basis for designing and executing improvement strategies in the subsequent Improve phase.

3.4 Improve

In the Improve phase, the primary focus is on systematically investigating and understanding the root causes of problems or inefficiencies identified in the previous stages. This aims to provide a deep understanding of the underlying reasons for the identified issues. By identifying root causes, the project team gains insights into the most effective ways to address the problems and implement targeted improvements. The outcomes of the Analyze phase serve as a basis for designing and executing improvement strategies in the subsequent Improve phase.

3.5 Control

The final phase, Control, is focused on ensuring that the improvements made during the earlier stages are sustained over the long term and that the process remains stable and consistent. This phase is critical for ensuring that the

improvements achieved in the earlier stages are sustained and integrated into the regular operations of the organization. By implementing controls, monitoring performance, and fostering a culture of continuous improvement, the Control phase helps prevent regression and ensures that the benefits of the DMAIC project are realized over the long term.

4.0 RESULTS AND DISCUSSION

4.1 Define

The phase identified MD as the defect of focus as it accounted for 42% of all defects monitored by FT P1 (Figure 4). Also, the average MD incidents per month is Y2.

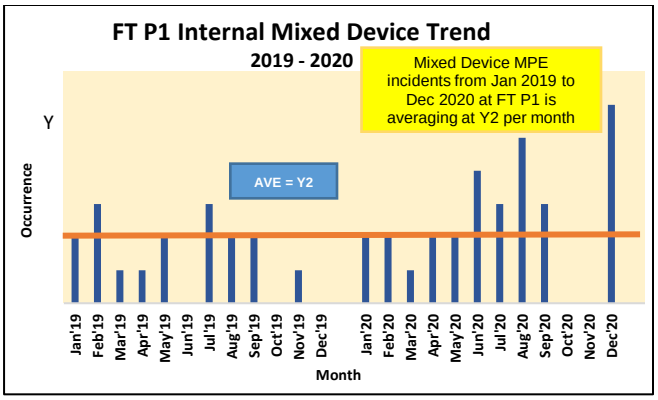


Figure 4. FT P1 Internal Mixed Device Trend. This shows the trend of Internal Mixed Device from 2019-2020 with a monthly average of Y2.

Furthermore, MD requires 100% reinspection and potential rework and re-test resulting to significant delay in cycle time. Figure 5 shows that the average number of units undergoing reinspection and re-test is X1 per month due to Mixed Device.

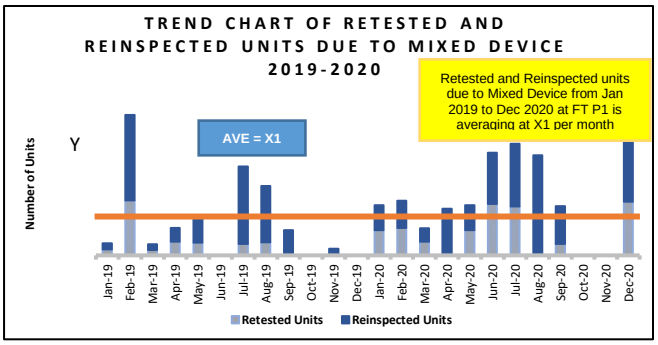


Figure 5. Trend Chart of Retested and Reinspected Units. This shows the trend of the monthly number of units that are retested and reinspected due to Mixed Device incidents from 2019-2020 with a monthly average of X1.

Final Test, Tape and Reel (TNR), PreGate, QA and Final Packaging Processes are the areas where Mixed Device can potentially occur, hence, are the focused areas for this project. Prevention controls are programmed in these areas as well as Detection controls considering the fact that some controls are anticipated to have some level of human dependency.

A cross-functional DMAIC team was formalized to address the Mixed Device issue. This had the strong sponsorship of onsemi Carmona's leadership team.

4.2 Measure

Attribute Measurement System Analysis (MSA) was performed at FT. The result showed that the overall judgement of the inspection system is effective and consistent (Table 1). Hence, the stated problem on MD resulting to reinspection and retest is validated to be true.

Table 1. Summary of Attributes MSA Study

KPOV (Output or Response Variable)	MSA Method	Criteria	Actual Result	Remark/s
Mixed Device Incidents	Consistency	≥ 90%	Test: 100%	Pass
			TnR: 100%	Pass
			QA: 100%	Pass
	Effectiveness (Individual)	≥ 90%	Test: 98%	Pass
			TnR: 100%	Pass
			QA: 100%	Pass
	Effectiveness (Overall)	≥ 90%	Test: 98%	Pass
			TnR: 100%	Pass
			QA: 100%	Pass
	Miss Rate (Under-Rejection)	≤ 2%	Test: 0%	Pass
			TnR: 0%	Pass
			QA: 0%	Pass
	False Alarm Rate (Over-Rejection)	≤ 5%	Test: 2.78%	Pass
			TnR: 0%	Pass
			QA: 0%	Pass

4.3 Analyze

The extensive root cause analysis process resulted to the identification of a total count of 105 KPIVs: 58 KPIVs for Final Test, 24 KPIVs for TNR, 9 KPIVs for PreGate, 9 KPIVs for QA and 5 KPIVs for Final Packaging. (See Appendix B)

After prioritization and grouping, the total number of KPIVs was reduced to 50 unique KPIVs: 30 KPIVs for Final Test, 12 KPIVs for TNR, 6 KPIVs for PreGate, 1 KPIVs for QA and 1 KPIVs for Final Packaging (See Appendix C). All these were subjected to thorough validation.

The next sub-sections illustrate how the actual validation was carried out on sample key KPIVs for Final Test, TNR, PreGate, QA and Final Packaging.

4.3.1 KPIV 11: Multiple lots with multiple Black Boxes (BB) were placed in the staging rack with no visual separator

To validate this potential cause, actual observation was done in the line to check and assess staging racks with lots in multiple BBs. Here, it was found that lot in multiple BBs is hard to distinguish with another lot when placed all together in one staging rack (refer to Figure 6).

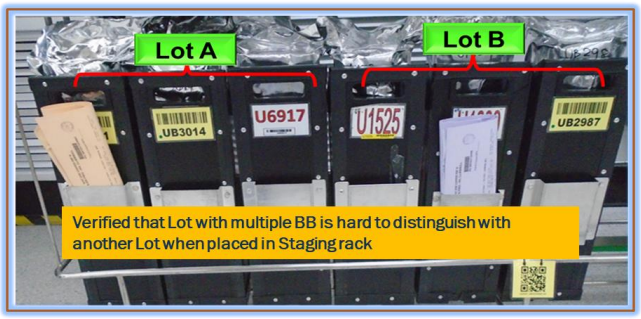


Figure 6. Actual Photo Staging Rack lots in Multiple BBs. This shows that lots with multiple BBs stage in one rack is hard to distinguish from another lot.

4.3.2 KPIVs 13&15: Track Gap is too thin/thick across the handler stages and EPAD package type is prone to being stuck

A characterization DOE (Design of Experiment) was performed to validate these potential causes (Appendix D). The result showed that at a 95% confidence level, only Track Gap, with p-value=0.0008 has a significant effect on the presence of stuck units across handler stages (Figure 7).

Effect Likelihood Ratio Tests

Source	Nparm	DF	L-R ChiSquare	Prob>ChiSq
Package Type	1	1	0	1.0000
Track Gap	1	1	11.275173	0.0008*
Package Type*Track Gap	1	1	0	1.0000

Figure 7. JMP Result. This shows that only Track Gap is a significant factor on the presence of stuck units across handler stages.

4.3.3 KPIV 44: Standby rack is far from the machine operator

In order to validate this potential cause, 3 areas underwent an IE study to check and assess the layout of staging racks (Figure 8). It was found that staging racks are far from the operator as a longer time is incurred to stage/retrieve the lot. For example, the travel distance of an operator from the Analog line to get lots that are next to the process is 126.83 meters and takes 3 minutes travel time.

	From	To	Travel Distance (m)	Walksteps	Time (min)
Current	A	F	126.83	166.44	3.00

Figure 8. Sample Layout Assessment (Analog Line). This shows that staging racks are far from the operator as a longer time is incurred to stage/retrieve the lot.

4.3.4 KPIVs 48&50: Multiple sets of gate samples and multiple R2 lots are staged together in one BB

To validate these potential causes, a Gemba Walk was performed. The result of the line walk showed that multiple R2 lots (a combination of partials to make a full or non-MPQ lot) and Gate samples of different lots are indeed staged in one BB (Figure 9).

Figure 9. Actual Photo of Staging Gate Samples and R2 lots. This shows multiple R2 lots and Gate samples of different lots are staged in one BB.

4.3.5 KPIV 49: Left tube was in slant position, and it was not easily visible due to tube height and black box were almost the same.

Actual checks and assessments were done to validate this potential cause. The BB design was studied and found that this is prone to the left tube in a slant position as this will not be easily seen during housekeeping (Figure 10).

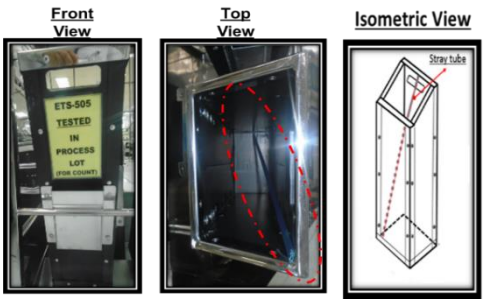


Figure 10. Actual Photo of BB for count. This shows that BB design is prone to left tube in slant position.

4.3.6 KPIV FB3: No visual identifier of Multiple lots staged in one pushcart

Actual observation was performed to validate this potential cause. It was found that multiple lots staged on one pushcart have no clear separator (Figure 11).

Figure 11. Actual Photo of Pushcarts with Multiple Lots. This shows that multiple lots staged on one pushcart have no clear separator.

After going through the validation process, a total of 44 KPIVs were found to be truly inducing MD in different FT processes (24 KPIVs for Final Test, 12 KPIVs for TnR, 6 KPIVs for PreGate, 1 KPIVs for QA and 1 KPIVs for Final Packaging). The valid KPIVs are summarized in Appendix E.

4.4 Improve Phase

A total of 44 CAPAs were formulated. All these went through the potential problem analysis process to ensure that no new problems are created and that the execution is going to be smooth (Appendix H). A sample summary of these CAPAs is illustrated in Appendix G.

The next sub-sections illustrated the corresponding CAPAs implemented for the six valid KPIVs shown in the Analyze phase.

4.4.1 CAPA for KPIV 11: Multiple lots with multiple Black Boxes (BB) were placed in the staging rack with no visual separator

In order to address this cause, In-house fabricated lot separators were now being used to clearly identify one lot to another (Figure 12). Standard procedure in using and managing these separators were documented and downloaded to manufacturing. With this, different lots in multiple BBs can now be easily identified.

Figure 12. Actual Photo of Before and After Scenario. This shows that lots can now be easily identified with the use of in-house fabricated lot separators

4.4.2 CAPA for KPIV 13: Track Gap is too thin/thick across the handler stages

An optimization DOE was performed to determine the best setting of Track Gap that will minimize the occurrence of stuck units in test handlers (Appendix F). The result showed that from the prediction profiler, the predicted best setting of Track Gap that will "zero out" the occurrence of jam incidents (@100% chance) is 0.28 mm (Figure 13). This was then fabricated and deployed to all applicable machines.

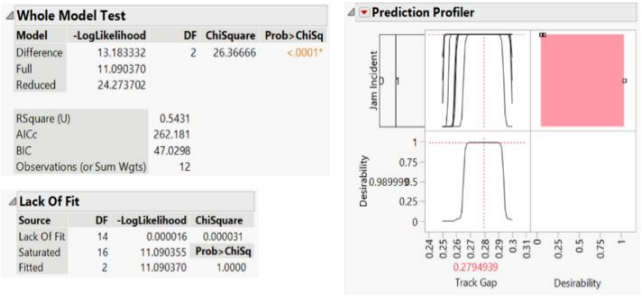
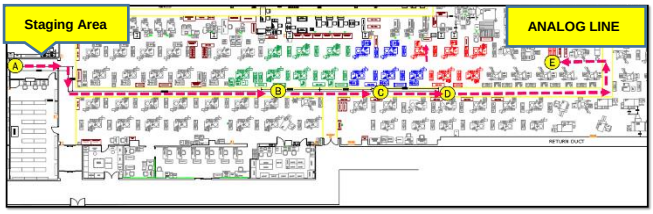


Figure 13. JMP Result. This shows the predicted best setting of Track Gap that will "zero out" the occurrence of jam incidents (@100% chance) is 0.28 mm. The validation that follows has proven that this is true.

4.4.3 CAPA for KPIV 44: Standby Rack is far from the machine operator

A re-layout was done on the staging rack for easy access of the operators (Figure 14). The travel distance of an operator from Analog line to get lots that are next to process is reduced from 126.83 meters down to 88.7 meters, and the travel time is from 3 minutes down to 2.10 minutes.



	From	To	Travel Distance (m)	Walksteps	Time (min)
Current	A	F	126.83	166.44	3.00
Proposal	A	E	88.70	116.40	2.10

Figure 14. Actual Photo of New Flow and Layout. This shows the new flow and layout of the staging racks to ensure easy access of our operators.

4.4.4 CAPA for KPIVs 48&50: Multiple sets of gate samples and multiple R2 lots are staged together in one BB

BB for Gate samples and R2 lots were redesigned such that only one gate sample and one R2 lots will be catered at a time (Figure 15).

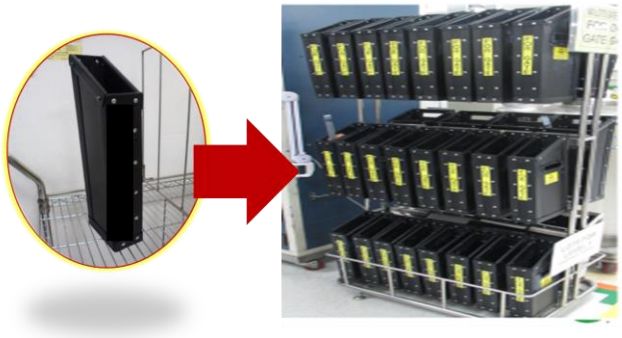


Figure 15. Actual Photo of BB in New and Smaller Design. This shows the new BB design that will only cater one gate sample and one R2 lot at a time.

4.4.5 CAPA for KPIV 49: Left tube was in slant position, and it was not easily visible due to tube height and black box were almost the same

BB for count were redesigned to guarantee no left tube was in slant position in the BB (Figure 16).

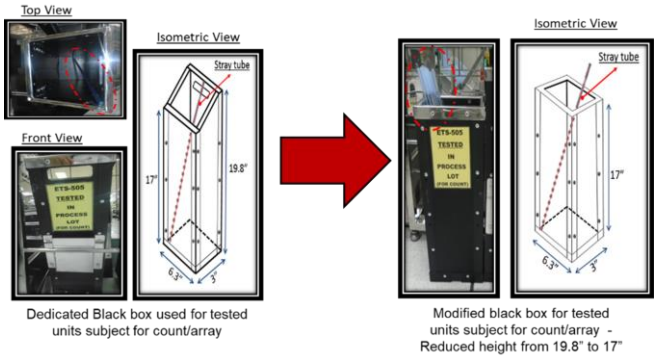


Figure 16. Actual Photo of Before and After BB Design. This shows the new BB design for count to guarantee no left tube was in slant position in the BB

4.4.6 CAPA for KPIV FB3: No visual identifier of Multiple lots staged in one pushcart

Pushcarts for lots in pizza boxes were redesigned to have clear separation for one lot to another (Figure 17).

Figure 17. Actual Photo of Before and After Pushcart Design. This shows the new pushcart design for lots in pizza boxes have clear separation for one lot to another.

4.4.7 Overall Result

After the implementation of the CAPAs in the scoped FT Process in October 2022, all project metrics showed significant improvement. The incidences of MD in EFAR, GMRB/MPE were all zeroed out.

This translated to at least 14 months now without any MD incidence, and still counting (see Figure 18).

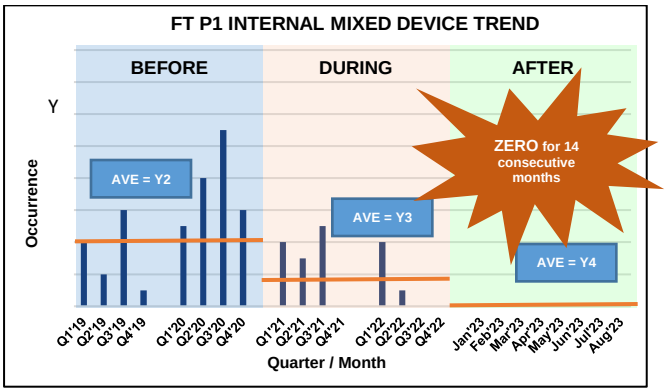


Figure 18. FT P1 Internal Mixed Device Trend. This shows the trend of Internal Mixed Device from 2019-May 2023. Zero MD for 14 consecutive months

Also, zero MD resulted to zero reinspected and retested units (Figure 19)

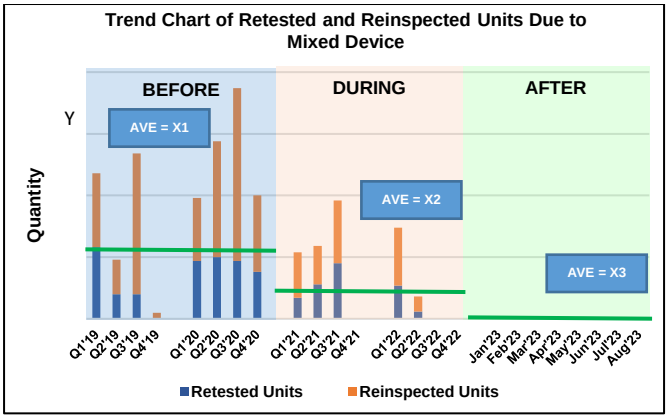


Figure 19. Trend Chart of Retested and Reinspected Units. This shows the trend of the monthly number of units that are retested and reinspected due to mixing. Now, this is zero.

4.5 Control Phase

To ensure that the gains realized by the implementation of the corrective and/or preventive actions are locked up permanently, all improvement actions were standardized and fanned out to all applicable processes and machine technologies. All identified controls were documented in Work Instruction and PFMEA. Training were also provided to ensure controls would be done based on standards.

5.0 CONCLUSION

This paper showed how solutions like optimization DOE, fixtures re-design and re-layout collectively helped in eliminating the chronic problem on Mixed Device. DOE was needed in finding the optimum setting of track gap that will zero out jams and, thus eliminate stuck unit incidences that invites Mixed Device. The re-design of black boxes and push carts also helped in providing a Poka-Yoke mechanism against simple operator lapses. The re-layout of the work area involving the staging rack also provided additional help in preventing any potential for mix-ups.

The key to the success of this project is understanding the problem at the grassroots from the start, then creating an operator-friendly environment, where the potential for human errors is eliminated. By the comprehensive approach undertaken in addressing the complex issue and by focusing on proactive measures, Mixed Device had become a thing of the past.

6.0 RECOMMENDATIONS

To effectively address chronic quality issues that have dependence on human, it is crucial to involve everyone at the grassroots level --- the operators and technicians. These people are present on the ground 24/7 and they know many things.

When dealing with problems that are caused by the human factor, the best approach is to apply error-proofing. This can be achieved by addressing variation through DOE, and by doing product-process re-designs as appropriate. All these should be geared towards eliminating the opportunities for creating the problem.

Shigeo Shingo, the father of Poka-Yoke, was right in saying that the more that a problem is caused by man, the more that the problem can be prevented by Poka-Yoke.

7.0 ACKNOWLEDGMENT

We are grateful to onsemi Carmona management for their trust and support in this project, and to all the SGA Teams for their valuable suggestions that helped us eliminate Mixed Device.

Our gratitude also goes to Peter Awayan for guiding us throughout the project; to our families for their unending love and support; and finally, to God Almighty, the creator and ultimate designer.

8.0 REFERENCES

None.

9.0 ABOUT THE AUTHORS

Analiza Eugenio attained her Bachelor of Science degree in Statistics from UP Los Banos. In addition, she pursued a Master of Science degree in Statistics at the same university, completing thirty-three units. To further enhance her practical expertise in Statistics, she pursued a master's degree in Statistics at UP Diliman. She obtained her LSS BB certification from onsemi in December 2022. Also, she completed her Massachusetts Institute and Technology (MIT) Training on Data Science and Machine Learning last July 2023. Currently, she is serving as a Senior Process Engineer at onsemi Philippines.

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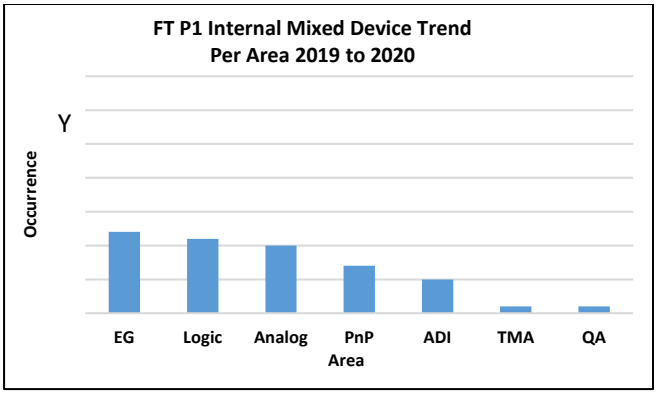
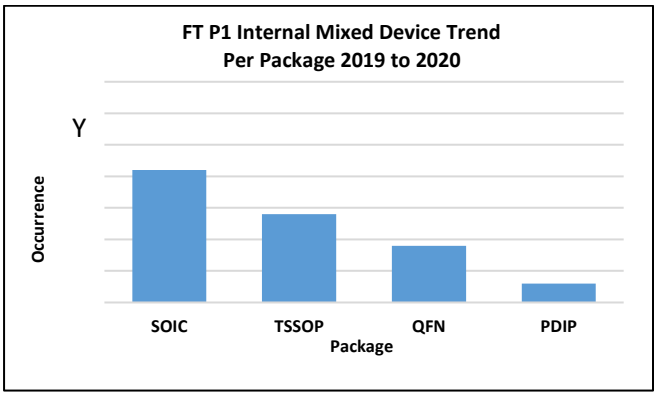
10.0 APPENDIX

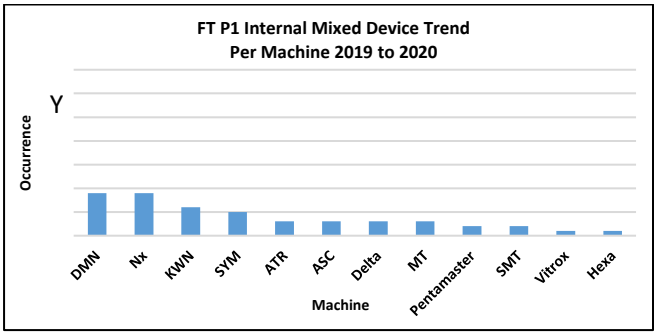
APPENDIX A – Illustration of MD Baseline



Appendix A.1. Illustration of MD Baseline per Area. This shows that MD is occurring in all areas at FT P1.



Appendix A.2. Illustration of MD Baseline per Package. This shows that MD is occurring in all packages in FT P1.



Appendix A.3. Illustration of MD Baseline per Machine. This shows that MD is occurring in all machine technology at FT P1.

APPENDIX B – Sample Cause and Effect Matrix (Identification of KPIVs)

C&E Matrix

Process Step No.	Process Step	Input	KPIV No.	Characteristic of Input (KPIV)	Specification / Criteria	Process Output / Criteria: Occurrence (OPIV)	Process Output / Criteria: Impact to MD	Total
					Importance to Customer	10	10	
					Impact of KPIV to Output (0 - None, 3 - Minor, 6 - Moderate, 9 - High)			
A2	Housekeeping	Operator	1	Operator failed to perform proper housekeeping	Operator to follow the correct housekeeping procedure	4	4	80
A2	Housekeeping	Operator	2	Operator failed to perform housekeeping	Operator to perform housekeeping every start and end of lot	2	4	60
A2	Housekeeping	Operator	3	Operator placed the stray tube in the BB/machine of the lot to be processed without checking details	Operator to dispose any stray tube	2	9	110
A2	Housekeeping	Handler	4	Machine encountered jamming	Handler should run smoothly	7	1	80
A2	Housekeeping	Tubes	5	Tubes that are engineering samples were left in the vicinity of the machine	Sample tubes should be secured properly	4	5	90
A5	Lot Details checking vs SO vs Machine	SO	6	Multiple SO were brought by the operator during lot details checking	One SO per transaction	10	10	200
B2	MH to get the Lot from RS and put in the Mfg Staging Rack	Lots with multiple BB	7	Multiple lots with multiple BBs were taken from RS and brought to Mfg staging Rack without clear separation	One lot at a time; Lots should be clearly separated from each other	10	8	180
B4	Check actual unit marking vs SO	Operator	8	Operator return the tube to the BB of another lot after checking actual unit mark vs. SO	Operator to return the tube to the mother lot after checking actual unit	2	7	90
B5	Lot combination transaction (if applicable)	Operator	9	Operator failed to check lot details	Operator to check lot details	2	2	40
B5	Lot combination transaction (if applicable)	Operator	10	Operator failed to check BB# vs. SO	Operator to check actual BB# vs. SO	2	2	40

Appendix B. Final Test Cause and Effect Matrix. This shows a sample of identifying KPIVs.

APPENDIX C – Sample Cause and Effect Matrix (Prioritization of KPIVs)

C&E Matrix

Process Step No.	Process Step	Input	KPIV No.	Characteristic of Input (KPIV)	Specification / Criteria	Process Output / Criteria: Occurrence (OPIV)	Process Output / Criteria: Impact to MD	Total	Rank	Prioritized/Not Prioritized
					Importance to Customer	10	10			
					Impact of KPIV to Output (0 - None, 3 - Minor, 6 - Moderate, 9 - High)					
A2	Housekeeping	Operator	1	Operator failed to perform proper housekeeping	Operator to follow the correct housekeeping procedure	4	4	80		Not Prioritized
A2	Housekeeping	Operator	2	Operator failed to perform housekeeping	Operator to perform housekeeping every start and end of lot	2	4	60		Not Prioritized
A2	Housekeeping	Operator	3	Operator placed the stray tube in the BB/machine of the lot to be processed without checking details	Operator to dispose any stray tube	2	9	110		Prioritized
A2	Housekeeping	Handler	4	Machine encountered jamming	Handler should run smoothly	7	1	80		Not Prioritized
A2	Housekeeping	Tubes	5	Tubes that are engineering samples were left in the vicinity of the machine	Sample tubes should be secured properly	4	5	90		Not Prioritized
A5	Lot Details checking vs SO vs Machine	SO	6	Multiple SO were brought by the operator during lot details checking	One SO per transaction	10	10	200		Prioritized
B2	MH to get the Lot from RS and put in the Mfg Staging Rack	Lots with multiple BB	7	Multiple lots with multiple BBs were taken from RS and brought to Mfg staging Rack without clear separation	One lot at a time; Lots should be clearly separated from each other	10	8	180		Prioritized
B4	Check actual unit marking vs SO	Operator	8	Operator return the tube to the BB of another lot after checking actual unit mark vs. SO	Operator to return the tube to the mother lot after checking actual unit	2	7	90		Not Prioritized
B5	Lot combination transaction (if applicable)	Operator	9	Operator failed to check lot details	Operator to check lot details	2	2	40		Not Prioritized
B5	Lot combination transaction (if applicable)	Operator	10	Operator failed to check BB# vs. SO	Operator to check actual BB# vs. SO	2	2	40		Not Prioritized

Appendix C. Final Test Cause and Effect Matrix. This shows a sample of prioritization of KPIVs

APPENDIX D – Design of Experiment (DOE) Plan: Characterization

Design of Experiment (DOE) PLAN

Characterization

Study #	
Date	
Pass/Fail	
Process	
Equip	
Start	
Finish	
Page	of

Problem Statement

Unit stuck at test handler is known to be among the many reasons for mixed device. Hypothesized to be causing stuck units are: variation in Package Type, differences in track sizes across the handler stages and differences in Shimming used.

Objective

To verify which among the hypothesized causes are really contributing to unit stuck and eventually mixed device

Variables Under Study

Dependent Variable(s) (Response)	Data Modelling Type	Number of Replicates	Specification	Unit of Measurement
Jam Incidents	Ordinal	2 (1 tube/replicate, (86 units/tube)	No incidents of jamming	

Independent Variable(s) (Factor)	Data Modelling Type	Number of Levels	Levels	Unit of Measurement
Package Type	Nominal	2	EPAD, Non EPAD	
Track Gap	Continuous	2	0.25, 0.30	mm

Experimental Design/Model

2x2 Full Factorial

No. of Center Points

None

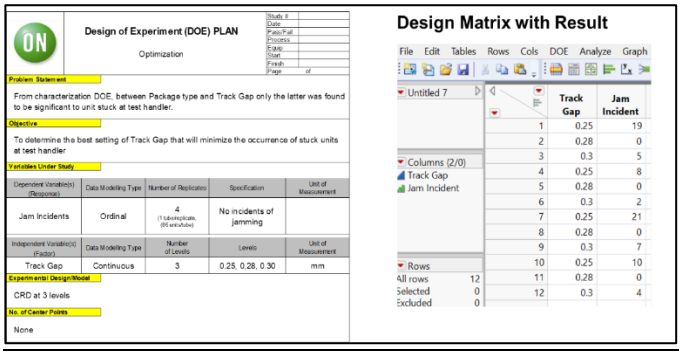
Appendix D. Design of Experiment (DOE) Plan: Characterization. This shows the detailed plan on how to perform DOE.

APPENDIX E – Sample Test Validation Result Summary

KPIV	Process Step	Input	Characteristic of Input (KPIV/Potential Root Cause)	Hypothesis	Validation Plan	Result
6	Lot Details checking vs SO vs Machine	SO	Multiple SO were brought by the operator during lot details checking	Multiple SO brought by the operator to perform lot checking can result to Swapping of SO, another MD incident.	1. Consider 10 operators, allow them to bring more than 3 SO to perform lot details checking 2. Observe how they will return the SO to its corresponding assigned lot 3. Record result	Valid
7	MH to get the Lot from RS and put in the Mfg Staging Rack	Lots with multiple BB	Multiple lots with multiple BBs were taken from RS and brought to Mfg staging Rack without clear separation	Lots with multiple BB can induce MD when not clearly separated	1. Consider 10 lots with multiple BB 2. Observe how operators get all the BBs of each lot retrieval at RS. Is there confusion 3. Record Result	Valid
11	Lot combination transaction (if applicable)	Lots with multiple BB	Multiple lots with multiple BBs were placed in the staging rack with no visual separator	Lots with multiple BB can induce MD when not clearly separated	1. Consider 10 lots with multiple BB 2. Observe how operators get all the BBs of each lot during lot combination process. Is there confusion 3. Record Result	Valid
12	All tested tubes should be in upside down position	Tubes	Crimp side of the tube is prone to left unit	Current Tube Design is prone to stuck unit, potential MD.	1. Consider Empty tested tubes in the container in different areas 2. Observe for stuck units at the crimp side 3. Record result	Valid
14	Housekeeping (clearing of handler)	Handler	Shimming used is too thin/thick	Shimming thickness can cause MD	Perform DOE as per experiment plan	Valid

Appendix E. Sample Test Validation Result Summary. This shows the list of validated true root causes for Test process.

APPENDIX F – Design of Experiment (DOE) Plan: Optimization.



Appendix F. Design of Experiment (DOE) Plan: Optimization. This shows the detailed plan on how to perform DOE.

APPENDIX G – Sample CAPA Summary List

Selected CAPA No.	CAPA	Effectiveness	Risk to Customer	Difficulty to Implement	Cost	<<<<Selection Criteria	Decision
		10	10	10	8	<<<<<<<<Importance	
		--- Correlation of Solution to Criteria ---				-------- Total --------	
1	Relocate the label	8	10	8	8	324	GO
4	Redesign BB to cater only 1 R2 Lot	10	10	5	5	290	GO
	Install partitions on BB	5	10	3	2	196	GO
6	Redesign BB to cater only 1 gate sample	10	10	5	5	290	GO
7	Redesign Bulk bin by installing transparent cover	8	10	6	6	288	GO
8	Create an OPL on how to perform bulkbin cleaning	7	10	9	8	324	GO
9	Create an OPL on how to treat a tube with stuck unit	7	10	9	8	324	GO
10	Redesign the tube by modifying the crimp to eliminate stuck up units	10	10	7	5	310	GO
11	Implement a new breaktime schedule	8	10	5	8	294	GO
12	Automated endorsement every end of shift with history of incoming operator's acknowledgement	8	10	5	8	294	GO

Appendix G. Sample CAPA Summary List. This shows the list of CAPAs for deployment

APPENDIX H – Sample Potential Problem Analysis

CAPA No.	Permanent Action/s	Guide Questions to identify Potential Problem	Identified Potential Prole/Risk	Prevewntive Measure to Address Potential Problem (Person In Charge/Status)
1	Relocate the label	What other problem might be created	None	None
		What can go wrong in the execution	Wrong location during replacement of tube/label	Create OPL when replaceing tube/label. Emphasis on the correct location of label (Roda D./Completed)
4	Redesign BB to cater only 1 R2 Lot	What other problem might be created	None	None
		What can go wrong in the execution	Operator not to consistently use the new BB for R2 lots	Document in WI (Ben J./Completed)
			No available BB	N+5 (Zeny M./Completed)
6	Redesign BB to cater only 1 gate sample	What other problem might be created	None	None
		What can go wrong in the execution	Operator not to consistently use the new BB for gate samples	Document in WI (Ben J./Completed)
			No available BB	N+5 (Zeny M./Completed)
7	Redesign Bulk bin by installing transparent cover	What other problem might be created	None	None
		What can go wrong in the execution	Damaged Cover	Include in PM every quarter (Tonio P./Completed)
8	Create an OPL on how to perform bulkbin cleaning	What other problem might be created	None	None
		What can go wrong in the execution	Operator failed to follow the OPL	Documented in WI (Myla O./Completed)
				Include in MD Audit checklist (Myla O./Completed)
9	Create an OPL on how to treat a tube with stuck unit	What other problem might be created	None	None
		What can go wrong in the execution	Operator failed to follow the OPL	Document in WI (Myla O./Completed)
				Include in MD Audit checklist (Myla O./Completed)

Appendix H. Sample Potential Problem Analysis. This summarizes all the potential risks that might be encountered in CAPA deployment.