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Automation for Traceability and Reliability

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ABSTRACT
Growing demand for electronic products in highly regulated markets increase quality requirements in manufacturing. This translates into increased demands on manufacturing execution systems (MES) to support fast and reliable tracking processes. The traceability of product and process records are a fundamental part of a final assembly of the product and must be reliable to eliminate reprocessing, downtime or incorrect records during complex integration or assembly processes. The acquisition of the data and supporting manufacturing systems must also be aligned with the high demands of the products. It is critical that these needs are evaluated as part of the standard work within the value stream map (VSM) to insure the installed capacity of a production line aligns with the takt time. Factors like the number of stations, data acquisition rates, communication standards, and operator motion, need to be evaluated against the components that must be integrated or installed on the final device. Additionally, just as product yield, error rates for wrong scans, or missing scans need to be included in the Overall Equipment Effectiveness (OEE) calculation.

Automation in capture of traceability data represents a good option to eliminate human intervention in those operations. This can increase the line throughput by reducing the low skill scanning activities and take 100% advantage of these highly skilled team members to transform the product. Automating does not always require expensive equipment that completely replaces human activity, but focuses on simple operations that will bring benefits of savings in labor, floor utilization, and elimination of errors.

Key words: Data integrity, scanning process, traceability.

INTRODUCTION

In many legacy systems manual scanning into the MES tool is performed by team members. Though a simple task, with a single unit this task becomes more prone to error with multi-up panels. Additionally, compounding the process is the repeated scanning that occurs across the entire value stream, adding labor time and defect opportunities. Finally further compounding the traceability requirement requires manual scanning at many level the material and product, for integrity in the association of manufacturing part numbers, printed circuit boards, (PCBs), assembly materials, and product serial numbers.

The first in an assembly production line, often the SMT Process, sets the relationship between the circuits in the panel which can be leveraged in both automated and manual scanning entry points throughout the VSM. Thus it is critical that this association is executed to a standard. Often as a manual entry point, the complexity of this step is to scan each PCB contained in a panel will lead to association errors at subsequent steps. For highly regulated product this type of error is just as significant as the product not being function and furthermore this quickly erodes the end customer confidence in traceability information.

These defects can lead to increased scrap, line down time, delays in delivery, and customer complaints. Thus it is critical to build an error proof data collection solution.

DATA INTEGRITY

The data integrity assurance must be considered by implementing a solution that guaranties the accuracy of the customer's information. With panelized or arrayed PCB layouts the data integrity needs to consider the following factors at each operation:

1. Offline programming standards for circuit assignment and orientation
2. Offline programming standards for inverting / flipping the circuit
3. Unique panel identifier (ID) location and orientation
4. Sequence of processing
5. Direction of process, particular with manual assembly processes

For the offline programing solutions, they will often assign a circuit numbering sequence in the panel back at the PCB layout tools. However manufactures are confronted with countless variation in the tools and designer preferences in setting these standard. This variation is further complicated when the machine programming solutions ignores or applies their own standard in the sequencing. And just like the PCB layout tools, organizations are challenged with various legacy solutions throughout the VSM that create different circuit assignments. All this variation can cause material and defect assignment to the wrong circuits (see **Figure 1**).

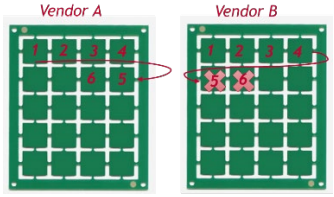


Figure 1: Example of how different programming sequences can lead to wrong circuit assignment

As shown in the above example, the date in some records may appear correct while other are in error due to the order of assignment. Thus it is critical that a deep analysis occur during the process design of the traceability standard.

In addition to the programming standards, the processing orientation standards can further complicate the data collection. How the team member on the manufacturing line flips the board during assembly can create similar circuit association errors (See **Figure 2**). Often these variance do not create error in component lot traceability. However, when a new lot is introduced with in the assembly some of the panels can become incorrect. This type of error if often not detected by the quality controls since only impacts a couple of units within the manufacturing lot.

Figure 2: Example of condition when program assignment does not align with manufacturing flow.

In many operations teams attempt to eliminate these errors by tracking the data by a panel level serial number and associate the circuit serial numbers within the panel. However, this process also has orientation and sequence implications if manually scanned. As shown in **Figure 3**, the team member is asked to follow a specific sequence but the reader capturing the wrong barcode, or the team member skipping a scan is a common challenge.

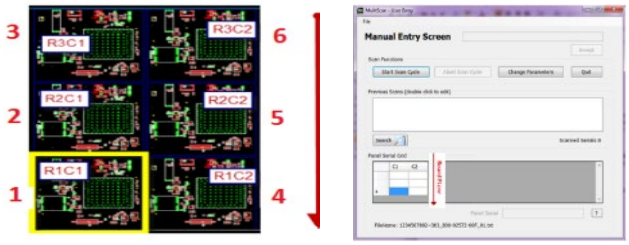


Figure 3. Sequence of data acquisition and software interface

Therefore due to previous statement, the goal is to provide certainty and data integrity by implementing a holistic solution that helps to reduce the data collection complexity and insure compliance to standards.

IMPROVEMENT OPPORTUNITIES

- Productivity loss.

With modern MES solutions route enforcement is common. These systems will verify the progress of each unit and not allow processing if the prior step is not successfully completed. When panels have been separated into the individual circuits, the errors previous reported can lead to the wrong routing for deviations or repairs. It is common to receive e-mails or production reports mentioning failures on scanning sequence. It is often time consuming to uncover the root cause of the error and process an effective containment. Units may have progressed into finished higher level assemblies or escaped to the customer. All of this effort is a loss in productivity for the manufacturing operation.

- Technology complexity.

At both scanning at each operation or in the panel to circuit association step, manual scanning errors increases when the codes become smaller and more tightly spaced (See **Figure 4**). Additionally, nested or irregular matrix of the panel can lead to a high probability to scan different or wrong information.

Example:
Panel quantity = 150 codes
Space between codes = 0.157 inch

Figure 4. Example of high populated panel with small QR codes

- Labor and Cycle time.

Each scan is a non-value add activity within the process which leads to additional labor costs in the units. In some operations and assemblies, the scanning time can exceed the value add time. Team member have need a ramp up period of time on every model change which impacts the throughput. Because of the design of the bar code and size, the cycle time can vary between models. See **Figure 5**, on the 3 models showing visible different mean scan times for the panels (model A - 7.43 sec / Model B - 19.62 sec / Model C - 24.65 sec).

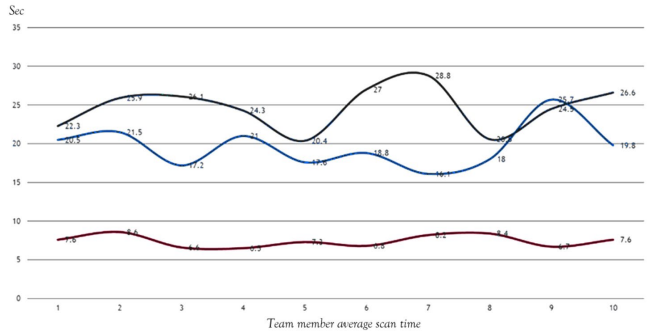


Figure 5. Difference between cycle time in 3 sample models.

Finally, as shown in **Figure 5**, the variability in cycle time, driven mostly by team member differences, and some times label integrity, affect not only line balancing, but the operation output become unrepeatable for the end customer.

AUTOMATIC DATA ACQUISITION SOLUTION COMPARE

When presented with the variances between operations, programming and team members, an automated data acquisition solution was deemed necessary. Three approaches were evaluated toward this solution: off the shelf standalone equipment, integrated equipment, custom data acquisition.

Off the shelf standalone solutions:

There is some available solution in the market that can aid with the auto collection of the bar codes. However, sometimes they does not represent the best choice to be a deployable solution; because they represent a rigid solution, which need additional technical time investment to be configured to each single customer. Furthermore, these solutions are often only addressing one process step in the operation at a considerable expense.

Integrated equipment:

These solutions use camera on the process equipment to scan each bar code and panel IDs in order to build the association. The advantage is these features are available at no additional capital costs. It just requires the integration of the output into the MES solution. However, as with the off the shelf solutions, these systems operate with their own rules to treat the circuit assignment, rotation and processing sequence. The challenge is overcoming all the variances in the process. In addition, often these process assets are complex systems with high capital costs. A though the serialization capture feature does not add capital costs, it does impact the capacity of the asset. This can lead to overall higher unit cost even over the off the shelf solutions.

Custom Data Acquisition:

Modern cameras and software can quickly be integrated into to capture bar codes. Additionally the resolution of today's cameras allows for a single field of view to read and capture all the serial numbers at once. Additionally, a custom automated system to get the traceability information allows for increased flexibility to integrate into MES systems. Furthermore, because of the ease of use, the development costs, and cycle time are minimal.

The support to this solution is local, with own technical resources, and if well planned; it can be possible to get a 24 hour response plan. Additionally, the modern software is often camera agnostic thereby allowing flexibility to change between vendors. This is important when supply chain challenges occur or obsolescence occurs. This also allows for using lower cost commercial vs industrial cameras in the solutions.

Comparison:

Performing a comparison between a commercial solution and the internal development, it represent a high opportunity to save money and time, if the solution is deployed to whole production lines (See **Figure 6**). Finally the simplicity and low costs of these solutions all for global scalability.

Customer Needs		
Cost	Lead Time	Scalability
$180K USD	8 – 10 weeks	Supplier set up requested for each different model
$36K USD	4 weeks	100% Internal Support

Figure 6. Advantages of develop an internal data acquisition solution.

SOLUTION PROPOSAL

As it was previously mentioned, the proposal is to create a solution than improves data acquisition, guaranties the integrity of the information, with a high and quick support response time, and feasible to be implemented with a reasonable budget. Therefore a flexible internal software application was developed to organize and provide the sequence (of bar or QR codes) tied to the global procedure. This exactly emulates and covers the original requirements of the traceability system.

The camera was chosen from different options available in the market. A quick comparison matrix allowed for an evaluation of specifications, capabilities and extra features. With such a simple concept, with a camera and software, selected / developed, a prototype can be established quickly to make real world evaluation of input variables.

Figure 7. First prototype of the automatic data acquisition system.

VERIFICATION / RESULTS OF EXPERIMENTS

The prototype was evaluated in production work orders, and the data was monitored to debug any challenging input variances. The final result of several test, was the verification of the data obtained.

IMPLEMENTATION

Once the test, experiments and validations are satisfactory, next step is to start the formal implementation.

This process took about 6 months to complete the following activities

- Company approved software environment development.
- Evaluate and configure the hardware to be implemented.
- Chassis / cabinet design and fabrication.
- Panel nest for panels design and fabrication.
- All component integration.
- Medical protocols release (in this case it was necessary due to the customer becomes to medical sector).
- Final verification.
- Control / up and run implementation.

The software is then subjected to the rigors of U.S. Code of Federal Regulations 21 CFR 820 – Quality System Regulation and European Council Directive GMP Annex 11: Computerized Systems for non-product software validation. This retires the risks associated and documents the performance of the software. Additionally as a good manufacturing practice it invokes rigor in the change control processes of the software.

STANDARDIZATION & SUSTAINING

It is necessary to create or assure the sustainability of the new operation; depending on each particular situation the most recommendable is to assure a training plan for operation people, and create visual aids that serve as literature reference.

The technical documentation and training is necessary to sustain the solution. Programming certification for the support personnel, who will be the responsible to set up all the new panel models and sustain the final solution.

Figure 8. Final automatic data acquisition developed solution.

CYCLE TIME IMPROVEMENTS

With the integrity build into the data collection, the second function of the new solution is get all the information by pressing just one button once. After the implementation, it was confirmed an important improvement in the 3 studied models. Now the new time consumption for any panel with any quantity of codes takes no more than 3 seconds (original data before solution implementation, used to show time from 7 to 24 sec.) It represents an 83% of improvement in terms of time. Additionally, the added benefit of a consistent

operation is achieved so predictable throughout can be achieved within the operation.

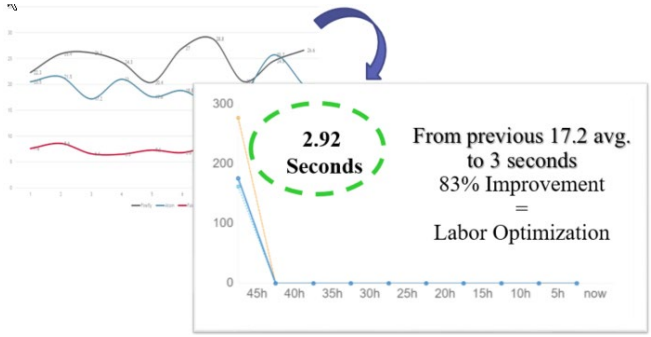
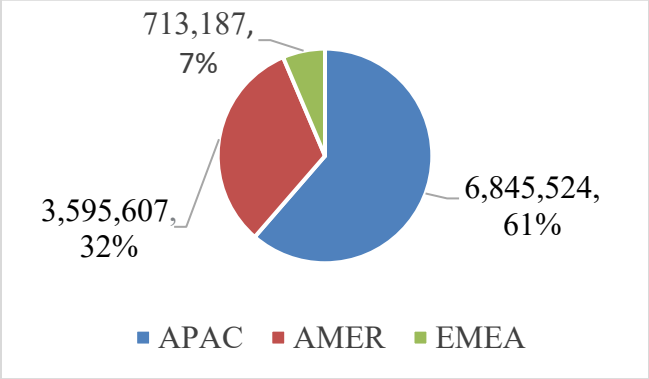


Figure 9. Improvement scanning time, based on the average of the 3 models that were selected to initiate this solution development.

Scaling this improvement across a global company create real productivity improvements. Pulling data from a global MES solution shows nearly 11 million of scanning events for calendar year 2021, covering the 3 regions (Asia, America and Europe).



A projection of improvements can be made if from the total of scanning events, are discarded the ones that represent a single scan shot of different processes (20% approximately); Then in round numbers, only the 80% of this 11 Million will be considered as applicable to be affected by the new solution.

This 80% represent 8.8 million of scanning events, and this number will be impacted by the 83% cycle time improvement. Considering the time savings above as the standard improvement this would translate into nearly 35,000 hours save annually.

SUMMARY

Today's manufacturing companies employ many advanced technologies through highly automated processes, however it is also important to detect those particular processes that represent high variability even though sometimes, they can seem "hidden" because they are surrounded by some other "more important processes". Automation does not always have to represent an expensive investment, simple elegant solutions often provide the greatest value.

In this study it was demonstrated how process traceability records need to deal with complex and variable inputs as well as challenges among our machine processes. Creating a custom data collection solution that manages these sources of variance while improving the accuracy, and productivity with data collection was achieved.