Thermal Bond Process Characterization

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Abstract

Process Characterization is a required step in the commercialization of a new product. The intent of this process characterization is to ensure that the Midjoint Thermal Bond manufacturing process delivers a consistent product that complies with its design specifications and quality requirements. Product's consistency is achieved by identifying the process parameters that have direct impact in the product quality, stablishing acceptance criteria and testing the operating parameters rages [1].

Statistical analysis data plays an important role identifying the Key Process Inputs (KPI) by creating a Design of experiment (DOE). A DOE analyses the interaction of the combination of process inputs to obtain the desire output. The Process Validation confirms that the KPI identified during the process characterization produces consistent product considering variations like material change and operator variability [2]. Process parameters for Midjoint Thermal Bond were defined after process characterization activities were completed. Samples built using the defined operating range parameters complied acceptance criteria.

Introduction

There are some deliverables that need to be completed to execute a manufacturing line transfers. From the Test and Validation perspective, is evaluated if the process will be recharacterized and revalidated or if the transferring site will be leveraging the validation. Requirements needed to complete a validation documentation leverage are: The process equipment is the same or equivalent, No change in process requirement, and same components are used for the new product. The documentation to complete the leverage of the validation must include: Risk assessment, acceptance criteria for Operational Qualification/ Performance Qualification (OQ/PQ) and sample size. Is also required a justification rationale including the Acceptance Activities and the KPI. On the other hand, if the validation will be performed from the transferring site, must be documented in a Process Characterization Report referencing its Test Method Validation Report.

Background

The Thermal Bonding System is a custom standalone machine intended to complete a Catheter bonding process between the Exhaust Tube and the Window Tube. The Exhaust tube is loaded onto a process mandrel and butted up with the Window tube. A Heat shrink tubing is loaded over tubing joint and then loaded into the Thermal Bonding Platform. Once at the equipment platform, the heat shrink and components are aligned using a crosshair generator in a monitor. Upon initiation of the machine cycle, heated dies close over the assembly to reflow the components. After cycle completion, the assembly is removed from the machine and the heat shrink and mandrel are removed from the part. The Thermal Bonding System utilizes electricity and compressed air. All settings: Temperature, Die Head Pressure, Grip Pressure and Dwell Time are controlled using dials and switches located on the front panel of the equipment. This equipment utilizes timers and relay logic and uses no software [3].

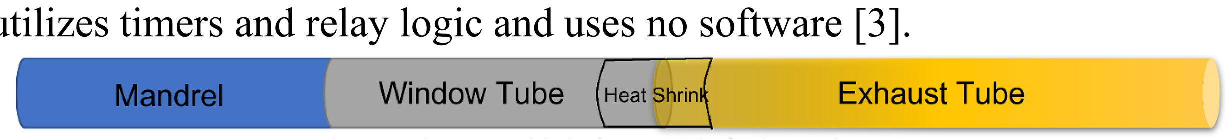

Figure 1: Exhaust Tube Assembly before Midshaft Thermal Bond Process

Problem

A Thermal Bonding Process Validation is required as one of the deliverables of a manufacturing line transfer. The strategy of the transfer is to duplicate the manufacturing line and operate at the same time during volume increment and then shut down the manufacturing line at USA. This means the components, equipment, manufacturing documents, and procedures are replicated and leverage from the USA site. When validating the the Midjoint Thermal Bond process for the Puerto Rico site, the process output did not meet the acceptance criteria using the process parameters defined in a previous validation at the USA site. This means process validation could not be leverage and Puerto Rico site must complete a process characterization to validate the Thermal Bonding process.

Methodology

Samples of Exhaust Tube Assy were prepared and tested in the Clean Room using the Thermal Bonding System under normal operating. Process parameters of the USA manufacturing site could not be leverage because the P.R. process output did not meet the acceptance criteria. Nevertheless, USA parameters were used as a reference for P.R site DOE. Table below contains the process setting that were considered to define the normal operating range for P.R process.

Table 1: Evaluated setting for normal operating range for P.R Site

Parameter/ Setting	Value
Dwell Time	45 sec - 65 sec
Temperature	420°F - 430°F
Grip Pressure	5 psi - 30 psi
Die Pressure	5 psi - 30 psi

A fourth-factor resolution full factorial DOE with one center point was chosen for a total of 25 runs. The fourth factors used Dwell Time, Temperature, Die Pressure and Grip Pressure parameters. A resolution full factorial was chosen to obtain the maximum resolution within the factors. Minitabmwas used to analyze results on the Midjoint Thermal Bond Process based on DOE input combinations. A full factorial Pareto Chart of the Effects for Midjoint Pull Test was generated in order to evaluate the effects of these potential key sources of variability. An alpha α= 0.05 was maintained for the analysis.

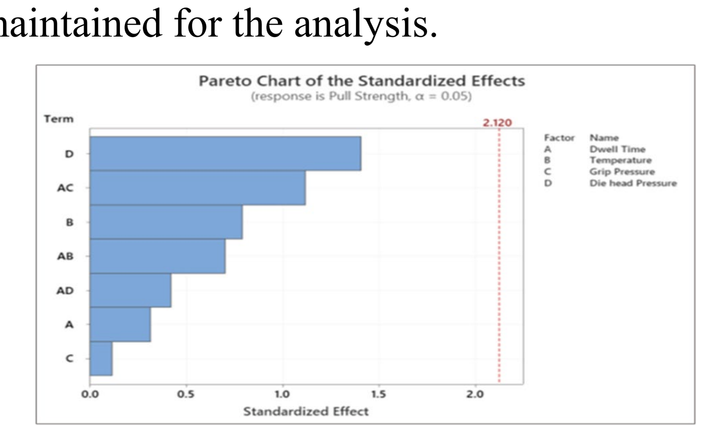

Figure 2: Pareto Chart of Standardized Effects

Pareto Chart indicates a trend of Factor D (Die Pressure) and Factor AC (Dwell Time & Grip Pressure) as potential statistically significant factors. Main Effect Plot analysis was performed to see the relationship between factors and pull strength. Was observed that change in Die Pressure have more impact in the Pull Test results than Dwell Time and Temperature factors.

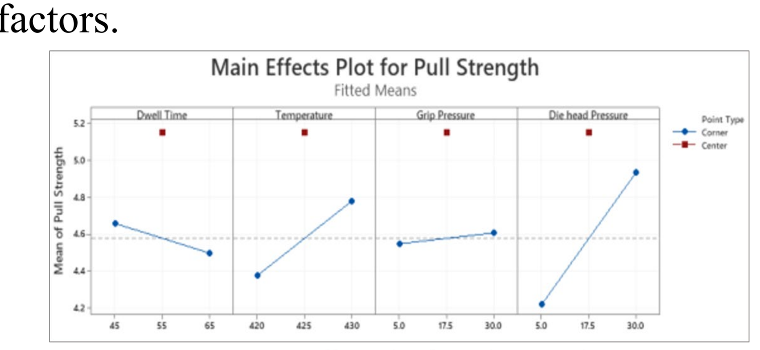

Figure 3: Main Effect Plot for Exhaust Tube Assy

Response Optimizer Chart was performed to identify the potential combination of factors settings that jointly optimize the Pull Strength.

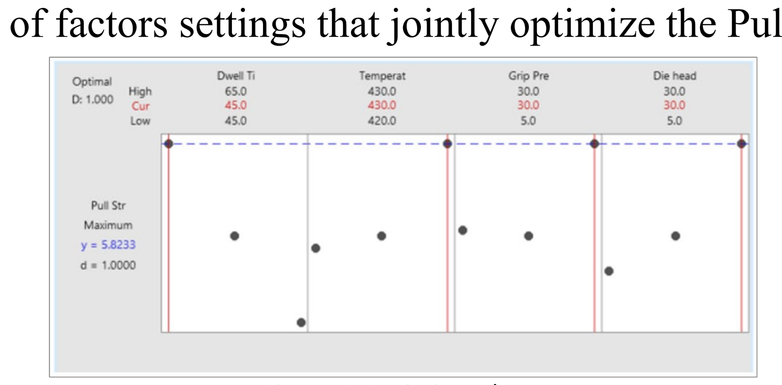

Figure 4: Optimizer Chart

Based on the Optimizer Chart Results, the Process Characterization settings for the Exhaust Tube Assembly as follow.

Table 2: Final Operating Parameters for Exhaust Tube Assembly

Parameter/ Setting	Low	Nom	High
Dwell Time (seconds)	50	53	55
Temperature (Fahrenheit)	420	425	430
Grip Pressure (psi)	15	22.5	30
Die Head Pressure (psi)	15	22.5	30

Once the process parameters were statistically defined, fifteen samples were manufactured for each process condition (NOR Low, Nominal and NOR High) for a total of forty-five samples. Units were built following the Midjoint Thermal Bond manufacturing instruction using time, temperature and pressure parameters.

Results and Discussion

15 Exhaust Tube Assy were built using NOR Low parameter settings. All samples were inspected following the visual acceptance criteria and pull strength specification. As result the data complies with normality test, p >0.05. Process Capability Sixpack analysis was performed resulting with a Ppk =3.45, greater than the acceptable Ppk ≥0.69 for a sample size of 15 for a variable data with 95/90 of confidence /reliability.

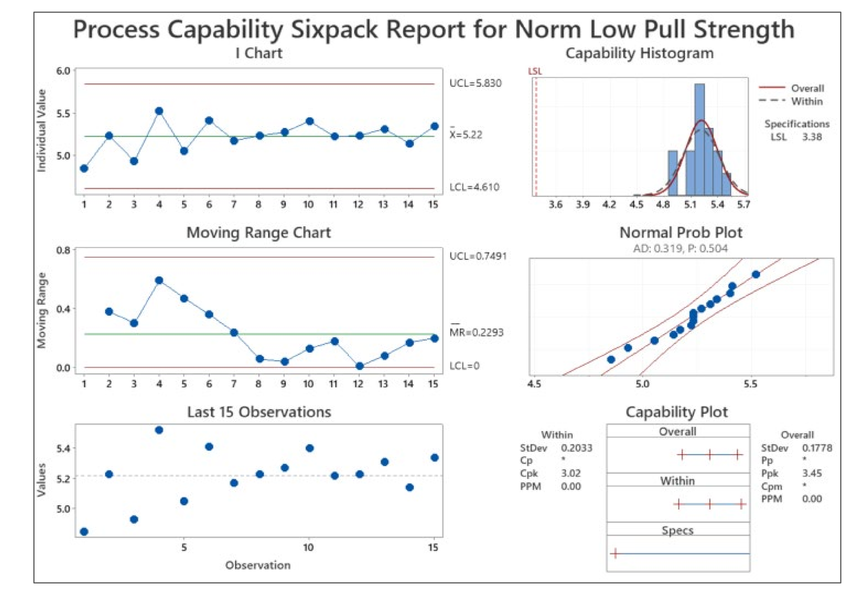

Figure 5: Process Capability Report for Norm Low Parameter Settings

15 Exhaust Tube Assy were built using Nominal parameter. All samples were inspected following the visual acceptance criteria and pull strength specification. As result the data complies with normality test, p>0.05. Process Capability Sixpack analysis was performed resulting with a Ppk =1.98, greater than the acceptable Ppk ≥0.69 for a sample size of 15 for a variable data with 95/90 of confidence /reliability.

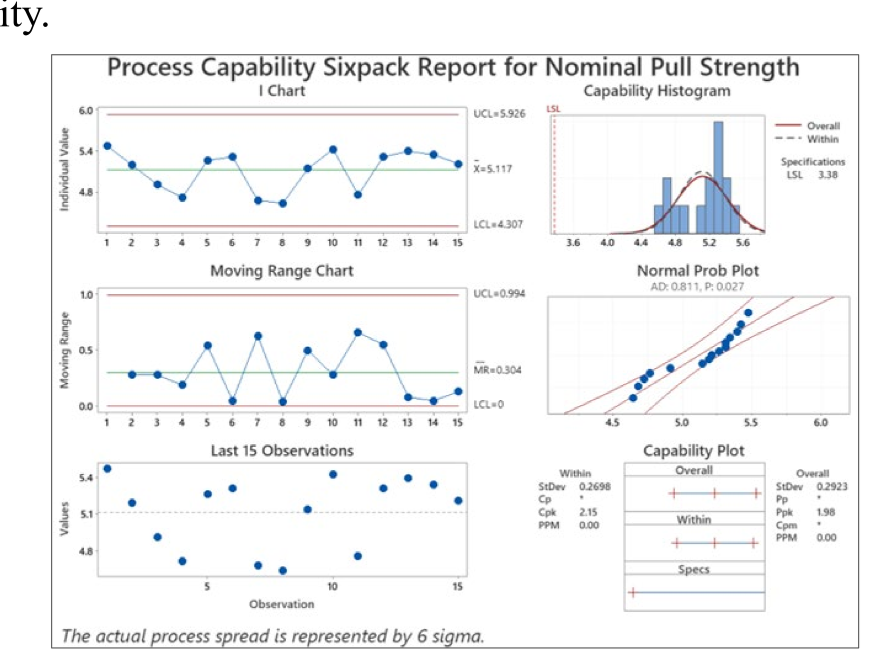

Figure 6: Process Capability Report for Nominal Parameter Settings

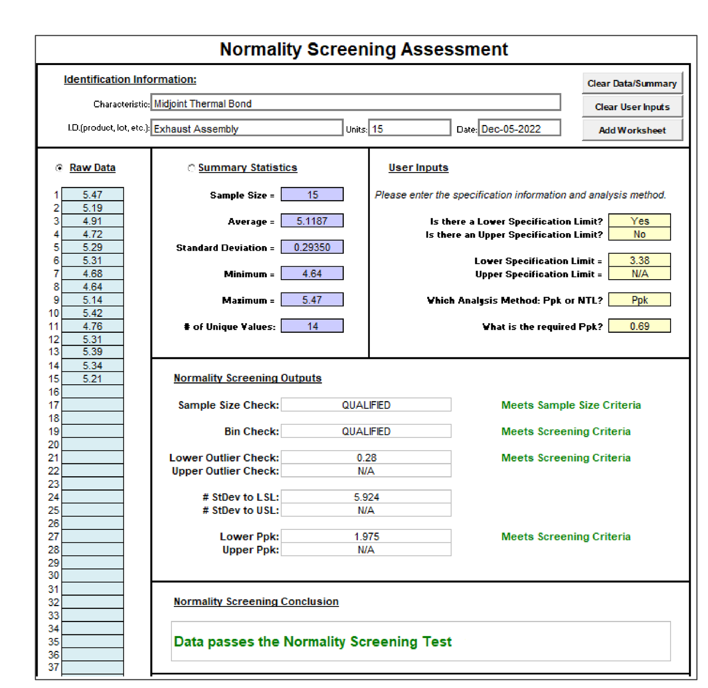

Figure 7: Normality screening Assessment Nominal Parameter Settings

15 Exhaust Tube Assy were built using Nor high parameter. All samples were inspected following the visual acceptance criteria and pull strength specification. As result the data complies with normality test, p>0.05. Process Capability Sixpack analysis was performed resulting with a Ppk =1.44, greater than the acceptable Ppk ≥0.69 for a sample size of 15 for a variable data with 95/90 of confidence /reliability.

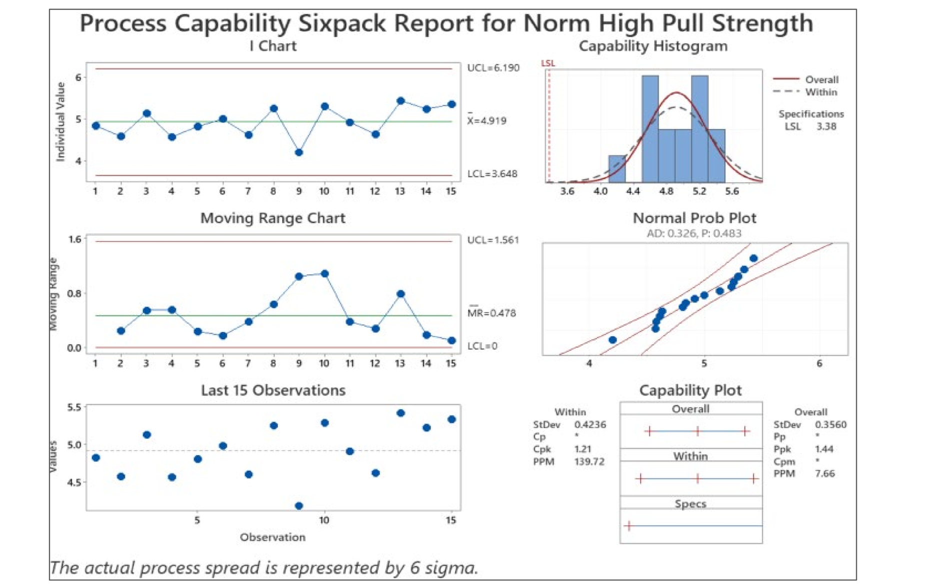

Figure 8: Process Capability Report for Norm High Parameter Settings

Conclusions

The scope of this report was to characterize Midjoint Thermal Bond Process to define process conditions and control limits for Key Process Inputs (KPI). All Process Characterization testing has been executed and NOR Low, Nominal and NOR High Operating Range for Midjoint Thermal Bond Process has been defined. Operating rage for each parameters are the following: Dwell Time 50 – 60 seconds, Temperature 420°F - 430°F, Grips pressure 15 psi - 30 psi and Die head pressure 15 psi - 30 psi. All samples complied with specifications as per the manufacturing instruction and met the minimum Pull Strength specification (3.38 lbs.) min specified in the product drawing. Process Capability Sixpack analysis for samples built with NOR Low, Nominal and NOR High Operating Range resulted with a Ppk greater than the acceptable Ppk ≥0.69 for a sample size of 15 for a variable data with 95/90 of confidence/ reliability.

Future Work

The are other Reflow processes that need to be validated to complete the transfer of manufacturing line. The knowledge learned during this process characterization in terms of the equipment technology, statistical analysis, and KPI will be leverage for the new validations.

Acknowledgements

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