Implementation and Validation of Automated Blasting Machine for the DRMAS Head in the DRMAS Automated Cell

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Abstract

The Wet Blaster blasting system is one of the multiple computerized systems that compose the DRMAS Automation Cell at the Medtronic Humacao site as part of the Project Transfer strategy. This equipment can execute one subprocess without human intervention. However, manual intervention is performed to perform part inspection and ensure it meets standard criteria in the final manufacturing of the product. The objective of this project should be the completion of an Installation Qualification to test that the equipment complies with the standard of manufacturing production and an Operational and Performance Qualification process Report that examines the capabilities of the current process in producing a safe, high-quality product under simulated conditions. To reduce human dependency, an opportunity to automate part of the blasting process was identified and integrated into the DRMAS Automated Cell. After this phase of the blasting process, an ABB robot takes the part from point A to point B and places it in an exit chute for final inspection.

Key Terms *- Automation, Installation Qualification, Process Development Report Chronic, Spinal.*

Problem Statement

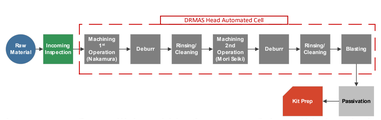
The medical device industry is a highly regulated sector of the economy, and regulatory environments, both at home and abroad, have significant implications for the industry's performance [1]. Accordingly, the U.S. medical device industry devotes considerable resources toward product approval processes, clinical trials, user fees, and plant audits/inspections. The U.S. Food and Drug Administration's Center for Devices for Radiological Health (USFDA/CDRH) governs the regulatory oversight of medical devices.

The USFDA maintains three risk categories that determine the type and depth of review necessary for marketing medical devices. Process validation is essential to medical device manufacturing but doesn't only sometimes receive the attention it deserves (and requires). The regulations provide the requirements (FDA QSR 820.75 and ISO 13485 7.5.2), but manufacturers often must understand or fully implement them. The consequences can be auditing findings from a Notified Body or Inspectional Observations on an FDA 483. Validation is in 820.75 and has three components: 820.75(a) relates to the initial validation of a process; 820.75(b) applies to process performance after validation; and 820.75(c) covers process changes or problems. Process validation establishes documented evidence that provides a high degree of assurance that a specific process consistently produces a product that meets predetermined specifications and quality characteristics.

Research Description

As part of the DRMAS Automated Cell, validation of different equipment needs to be performed before the process validation of the Wet-Blaster. Refer to Figure 1 below for 5.5/6.0 DUAL ROD MULTI-AXIAL SCREW HEAD manufacturing process flow, where all activities related to the implementation of all value stream processes covered by this validation plan are depicted. The Wet Blasting-Abrasive Blasting process for the DRMAS Head using the Wet-Blaster Automated Blasting Machine will be implemented in the current micro-blasting process within the manufacturing process flow to enhance:

Process Flow	Scope
Machining (Nakamura)	Out of Scope
Deburr	
Machining (Mori Seki)	
Deburr	
Aqueous	
Pre-Wet Blast Inspection	In Scope
Wet Blast	
Aqueous	
Post-Wet Blast Inspection	
2nd Wet Blast (upper rework extreme)	
Aqueous	
2nd Post-Wet Blast Inspection	



The complete process flow will be within the scope of the validation, including CNC machining with a semi-automated Dynamic Offset Calculator (DOC) and the wet blast process. Statistical Process Control (SPC) Inspections will be processed at 1 in every 10 parts. The process will use the component listed in the table below.

Drawing # - Description	Revision
55720006540-02 Solera Dual Rod Head, CoCrMo	A

Results and Discussion

Process Characterization of the Wet Blasting Process for the Dual Rod MAS Head P/N 55720006540-02 on the WET Technologies WTSS-36 platform was completed to develop the wet blasting process. This characterization identified high and low extreme process parameter inputs for the OQ portion of this plan. This characterization process also analyzed a rework process (2X wet blast). Mean shift data was analyzed for 1x and 2x blasts at the high extreme and 1x blasts at the low extreme. Recommended In-Process Specs were documented in this Process Characterization based on the mean shift data. The Process Characterization also analyzed each control feature's distribution and tolerance interval. The process was moved from PC-3764 into this OQ/PQ with some engineering team-assessed risk.

Process Characterization of the 3CO Dual Rod MAS Head P/N 55720006540-02 Machining on the Nakamura/Mori Seiki platform with WDOC offset calculations was completed to develop the automated WDOC offset calculations for the machining process that will be used during this Wet Blasting qualification.

All profile control features of this Dual Rod MAS Head will be converted from variable to attribute per the quality team's direction. The rationale for doing so is that the output for profiles is in the worst case, thus causing historically unknown distributions and low capability, although no results fail specification requirements. Along with converting profile requirements to attributes, we are increasing severity to the next level to provide increased qualification (PQ) acceptance requirements.

The OQ will confirm that the initiated machining In-Process (IP) specs are tight enough to cover the mean shift for 1x wet blast at the extremes and also confirm that the IP specs tolerance will be tight enough to cover any rework/reprocessing (2x roto) mean shift at the upper extreme inputs. Based on the PC results, the upper extreme parameters will create the most significant mean shift, and the low parameters will be the worst case for blast coverage.

The control features documented by severity in Appendix III - Plan and Completion Report Support Template will be required to meet the acceptance criteria. Additional analysis of the non-control features may be completed for engineering purposes in the report.

Once the lot(s) of the OQ have been all executed and data analyzed, the PQ orders may begin processing before the OQ completion report approval.

The OQ process inputs in the table below are with extremes slightly outside the upper and lower inputs that will be used in production to challenge the process. Therefore, the qualified wet blast process inputs range will be larger than the production inputs range. These qualified parts may be used for saleable parts after being fully processed.

The 59, 30, and 29 samples were inspected for CMM, Variable, and Attribute inspections, respectively, at QC. All required QC variable inspections for the two orders in the above table meet print and tolerance interval requirements. All required QC variable inspections for the two orders in the above table meet print requirements. The attribute analysis summary and variable analysis summary are attached in Appendix II. Supporting documents (Protocol training records, Inspection gauge logs, and process documentation sheets are attached in Appendix I. The raw data and the XMii

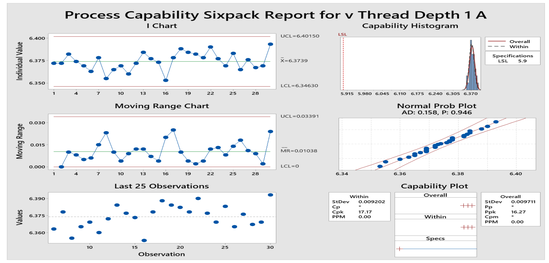
55720006540-02 OQ Orders							
LHR#	Batch#	OQ Condition	Blast Pressure (PSI)	Blast Time (sec.)	Blast Media Conc (%)	No. of Times blasted	Status
220137085	078851OW	High	36	41	40	1x (First blast)	Passed. Order on hold till approval of completion report.
			36	41	40	2x (Second blast)	
220137084	078850BW	Low	29	29	15	1x (First blast)	Passed. Order on hold till approval of completion report.

55720006540-02 PQ Orders			
Run#	LHR#	Batch#	Status
1	220137082	078850AW	Passed, Order will be held till the approval of the Completion Report.
2	220137083	078850BW	Passed, Order will be held till the approval of the Completion Report.
3	220137081	078850ZW	Passed, Order will be held till the approval of the Completion Report.

data are attached in Appendix XII by the performance manufacturing validation [2] results for OQ runs are in Appendices IV, V, and VI. All OQ orders are on hold until the completion report is approved. The 59, 30, and 29 random samples were inspected for CMM, variable, and attribute inspections at QC as established by Statistical Process Control [3]. All required QC variable inspections for the three orders in the above table meet print and tolerance interval requirements. All required QC variable inspections for the two orders in the above table meet print requirements. The attribute analysis summary and variable analysis summary are attached in Appendix III. Supporting documents (Protocol Training Records, Inspection gauge logs, and process documentation sheets are attached in Appendix I. The raw and XMii data are in Appendix XI and XII, respectively. Minitab analysis results for the individual PQ runs at QC are attached in Appendices VII, VIII and IX. The combined PQ data analysis of runs 1 to 3 met the variance and/or Ppk requirements on the required features at QC.

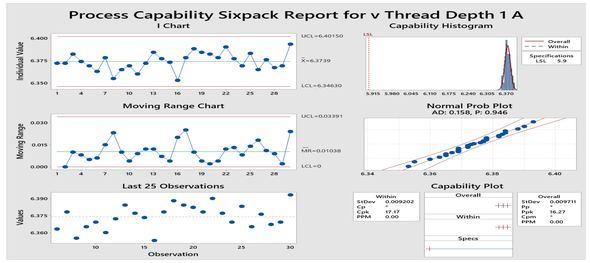
OQ Low

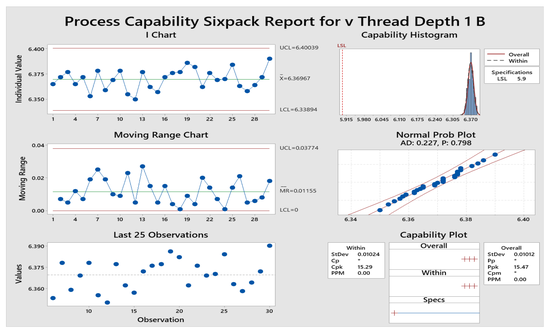
Data Analysis of the pre- and post-blast for the OQ tests the lower parameters of the process.

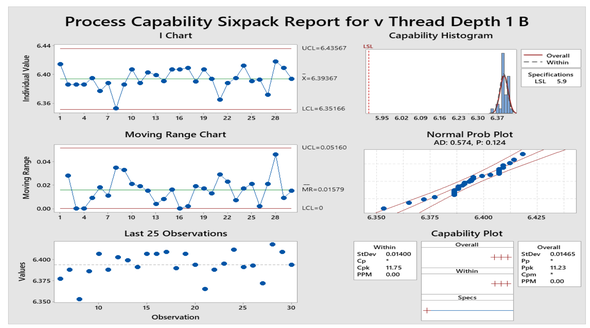


OQ High

Data Analysis for the pre-blast and post-bast Operational Qualification.

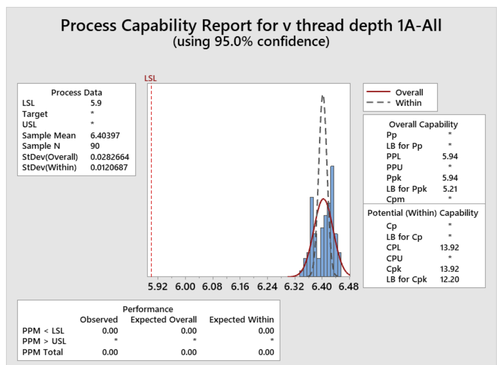


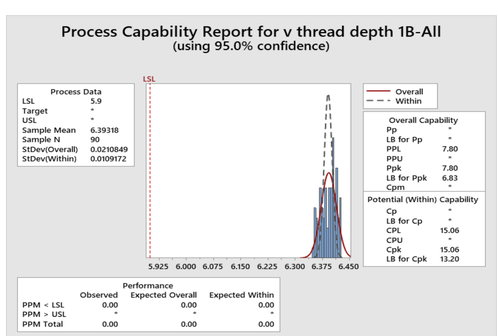




PQ Analysis

Data Analysis of the Performance Qualification to validate the established process.





Conclusions

This validation provides objective evidence that machining and wet blasting processes produce Solera Dual Rod MAS Heads that meet the predetermined requirements under challenging conditions. The mean shift between machining, 1x & 2x blast was compared to the existing IPs in place. The mean shift for all control features is within the specifications. The wet blasting process and semi-automated DOC process is validated because of this protocol. The passivation process after wet blasting does not impact the control feature dimensions. It is recommended that QC Inspections be removed after the wet blasting process. Product/process changes shall be reviewed to determine how much re-qualification for the process, equipment, or software is necessary.

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References

[1] S. I. Suk, "Pedicle screw instrumentation for adolescent idiopathic scoliosis: the insertion technique, the fusion levels, and direct vertebral rotation," in *Clin Orthop Surg* **3**, 2011, pp. 89–100.

[2] Medtronic, Perform Manufacturing Process Validation D00002956, Rev F, 2024.

[3] Medtronic, Statistical Process Control MPR_PPC_WI_009360, Rev K, 2023.