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

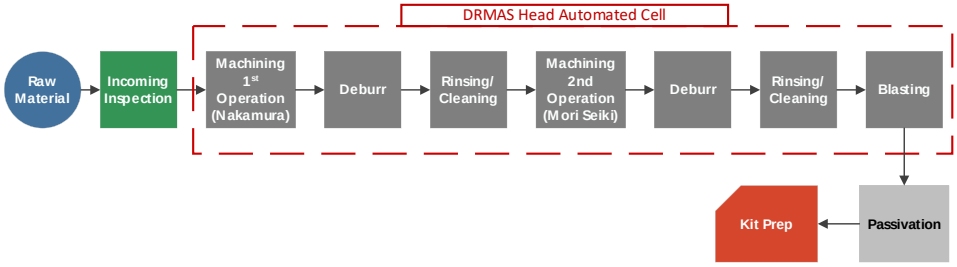

Figure 1
Diagram Flow of the DRMAS Head Manufacturer

the surface finishing of the Head using a semi-automated blasting machine.

The semi-automated micro-abrasive blasting process using the Wet Blaster Automated Blasting Machine will be implemented as an alternative to the manual micro-blasting process, following procedure 10080208DOC established in the Medtronic Humacao site.

RESEARCH OBJECTIVE

The purpose of this Operational/Performance Qualification is to provide objective evidence that machining and wet blasting processes produce Solera Dual Rod MAS Heads that meet predetermined requirements under challenge conditions for the process (operational qualification) and to establish by objective evidence that wet blasting, under normal operating conditions, consistently produces Solera Dual Rod MAS Heads that meet predetermined requirements (performance qualification).

The wet blasting process will be validated because of this protocol. Quality Control (QC) Inspections may be removed after the wet blasting process is successfully validated.

This protocol will validate the automated Dynamic Offset Calculator (DOC) process. For the Process Characterization Parts will be used from a portion of the qualified process for the Dual Rod MAS Heads and will only be processed through Nakamura, Deburr, Mori Seki, Deburr, and then Aqueous Cleaned (additional step to clean before inspection). These process steps are considered out of scope.

The following steps will be in the scope of the characterization study following aqueous: Pre-Wet Blast Inspection, Wet Blast, Aqueous Clean, and Post-Wet Blast Inspection. The rework upper extreme will go through this process flow a 2nd time. The Wet Blasting process is as follows: After the door is closed, the blast cycle will start with table rotation. At the end of the blast cycle, the "rinse" cycle will begin while the table is still rotating.

The process flow is shown below:

Table 1
Process that is in Scope and Out Scope

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	

LITERATURE REVIEW

This validation aims to determine that the process works consistently according to plan, for which the system is put to work according to their schedule, and all information and relevant data is recorded. The results must demonstrate that the process meets predetermined specifications. It

should be completed using validated equipment in the specified location and locally validated. Suppose the equipment, systems, or establishment are modified or changed. In that case, premises where the process takes place or must be revalidated, and the process changes after making and approving the qualifications of systems, equipment, and establishment, as appropriate.

Validation benefits are:

- Prevent deviations.
- Optimize the equipment use and the personnel in the critical process.
- Make the planning and production control.
- Increase the knowledge about the process and the product.
- Verify the capability of the process.

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.

Table 2
Part Numbers Associated with this Qualification

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

Figure 2
DRMAS Head

Figure 3
Wet Blaster Machine

Before Wet Blasting, the components will be machined using Dynamic Offset Calculation (DOC). The DOC will work semi-automated by extracting inspected data from IQS and the Dynamic Offset Calculation application and automatically entering this data into a Dynamic Calculation Worksheet. The Dynamic Offset Calculation Application will generate a printout of the offsets that the machinist will manually enter into the CNC controller. The semi-automated DOC will improve the ability to center the process. This was developed in the Process of Characterization**.**

The OQ process flow for this plan is documented below.

Table 3
OQ Cell Complete Qualification Process Flow

Validation Hold
Cell Complete - Machining (Nakamura NTY3) w/ DOC
Cell Complete – Deburr (Burr King 1000)
Cell Complete - Nakamura CMM Inspection (1st / SPC)
Cell Complete - Machining (Mori Seiki SL-154) w/ DOC
Cell Complete – Deburr (Burr King 1000)
Cell Complete - Mori Seiki CMM Inspection (1st pc Only)
Cell Complete - Bench Inspections
Aqueous Clean - Validation (Crest Ultrasonics 1100D)

Pre-Wet Blast Validation Inspection (Starrett HD-400; Global Advantage 555)
Validation Hold
Cell Complete - 1X Wet Blast (Wet Technologies Wet Blaster Custom serial WT18-044-500)
Aqueous Clean - Validation (Crest Ultrasonics 1100D)
QC Validation Inspection (Starrett HD-400; Global Advantage 555)
Validation Hold
2X Wet Blast - Upper Extreme Only (Wet Technologies Wet Blaster Custom serial WT18-044-500)
Aqueous Clean - Validation (Crest Ultrasonics 1100D)
QC Validation Inspection (Starrett HD-400; Global Advantage 555)
Validation Hold

The PQ process flow for this plan is documented below.

Table 4
PQ Cell Complete Qualification Process Flow

Validation Hold
Cell Complete - Machining (Nakamura NTY3) w/ DOC
Cell Complete – Deburr (Burr King 1000)
Cell Complete - Nakamura CMM Inspection (1st/SPC)
Cell Complete - Machining (Mori Seiki SL-154) w/ DOC
Cell Complete - Deburr (Burr King 1000)
Cell Complete - Mori Seiki CMM Inspection (1st pc Only)
Cell Complete - Bench Inspections (1st/SPC)
Cell Complete - Wet Blast (Wet Technologies Wet Blaster Custom serial WT18-044-500)
Aqueous Clean - Validation (Crest Ultrasonics 1100D)
QC 8530 Validation Inspection (Starrett HD-400; Global Advantage 555)
Validation Hold

METHODOLOGY

The company's process development and procedures were followed to implement the new wet-blasting automated machine process. Computer System Validation (CSV) Life Cycle methodology is the best that can be used to describe the process that will be followed to implement the new blasting system. CSV Life Cycle includes the following phases:

- Definition – to define the process needs and develop system requirements and specifications.
- Development – Equipment development as per system requirements and specifications.

A risk analysis is developed as part of the development and definition phases. Process risk analysis is an activity that progresses throughout process development and validation. The process risk analysis will identify failure modes and causes that must be evaluated during process characterization. This will link process inputs to process outputs to help establish the basis for validation work.

- Testing - The testing phase includes the following:
  - Master Validation Plan – The Master Validation Plan establishes the validation strategy for a process and provides a reference for all the validations performed.
  - Equipment Testing – Intended to demonstrate that the equipment is appropriately identified, installed, and documented and meets its intended use for the manufacturing areas.
- Process Characterization (PC) – Intended to determine proven acceptable range and nominal settings for use in production. During process characterization, methods such as range-finding experiments, screening experiments, etc., identify variables that significantly impact the process outputs within their controlled range of variation.

- Hypercare – The period of heightened support and attention immediately after the implementation of the manufacturing process.

The operation requirements are as follows: Finish Goods and Design Documents must be at pre-production status, the Master Validation Plan must be approved, or the Manufacturing Documentation must be developed and approved. Manufacturing traceability is defined and implemented, such as operators being trained and certified for the procedures used.

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

Table 5

OQ 55720006540-02 Run Orders

55720006540-02 OQ Orders							
LHR#	**Batch#**	**OQ Condition**	**Blast Pressure (PSI)**	**Blast Time (sec.)**	**Blast Media Conc (%)**	**No. of Times blasted**	**Status**
220137085	0788510W	High	**36**	**41**	**40**	1x (First blast)	Passed. Order on hold till approval of completion report.
			36	**41**	**40**	2x (Second blast)	
220137084	0788508W	Low	**29**	**29**	**15**	1x (First blast)	Passed. Order on hold till approval of completion report.

Table 6

PQ 55720006540-02 Orders Run

55720006540-02 PQ Orders			
Run#	LHR#	Batch#	Status
1	220137082	0788504W	Passed, Order will be held till the approval of the Completion Report.
2	220137083	0788506W	Passed, Order will be held till the approval of the Completion Report.
3	220137081	0788502W	Passed, Order will be held till the approval of the Completion Report.

data are attached in Appendix XII in accordance with 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, respectively, 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 attached 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-blast and post-blast for the Operational Qualification testing the lower parameters of the process.

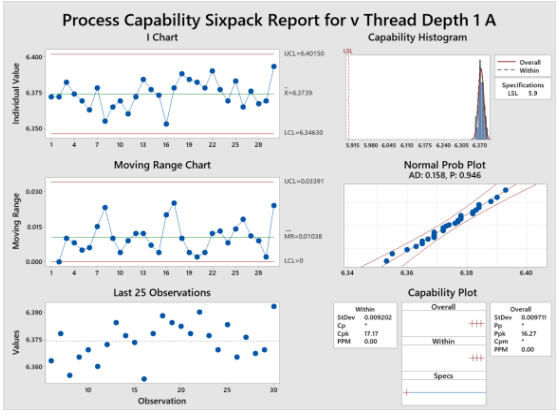

Figure 4

Process Capability Sixpack Report for V Thread Depth A-All

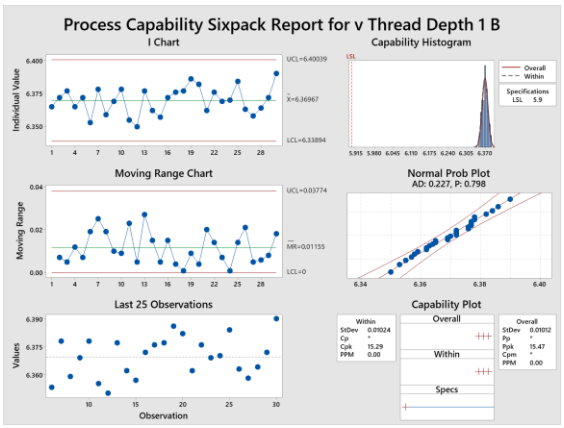

Figure 5
Process Capability Sixpack Report for V Thread Depth B-All

OQ High

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

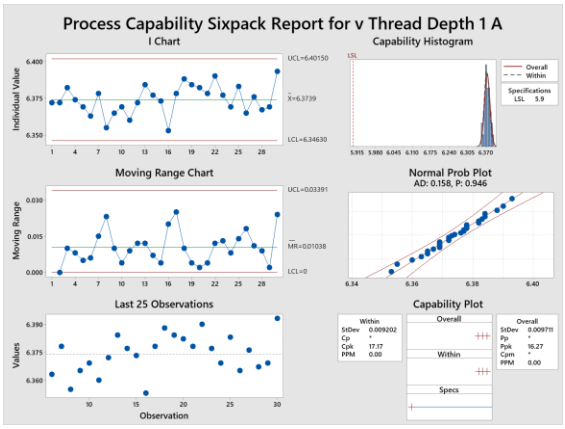

Figure 6
Process Capability Sixpack Report for V Thread Depth A-All

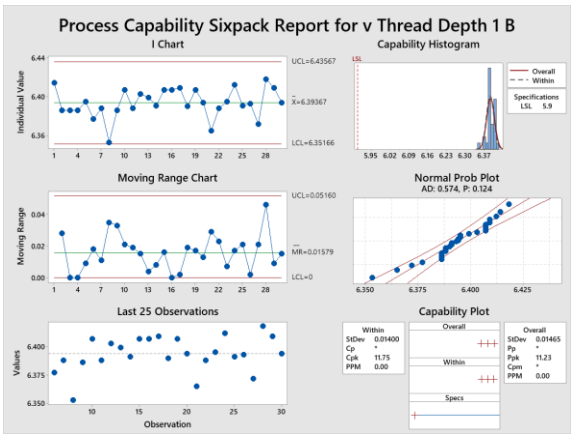

Figure 7
Process Capability Sixpack Report for V Thread Depth Ball

PQ Analysis

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

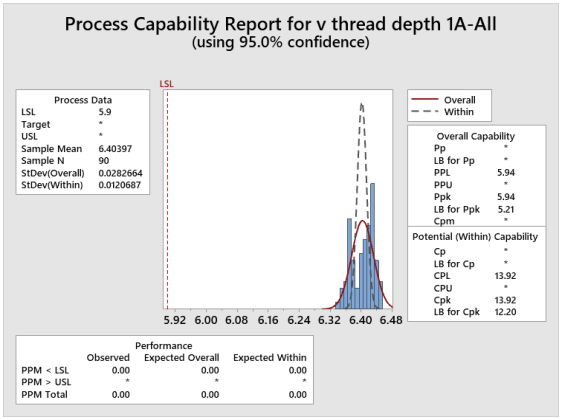

Figure 8
Process Capability report for V Thread Depth 1A-All

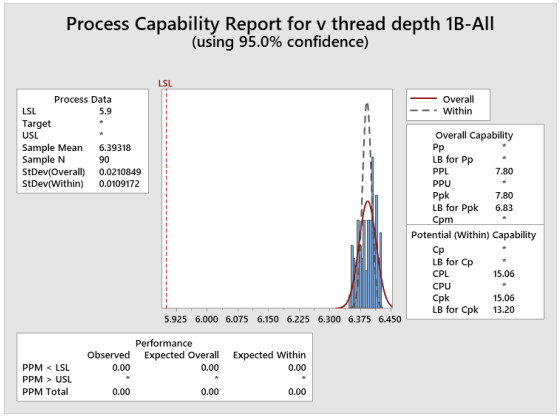

Figure 9
Process Capability Report for V Thread Depth 1B-All

CONCLUSION

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 for the process. The mean shift between machining, 1x blast, and 2x blast was compared to the existing In-Process specifications (IPs) in place. The mean shift for all control features is within the existing In-Process specifications. This performance qualification provides objective evidence that machining and wet blasting processes, under normal operating conditions, consistently produce Solera Dual Rod MAS Heads

that meet predetermined requirements. The wet blasting process is validated because of this protocol. This protocol validates the semi-automated DOC process. The passivation process after wet blasting does not impact the control feature dimensions. Thus, it is recommended that QC Inspections be removed after the wet blasting process. Also, product or process changes shall be reviewed to determine how much re-qualification for the process, equipment, or software is necessary. This type of change will determine re-validation activities.

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.