Equipment qualification protocol: IQ/OQ-E for Comco Microblasters		
Salt Lake City	Installation and Operational Qualification – Equipment for Comco Microblasters	
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1 Protocol Approval

1.1 The shaded boxes on the check sheets included in the protocol are for the information that is being pre-approved at the protocol stage. The unshaded boxes are for data to be entered during execution. The information entered these boxes is reviewed and post-approved at the completion/closure stage.

Electronic approval reference #	CN2038033

2 Executed protocol approval

2.1 Conclusion:

☑	Equipment qualification has passed. All acceptance criteria have been met and/or all exceptions have been closed. The validation/qualification study may proceed to the next stage of validation.
☐	Equipment qualification has failed. Not all acceptance criteria have been met and/or not all exceptions have been closed. The equipment cannot be released for use and the validation/qualification study cannot continue onto the next stage until all exceptions have been closed.

Electronic approval reference #	CN2038555 07Jan2019

Executed protocol approval conducted/approved by:				
Role See CQP-PDC-002 for notes on allocation of roles	**Scope of approval** In addition to the points below, all approvers have a general responsibility for the content of the document	**Executed protocol approval:**		
		Name (print)	**Signature**	**Date**
Prepared by	• Takes ownership of content	Name captured electronically. Refer PLM for details	Signature captured electronically. Refer PLM for details	Date captured electronically. Refer PLM for details

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Quality assurance representative	• Compliance with regulation • Good documentation practice • Appropriate level of challenge	Name captured electronically. Refer PLM for details	Signature captured electronically. Refer PLM for details	Date captured electronically. Refer PLM for details
Equipment Engineering	• Appropriate application of their speciality • Accurate interpretation of information.	Name captured electronically. Refer PLM for details	Signature captured electronically. Refer PLM for details	Date captured electronically. Refer PLM for details

3 Purpose and scope

3.1 The purpose of this protocol is to specify the tests required for equipment qualification of:

Equipment name/description	Make and model	Revision*	Identification No. *
Comco MicroBlaster MB-1000 NV00034618	Comco Model MB1000-1 ProCenter Plus CTR200-1	NV00034618 Rev. AA	NV00034618-001

* May be filled out during execution

3.2 Execution of this protocol establishes documented evidence that the equipment and ancillary system have been tested and verified to fulfill the specified requirements and is qualified for the intended use.

3.3 When all tests and verifications in this protocol have been completed, and the results and data collected are attached, it forms the record of the equipment qualification of the specified system.

4 Equipment description and background information

4.1 Background info

4.1.1 The Comco MicroBlaster MB-1000 is supplied by Comco Incorporated.

4.1.2 Two additional elements are required for the MicroBlaster to meet proper environmental requirements:

A **ProCenter Plus with HEPA filter technology** - The ProCenter Plus integrates both a workstation and the dust collector with advanced HEPA technology to reduce air particles, maintenance tasks, static and noise (operates at 68 dBA).

B **Desiccant Air Dryers (AD5100-3 with water filter)** - These dryers are mounted near the blaster, on the side of the ProCenter Plus. It is filled silica gel desiccant beads that absorb moisture to dew points as low as -25°F at flow rates up to 7.5 SCFM. **Note**: This Desiccant Air Dryer is unnecessary when working with Unasil Silicon Carbide 600 because it is an

abrasive that does not retain a lot of moisture, however it is an added air filtering mechanism that does not impact product quality.

4.2 Critical Outputs/Functionality

4.2.1 The Comco MicroBlaster MB-1000 removes slag, dross, oxide, and/or grit from the inner and outer surface of raw stents on the stent, sub-assembly production line. Stent visual inspection is a downstream process which is used to verify the quality of stents and its adherence to the product specifications before packaging.

4.3 Major components of equipment/fixture:

4.3.1 The Comco MicroBlaster, model #MB1000-1's main components are:

A An inlet air valve on the back of the MicroBlaster connects to the Desiccant Air Dryer (AD 5100 Series-3).

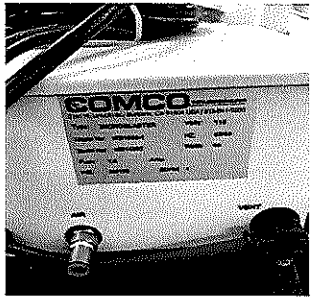

Figure 1: Reference picture of Air Valve on MicroBlaster

B An air pressure regulator to balance valve and air pressure in the system.

C An Ashcroft pressure gage. The pressure gage on the front of the unit indicates the air pressure in the abrasive tank.

D A power flow modulator for consistent powder delivery flow. The powder flow control knob controls the amount of clean, abrasive-free air that mixes with the abrasive in the mixing chamber. Turning the knob clockwise increases the concentration of media in the air stream.

E A mixing chamber. This is also called the "Quick-Fill" or "Flapper Valve" located on the top of the tank cover with a screw-on lid.

F The Footswitch is usually place on the floor to activate the abrasive hose pinch and the modulator, allowing abrasive to flow from the tank to the blasting nozzle.

G The pinch assembly is located on the rear panel of the MicroBlaster. The pinch squeezes the blue poly hose to stop the flow of air and abrasive.

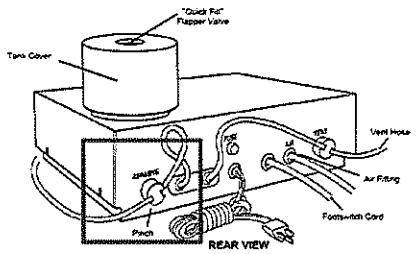

Figure 2: Reference picture of the pinch assembly on Micro Blaster

H A green handpiece nozzle (.030 Green MB1520-30). and a gold nozzle (MB1520-46 Hi/Performance Nozzle .046 Yellow) to perform the blasting process.

4.3.2 Picture of equipment:

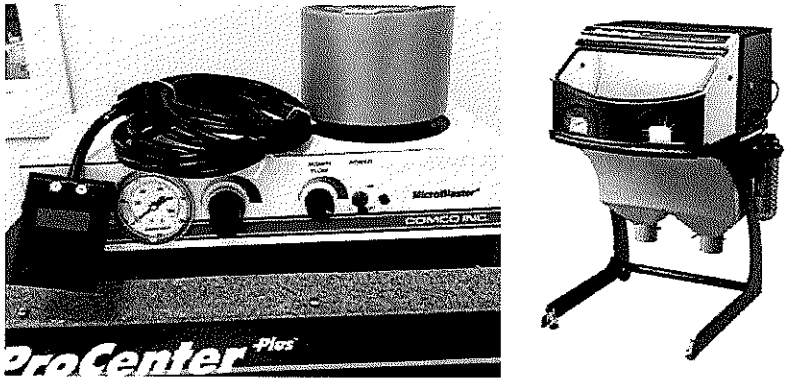

Figure 3: MicroBlaster MB-1000-1 and ProCenter Plus CTR200-1

4.3.3 System risk

All risks identified by using the Comco Microblaster equipment for the microblasting of the stents produced on the stent assembly line have been deemed to have an acceptable level of risk of manufacturing as per the 90685496 (pFMEA, Neuroform/Neuroform Treo Stent) and 90685497 (pFMEA, Wingspan Stent).

5 References and other validations/qualifications

Deliverable	PDM #	Revision
Equipment qualification template	CQI-PDC-002-02 - C	AA
SLC Tool Specification	NV00034618	AA
Equipment Technical Manual (ETM)	NV00035283	AA

Deliverable	PDM #	Revision
Microblasting Stents (WI)	90681356	AS
pFMEA, Neuroform/Neuroform Treo Stent	90685496	AE
pFMEA, Wingspan Stent	90685497	AE
Neuroform and Wingspan Stent Subassembly Master Validation Plan	90682515	AD

5.1 EQ planning Tool

The equipment Comco Microblaster was categorized as "simple equipment" as the equipment is a manual off the shelf equipment as per the CQI-PDC-002-02. The equipment is completely manual as pressure is activated using the foot swtich and the nozzle through which the abrasive delivery occurs is handheld. As per the process flow specified in the specification CQI-PDC-002-02, an equipment categorized as simple equipment does not require an execution of equipment planning tool.

6 Abbreviation and definitions

6.1 Abbrev/term – definition/explanation

Term/Abbreviation	Definition
EHA	Equipment Hazard Analysis
FS	Functional Specification
IU	Intended Use
PM	Preventative Maintenance
ETM	Engineering Technical Manual
IQ	Installation Qualification
OQ-E	Operational Qualification - Equipment

7 Execution instructions

7.1 Each checksheet contains the instructions for execution and acceptance criteria for the category specific tests and verifications.

7.2 All test equipment shall be calibrated and qualified, as applicable, prior to use in the execution of this protocol.

7.3 All test methods used to generate data to demonstrate conformance to acceptance criteria shall be validated or conform to accepted international standards, as applicable, prior to use in execution of this protocol.

7.4 Include data collected during the execution of the protocol in the attachments section of the executed protocol and reference the attachment in the results of the related checksheet. The data shall also include initials of the executor and the date

7.5 If product is produced or utilized, the following containment controls **shall** apply: N/A – No actual stent parts to be utilized for the qualification.

8 Protocol revision history

Revision	Change/reason for change	Date
AA	Initial Release - Installation Qualification Operational Qualification-Equipment: IQ/OQ-E Comco Microblaster	Refer PLM for Date details.

9 Checksheet applicability

Checksheet number	Checksheet title	Applicable? Yes/No	Not applicable rationale
1	Environmental requirements	Yes	N/A – Refer to checksheet below.
2	General installation	Yes	N/A – Refer to checksheet below.
3	Health and safety	No	Checksheet was deleted from this protocol as a review will be conducted by site EHS representative in accordance with 90755415 – EHS Equipment Evaluation Checklist. This checklist will be executed and included as an attachment to the executed protocol for every new piece of equipment.

Checksheet number	Checksheet title	Applicable? Yes/No	Not applicable rationale
4	Maintenance	Yes	N/A – Refer to checksheet below.
5	Ergonomics	No	Checksheet was deleted from this protocol as a review will be conducted by site EHS representative in accordance with 90755415 – EHS Equipment Evaluation Checklist. This checklist will be executed and included as an attachment to the executed protocol for every new piece of equipment.
6	Environmental Impact	No	Checksheet was deleted from this protocol as a review will be conducted by site EHS representative in accordance with 90755415 – EHS Equipment Evaluation Checklist. This checklist will be executed and included as an attachment to the executed protocol for every new piece of equipment.
7	Equipment use procedure and training	Yes	N/A – Refer to checksheet below.
8	Functional testing	Yes	N/A – Refer to checksheet below.

Comment: None

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Checksheet 1: Environmental requirements checksheet

Objective:	• To verify that all environmental requirements for the equipment/system being installed conform to specified requirements.
Procedure:	• Perform a visual and/or physical inspection of the environmental conditions. • Verify that the actual parameters for each condition correspond to the specified requirement. • Attach documented evidence, where appropriate.
Prerequisites:	• Test preparation is successfully completed, and all discrepancies are dispositioned.
Schematics:	• ETM, Comco MicroBlaster MB-1000-1 (NV0035283)

Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
1	Verify the MicroBlaster to meet proper environmental requirements, the Comco ProCenter Plus CTR200-1 combines a workstation with dust collector with advanced HEPA technology to filter particles from the atmosphere.	The MicroBlaster to meet proper environmental requirements, the Comco ProCenter Plus CTR200-1 combines a workstation with dust collector with advanced HEPA technology to filter particles from the atmosphere.	The MicroBlaster to meet proper environmental requirements, the Comco ProCenter Plus CTR200-1 combines a workstation with dust collector with advanced HEPA technology to filter particles from the atmosphere. ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 11 DEC 2018
2	**Air pressure:** Verify proper air pressure using pressure gauge. Pressure Gauge: Ashcroft	The pressure should be between: 40 and 140psi. Supply Pressure: 80-140 psi Working Pressure: 40-125 psi	Standard House Air Connected ☑ Yes ☐ No Record psi Information: Supply Pressure: 104 psi Working Pressure: 40 psi	☑ Pass ☐ Fail	A.M. 11 DEC 2018

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Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
3	**Ambient temperature:** Verify that ambient temperature is within the appropriate operating range of the equipment.	Ambient temperature range is: 68°F-85°F	Ambient temperature range is: 68°F-85°F ☑ Yes ☐ No Record Temperature: 68.5 °F	☑ Pass ☐ Fail	A.M. 17 DEC 2018
4	**Ambient humidity:** Verify that ambient humidity is controlled so that it is within the appropriate operating range of the equipment.	Equipment relative humidity (RH) range is less than 40% RH.	Equipment relative humidity (RH) range is less than 40% RH. ☑ Yes ☐ No Record Relative Humidity: 33 %	☑ Pass ☐ Fail	A.M 17 DEC 2018
5	**Lighting:** Adequate lighting both inside and outside the primary ProCenter Plus.	Light inside and outside the ProCenter Plus is functional.	Light inside and outside the ProCenter Plus is functional. ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M 11 DEC 2018

Comment: Supply Pressure tested using T0146B-010
working Pressure tested using NV00034618-001
Temperature and humidity monitored using Facilities Elpro monitoring as per NV00020888

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Checksheet 2: General installation checksheet

Objective:	• To verify that Installation Verification Protocol section is complete; any associated discrepancies have been dispositioned. • To verify that all installation was performed properly.
Procedure:	• Verify that the Actual Results meet expected results • Perform a visual and/or physical inspection of the items listed below • Record the document number, storage reference, revision/version, and location of all documents listed below • The location of documentation must be controlled by Stryker in PLM; internet sites are not appropriate as content may be changed or deleted.
Prerequisites:	• Test preparation is successfully completed, and all discrepancies are dispositioned.
Schematics/documentation:	• ETM, Comco MicroBlaster MB-1000-1 (NV0035283)

Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
1	**Identification:** Visually verify that the equipment is properly identified with asset number Record Asset Number	Identification seen on equipment	Identification seen on equipment ☑ Yes ☐ No Asset ID: NV0003 4618-001	☑ Pass ☐ Fail	A.M. 11 DEC 2018
2	**Equipment Location:** Check that equipment is properly located, supported, leveled, and securely anchored in accordance with the manufacturer's recommendations.	Equipment is properly located, supported, leveled, and secured in accordance with the manufacturer's recommendations.	Equipment is properly located, supported, leveled, and secured in accordance with the manufacturer's recommendations. ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 11 DEC 2018

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Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
3	**Location/configuration:** Verify that the equipment location and configuration is recorded in the Actual Results. Verify space/footprint requirements. NOTE: Configuration details about the equipment are available in the specification NV00035283 (ETM, Comco Microblaster)	**Location/configuration:** Drawings are checked and available in PLM. Equipment location and ETM version details are recorded in Actual Results. Sufficient access and space for physical requirements is available: • MicroBlaster: 17" x 10" x 9" • ProCenter Plus CTR200: 46"x30" wide x 34"	Drawings are checked and available in PLM ☑ Yes ☐ No Asset Location: SLC NON CEA STENTS ETM, Version: NV00035283, Rev AA Sufficient access and space for physical requirements is available: • MicroBlaster: 17" x 10" x 9" • ProCenter Plus CTR200: 46"x30" wide x 34" ☑ Yes ☐ No	☑ Pass ☐ Fail	A-M. 11 DEC 2018

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Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
4	**Power Supply:** Electrical power for MicroBlaster and ProCenter Plus. Record the utility values.	Micro Blaster1000-1 is supplied with 115V ± 10 VAC, 50/60 Hz. The ProCenter Plus CTR200-1 is supplied with 100-130 VAC/ 50-60Hz	Micro Blaster1000-1 is supplied with 115V ± 10 VAC, 50/60 Hz ☑ Yes ☐ No ProCenter Plus: 117.8 VAC 59.99 Hz The ProCenter Plus CTR200-1 is supplied with 100-130 VAC/ 50-60Hz ☑ Yes ☐ No MicroBlaster: 117.8 VAC 59.98 Hz	☑ Pass ☐ Fail	A.M. 11 DEC 2018

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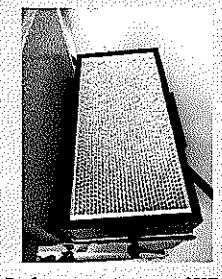
Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
5	**Tank Orifice:** Ensure correct Tank Orifice (Comco MB 1409-25) is installed and firmly tightened inside powder tank. Figure 4: Reference picture of a tank orifice MB 1409-25	• Correct orifice (Comco MB 1409-25) is installed & firmly tightened inside the powder tank. • Abrasive Particle Size used is Unasil 600 (20-50 microns). • Orifice# 1409 25 is verified using a .025" pin gauge.	• Correct orifice (Comco MB 1409-25) is installed & firmly tightened inside the powder tank. ☑ Yes ☐ No • Abrasive Particle Size used is Unasil 600 (20-50 microns). ☑ Yes ☐ No • Orifice# 1409 25 is verified using a .025" pin gauge. ☑ Yes ☐ No	☑ Pass ☐ Fail	19 DEC 2018 A.M.
6	**HEPA Air Filter:** Verify equipment to minimize dust from abrasives is properly connected and working properly. • Turn off the ProCenter Plus and unplug the power cords. • Lift the back cover off the ProCenter Plus. • Verify the back chamber of the ProCenter Plus has a HEPA filter placed inside the compartment. **Note:** The whole box with filter lifts out and can be replaced.	Back chamber of the ProCenter Plus has a HEPA filter placed inside the compartment.  Figure 5: Reference picture of HEPA filter	Back chamber of the ProCenter Plus has a HEPA filter placed inside the compartment. ☑ Yes ☐ No	☑ Pass ☐ Fail	11 DEC 2018 A.M.

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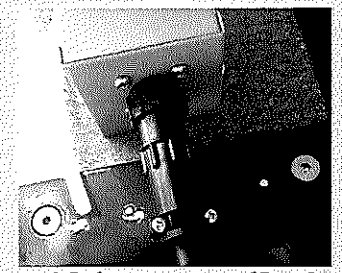
Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
7	Ensure footswitch is connected to relay box, as shown.  Figure 6: Reference picture of Foot Switch attached the Relay Box Ensure the relay box has a cord connect to the back of the microblasters Figure 7: Reference picture of Relay Box plugged in the plug in the back of the MicroBlaster	• Footswitch is connected to the bottom plug beneath the relay box. • Relay box has a cord connected to the back of the MicroBlaster.	• Footswitch is connected to the bottom plug beneath the relay box. ☑ Yes ☐ No • Relay box has a cord connected to the back of the MicroBlaster. ☑ Yes ☐ No	☑ Pass ☐ Fail	A-M. 11 DEC 2018

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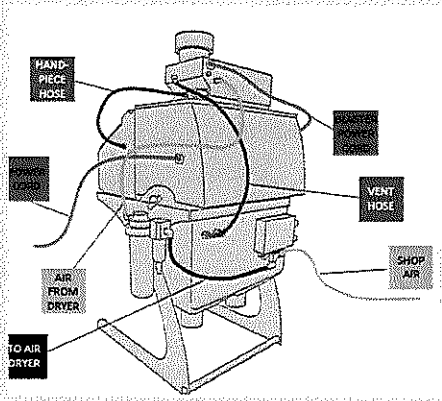
Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
8	**Hoses:** Ensure all the air hoses and power cords are connected as per below figure  Figure 8: Reference picture of Air hoses and power cords on the equipment.	The following hoses and power cords are properly connected. • Hand Piece Hose • Vent Hose • Clear Air Hose (Dryer to MicroBlaster) • Air Hose (Dryer to Inlet Air) • Shop Air Hose • MicroBlaster power cord to ProCenter. • ProCenter power cord to ceiling outlet. • Relay outlet plugged into the back of the Microblaster. • Footswitch plugged in to the relay switch.	The following hoses are properly connected. • Hand Piece Hose ☑ Yes ☐ No • Vent Hose ☑ Yes ☐ No • Clear Air Hose (Dryer to MicroBlaster) ☑ Yes ☐ No • Air Hose (Dryer to Inlet Air) ☑ Yes ☐ No • Shop Air Hose ☑ Yes ☐ No • MicroBlaster power cord to ProCenter. ☑ Yes ☐ No • ProCenter power cord to ceiling outlet. ☑ Yes ☐ No • Relay outlet plugged into the back of the Microblaster. ☑ Yes ☐ No • Footswitch plugged in to the relay switch. ☑ Yes ☐ No	☑ Pass ☐ Fail	A-M. 11 DEC 2018

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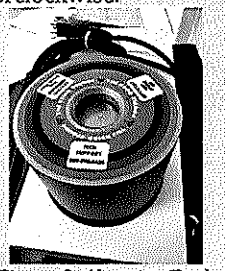
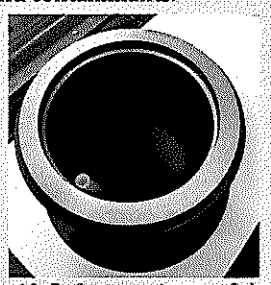
Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
9	**Abrasive Tank:** To initially setup the MicroBlaster: • Remove the tank cover by twisting it counterclockwise.  Figure 9: Abrasive Tank • Clean the tank by wiping the flapper and O-ring with a soft dry cloth. • Replace the tank cover and tighten firmly by hand.	• Inside of the tank is free of debris and contaminants.  Figure 10: Reference picture of abrasive tank open state. • The cover to the tank has an airtight seal **WARNING:** Never overfill the tank with abrasive media. It should always be about half-way full or the media will clump.	• The inside of the tank is clear of debris. ☑ Yes ☐ No • The cover to the tank has an airtight seal. ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 11 DEC 2018
10	Turn OFF the MicroBlaster. Then, turn the ProCenter OFF yo verify the gage pressure drops down to zero.	The air pressure gage drops to zero.	The air pressure gage drops to zero. ☑ Yes ☐ No Air pressure at shutdown: 0 psi	☑ Pass ☐ Fail	A.M. 11 DEC 2018

Comment: N/A J.a. 07Jan2019

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Checksheet 4: Maintenance checksheet

Objective:	• To verify and document that the maintenance requirements and preventative maintenance (PM) status have been identified for the equipment/system being qualified, including spare parts
Procedure:	• Execution should be supervised by maintenance representative whenever possible • Complete the list below for all maintenance requirements associated with the equipment/system being qualified • Attach documented evidence where appropriate
Prerequisites:	• None
Schematics/documentation	• Tool Spec for Comco Microblaster MB-1000-1 NV00034618 • ETM, Comco MicroBlaster MB-1000-1 NV00035283

Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
1	Verify that the Comco MicroBlaster and all associated ancillary equipment are entered into the maintenance system in accordance with documents: • Tool Spec for Comco Microblaster MB-1000-1 NV00034618 by verifying the following - PM Frequencies and associated activities are for the equipment is assigned in the EAM system. - Unplanned PM activity is assigned in the EAM system.	Verify equipment is entered into the PM system in accordance with documents: • Tool Spec for Comco Microblaster MB-1000-1 NV00034618	Verify equipment is entered into the PM system in accordance with documents: • Tool Spec for Comco Microblaster MB-1000-1 NV00034618 ☑ Yes ☐ No	☑ Pass ☐ Fail	A-M. 11 DEC 2018

Comment: The required PM activities as per NV00034618 have been assigned to the asset NV00034618-001 in EAM.

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Checksheet 7: Equipment use procedure and training checksheet

Objective:	• To ensure that the equipment use is properly documented for use (e.g., production standard operating procedure) and that the training system is updated to reflect the equipment use.
Procedure:	• Execution should be supervised/executed by a manufacturing engineering representative whenever possible • Representatives from operations should also participate • Review the equipment/operations procedure to ensure SOPs meet local documentation and training requirements
Prerequisites:	• N/A
Schematics/documentation	• WI, Stent Microblasting 90681356

Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
1	**Documentation creation/update:** Verify that SOPs or procedures are ready to be released to use the equipment for its intended use.	WI, Stent Microblasting 90681356 is available in PLM	WI, Stent Microblasting 90681356 is available in PLM ☑ Yes ☐ No Procedure # 90681356 Revision AS Status: In Work	☑ Pass ☐ Fail	A-M. 11 DEC 2018

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Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
2	**Training system update:** Verify that SOPs or procedures training is captured in the training system. Record training plan document number and version.	Training system shows evidence of training to relevant procedures	Training system shows evidence of training to relevant procedures ☑ Yes ☐ No Trainign Plan: Document # – NV00031225 Revision – AA	☑ Pass ☐ Fail	A.M. 11 DEC 2018

Comment: NOM. 11 DEC 2018
A.M.

Checksheet 8: Functional testing checksheet

Objective:	• To verify the equipment correctly initializes according to specifications. • To ensure that the equipment functionality performs as expected.
Procedure:	• Execution should be supervised/executed by a manufacturing engineering representative whenever possible • Representatives from operations should also participate • Review the equipment function for the items listed below
Prerequisites:	• Ensure (1) Machine is powered off, (2) A hand-piece nozzle is inserted into machine port, (3) Fill abrasive media in powder tank at least ½ full, , and (4) A piece of paper is available.
Schematics/documentation	• None

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Val reg #: 90682515	Document #: NV00035660	Rev.: AA

Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
1	**Power Switch:** Check power switches functionality.	Functions to toggle - power up & power down machine.	Machine powers up when Toggle power switch is set to On ☑ Yes ☐ No Machine powers down when Toggle power switch is set to Off ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 11 DEC 2018
2	**Power Switch:** Visually verify that the machine power switch is ON.	A Power indicator illuminates when power is ON.	A Power indicator illuminates when power is ON. ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 11 DEC 2018

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3	**Air Pressure Regulator:** Set the pressure setting between 30-40 psi by rotate pressure knob on front of machine. Figure 11: Reference picture of the Comco Microblaster with pressure setting display. To set / adjust pressure between 30-40 psi. • Turn air pressure control knob clockwise to increase pressure • Press footswitch • Turn counter-clockwise to decrease pressure • Record set pressure reading. **Note:** The pressure will NOT drop when turning counter-clockwise until the footswitch is depressed.	Pressure is set between the range 30-40 psi.	Pressure is set between the range 30-40 psi. ☑ Yes ☐ No Pressure setting: 40 psi	☑ Pass ☐ Fail	A.M. 11 DEC 2018

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4	**Handpiece:** Check hand-piece nozzle to make sure it is screwed up tightly and properly. Figure 12: Reference picture of Abrasive Blasting nozzle.	• Hand-piece nozzle is installed and inside the chamber. • Verify nozzle is screwed on tightly	• Hand-piece nozzle is installed and inside the chamber. ☑ Yes ☐ No • Verify nozzle is screwed on tightly ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 11 DEC 2018
5	Visually verify the abrasive in the powder tank is halfway full and O ring on the tank creates a firm seal.	Abrasive in the powder tank is halfway full. O-ring on the tank creates a firm seal.	• Abrasive in the powder tank is halfway full. ☑ Yes ☐ No • O-ring on the tank creates a firm seal. ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 20 DEC 2018

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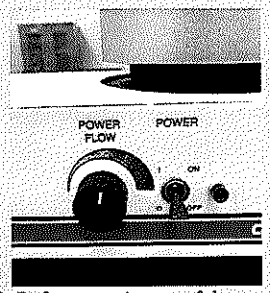
6	**Powder Flow Control:** Verify the functionality on the powder flow control knob. • To adjust the powder flow amount, turn the Powder Flow control knob clockwise to increase the power or counterclockwise to decrease the flow of the powder.  Figure 13: Reference picture of the powder flow control kno knob. • One hand holds nozzle and one hand holds a piece of paper. • The tip should be about 1/4" to 1/2" away from the surface to be blasted • Press the footswitch. • Release footswitch after approximately 2 seconds. • Blast process stops.	Powder flow is more by turning the powder flow control knob to maximum setting. Powder flow is less by turning the powder flow control knob closer to minimum setting.	Powder flow is more by turning the powder flow control knob to maximum setting. ☑ Yes ☐ No Powder flow is less by turning the powder flow control knob closer to minimum setting. ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 20 DEC 2018

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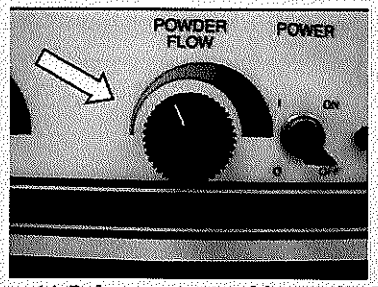
7	Verify the flow of powder when both pressure setting and flow control are changed • Set powder flow control knob dial setting at ⅓ clockwise from 9 o'clock position and set pressure to 30 psi and 40 psi. • One hand holds nozzle and one hand holds a piece of paper. • The tip should be about 1/4" to 1/2" away from the surface to be blasted • Press the footswitch. • Release footswitch after approximately 2 seconds. • Blast process stops.	Powder flow comes out adequately to perform process at 30 and 40 psi with the flow control knob dial setting at ⅓ clockwise from 9 o'clock position	Powder flow comes out adequately to perform process at 30 and 40 psi with the flow control knob dial setting at ⅓ clockwise from 9 o'clock position. ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 20 DEC 2018
8	Return the powder flow setting by turning the dial ⅓ clockwise from 9 o'clock position  Figure 14: Reference picture of the powder flow control knob set at 1/3rd clockwise position.	Powder flow setting is set at the required dial ⅓ clockwise from 9 o'clock position.	Powder flow setting is set at the required dial ⅓ clockwise from 9 o'clock position. ☑ Yes ☐ No	☑ Pass ☐ Fail	A.M. 20 DEC 208

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Ref	Item/verification method	Acceptance criteria	Actual Results	Pass/Fail	Performed by/date
Comment: None. A.M. 20DEC 2018					

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Signature verification sheet

Objective:	• To allow identification of the owners of signatures and initials applied to the protocols and execution records		
Procedure:	• Fill in the blank with your printed name, your title, your signature, and initials/date. • This is not required for those (e.g. reviewers and approvers) whose signatures are applied next to their written name. • See CQP-PDC-002, *Validation* regarding instructions for external personnel		
Printed name	**Title and organization**	**Signature**	**Initials/date**
AKHIL MOHAN	SR. EQUIPMENT ENGINEER, STRYKER	[illegible]	A.M. / 20DEC 2018
Jesús Alverio	Equipment Engineer / Oxford Lifescience	J. Alverio	J.A. / 07Jan2019
		N/A J.A. 07Jan2019	

Comment: None – A.M. 20DEC 2018

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Exceptions log

Objective:	• To allow identification and traceability of exceptions, if applicable, recorded during the execution of the protocol.		
Procedure:	• Follow CQI-PDC-002-06, *Validation Exceptions*. • <<Record summary of the exception in the table to allow for protocol closure>> <<or>> • <<Attach copies of exceptions to the executed protocol and list in Attachments log>>		
Exception number	**Details/description (item references, etc.)**	**Date closed**	**Checksheet reference initials/date**
N/A	N/A	N/A	N/A

Comment: N/A A.M. 20DEC 2018

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Equipment and test equipment/gage calibration

Objective:	• To verify and document that the equipment being qualified, and the test equipment/gages used during protocol execution (e.g. multimeter) are identified and calibrated.
Procedure:	• For each piece of equipment and test equipment/gage used in the execution of the protocol and in scope for calibration, record the details on this sheet and ensure the equipment complies with local calibration procedures.

Equipment ID #	Equipment description, make, and model	Calibration system ID#	Calibration due date	Initials/date
T0146B-010	Pressure Gauge, SMC	T0146B-010	28 FEB 2019	A.M. / 20 DEC 2018
NV00034618-001	Pressure Gauge, Ashcroft 0-150 psi	NV00034618-001	10 JUN 2019	A.M. / 20 DEC 2018
T0327-008	Fluke 87 Multimeter	T0327-008	27 DEC 2018	A.M. / 20 DEC 2018
NV00032422-001	Pin Gage Set, (Nominal 0.0252", Deltronic	NV00032422-001	30 OCT 2019	A.M. / 20 DEC 2018

Comment: None.

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Attachments

Attachment ID	Description
A01 – Temperature .pdf	Temperature Report of NV00034618 – 001 Location.
A02 – Humidity .pdf	Temperature Report of NV00034618 – 001 Location.
EHS_NV00034618-001.pdf	New Equipment EHS Assessment.
Electrical Certification.Pdf	3rd Party Electrical Evaluation
	N/A 14 Jan 2019