

Heat Sealer

Last Issue Date: 24/02/2020		Type Of Service				
Activity		A	B	C	D	E
1	<p>PHYSICAL INSPECTION - EXTERNAL: NOTE: The check is to include repairs, replacement, adjustments and cleaning if required.</p> <p>a) Check case and chassis alignment. b) Check power cord assembly. c) Check switches, indicators and fuses. d) Check display assembly / audio. e) Check control orientation. f) For units with castors check the brakes are operational. g) For units on rails or connected to cable systems check that end stops, centre stops, safety brakes, interlocks etc. are functional. h) Check that labelling and safety marking is legible and complete.</p>			Y	Y	
2	<p>PHYSICAL INSPECTION - INTERNAL: NOTE: The check is to include repairs, replacement, adjustments and cleaning if required.</p> <p>a) Check the belts. b) Check the friction strips. c) Check the circuit boards. d) Check the drive assembly. e) Check the chassis condition. f) Check the roller assemblies.</p>			Y	Y	
3	<p>FUNCTION TESTING: NOTE: The check is to include repairs, replacement, adjustments and cleaning if required.</p> <p>a) Check the drive motor. b) Check the heaters. c) Undertake an operational check of the heat sealer, including the temperature. Inspect the pouch and seam integrity.</p>			Y	Y	
4	<p>ELECTRICAL TESTING: Undertake the electrical safety tests.</p>			Y	Y	
5	<p>RECALIBRATION: Undertake recalibration. Provide a report to the site representative (hard or soft copy as requested) and to the facility manager.</p>				Y	
6	<p>VALIDATION: Undertake Performance Qualification to ensure the heat sealing process consistently produces acceptable sterile barrier systems: a) Undertake a Temperature Control Test. b) Undertake a Seal Integrity Test. Provide a report to the site representative (hard or soft copy as requested) and to the facility manager. Refer Special Comments for information.</p>				Y	Y
7	Record the service and testing in the customer service sheet / log book.			Y	Y	Y

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For more information please contact the applicable Facilities Management Service Provider.



Government of South Australia
Department of Planning,
Transport and Infrastructure

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Special Comments and Technical Data

C SERVICE: 6 MONTHLY. (REFER TO MANUFACTURER'S RECOMMENDATIONS. THE DEFAULT (MINIMUM FREQUENCY) IN AS4187 IS ANNUAL FOR HEAT SEALERS.

D SERVICE: ANNUAL.

E SERVICE: REFER BELOW FOR SPECIFIC INSTANCES WHEN PERFORMANCE QUALIFICATION IS REQUIRED IN ADDITION TO THE ANNUAL TESTING.

THE RESPONSIBLE ORGANISATION IS TO IMPLEMENT AN APPROPRIATE MEDICAL EQUIPMENT MANAGEMENT PROGRAM & THIS PREVENTATIVE MAINTENANCE SERVICE, THE VALIDATION PROCESS & ASSOCIATED DOCUMENTATION IS TO FORM PART OF THIS PROGRAM & COMPLY WITH: AS3551, AS4187.

THERE ARE NO SPECIFIC ISO STANDARDS. ISO 11607-2, ISO/DTS 16775 AND EN 868-5 PROVIDE GUIDANCE.

THIS IS A GENERIC TDS. REFER TO THE SPECIFIC MANUFACTURER'S OPERATIONAL AND MAINTENANCE MANUALS FOR INFORMATION.

FOR COMPLIANCE AS PART OF THE VALIDATION PROCESS PERFORMANCE QUALIFICATION (PQ) IS TO BE DONE AT AN ANNUAL FREQUENCY (MINIMUM).

PQ WILL ALSO NEED TO BE DONE IMMEDIATELY AFTER ANY OF THE FOLLOWING OCCURS:

- AFTER REPAIRS;

- AFTER A SERVICE (REGIME) IS CHANGED WHICH MIGHT ADVERSELY IMPACT THE QUALITY OF THE REUSABLE MEDICAL DEVICE;

- WHEN THE EQUIPMENT IS MODIFIED TO DELIVER A NEW PROCESS;

- WHEN THE LOAD / PACKAGING / LOADING CHARACTERISTICS ARE NEW OR MODIFIED FROM THE PREVIOUS REFERENCE LOAD.

THE PQ IS TO BE SCHEDULED AS PROMPTLY AS POSSIBLE TO ENABLE THE EQUIPMENT TO BE RESTORED INTO OPERATIONAL USE. THE TECHNICIAN IS TO LIAISE WITH THE FACILITY MANAGER.

FOR PERFORMANCE QUALIFICATION THE APPROPRIATE STAFF PERSONNEL FROM THE ORGANISATION ARE TO BE AVAILABLE TO ARRANGE & ASSIST WITH THE REFERENCE LOAD CONFIGURATIONS.

THE SERVICE AND PERFORMANCE QUALIFICATION IS TO BE DONE BY A TECHNICIAN WHO IS COMPETENT TO UNDERTAKE THE REQUIREMENTS FOR THE SPECIFIC MANUFACTURER'S EQUIPMENT AND COMPLY WITH APPLICABLE STANDARDS AND REGULATORY REQUIREMENTS.

THE ANNUAL (DEFAULT) PQ SHOULD BE DONE AT THE END OF THE ACTIVITIES FOR THE ANNUAL SERVICE PROVIDED THE TECHNICIAN IS COMPETENT TO UNDERTAKE BOTH.

VALIDATION IS A DOCUMENTED PROCEDURE FOR OBTAINING, INTERPRETING AND RECORDING THE RESULTS TO

EVIDENCE THAT A PROCESS WILL CONSISTENTLY YIELD PRODUCT COMPLYING WITH PREDETERMINED SPECIFICATIONS.

APPLICABLE LEGISLATION: PUBLIC HEALTH ACT AND WH&S ACT.

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