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Revision: A
Group: Protocol
Type: Protocol Performance Qualification
State: Released
Latest Released: YES
Implemented Date: 07/15/2020
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Revision History for (PRC089785)

SUMMARY OF CHANGES	
Revision No.	Description of Change
A	New Revision

PERFORMANCE QUALIFICATION PROTOCOL	
Document Title:	Performance Qualification Protocol for Electrical Safety Test Equipment
Document Number / Revision:	PRC089785, A
Site / Location:	Ethicon Endo-Surgery Service and Repair Depot, Cincinnati, Ohio
Project / Area:	Service and Repair
Product/Process:	Electrical Safety Test Equipment
Equipment:	All Equipment utilized in the process will be identified under the Scope and Background (table 12)
Validation Assessment Reference:	DOC025519 Rev A

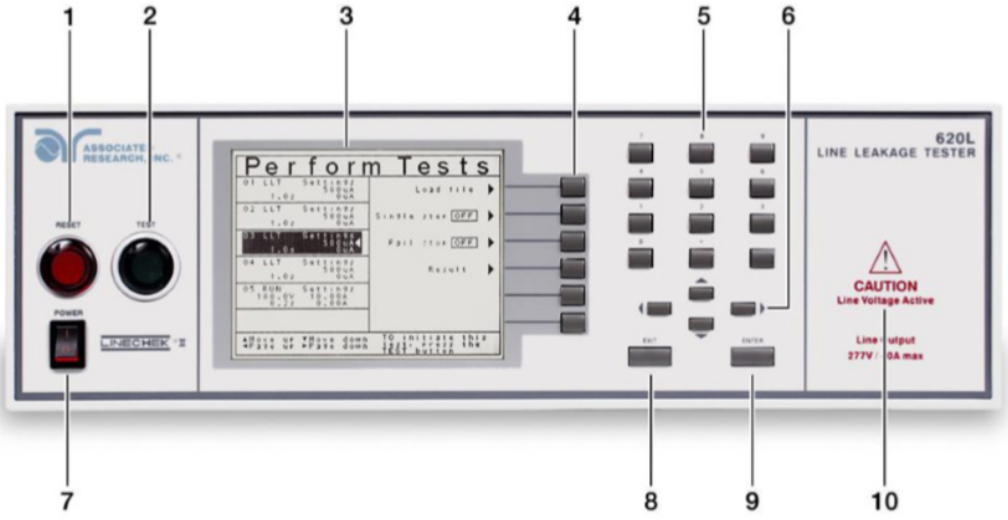


Figure 1: Front Side- Line Leakage Tester

Table 1:Front Side-Line Leakage Tester

1	RESET BUTTON
2	TEST BUTTON
3	GRAPHIC LCD
4	SOFT KEYS
5	NUMERIC DATA ENTRY
6	UP, DOWN, LEFT, AND RIGHT, ARROW KEYS
7	POWER SWITCH
8	EXIT KEY
9	ENTER KEY
10	LINE VOLTAGE INDICATOR

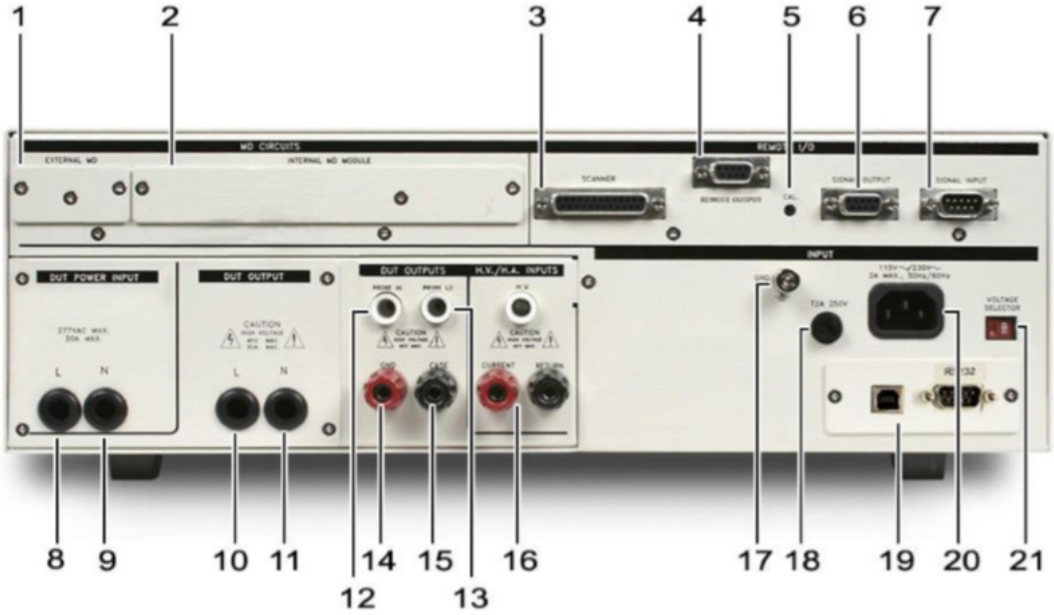


Figure 2: Rear Side-Line Leakage Tester

Table 2:Rear Side-Line Leakage Tester

1	EXTERNAL MEASURING

	DEVICE
2	INTERNAL MD MODULE
3	SCANNER CONNECTOR
4	REMOTE OUTPUT
5	CALIBRATION BUTTON
6	REMOTE SIGNAL OUTPUT
7	REMOTE SIGNAL INPUT
8	DUT POWER INPUT LINE
9	DUT POWER INPUT NEUTRAL
10	DUT POWER OUTPUT
11	DUT POWER OUTPUT
12	PROBE HI
13	PROBE LO
14	GND
15	CASE
16	Safety Tester Connections
17	CHASSIS GROUND (EARTH) CONNECTION
18	FUSE RECEPTACLE
19	BUS INTERFACE
20	INPUT POWER RECEPTACLE
21	INPUT POWER SWITCH

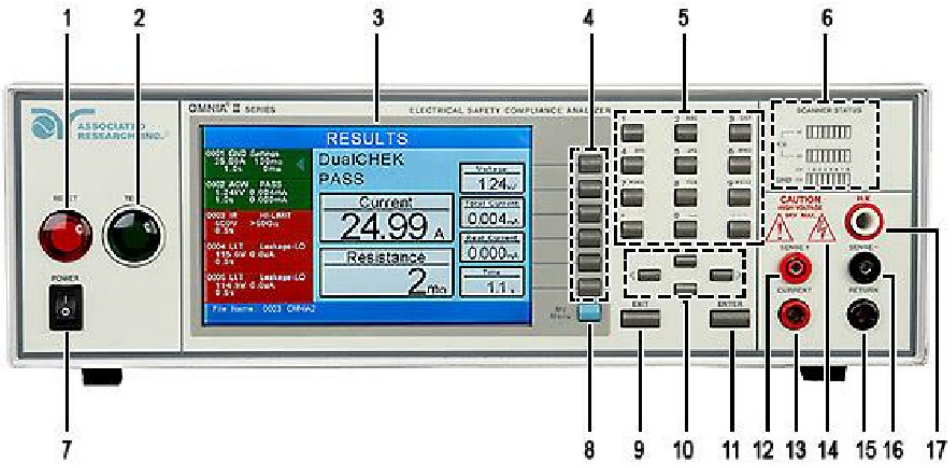


Figure 3: Front Panel - OMNIA II Electrical Safety Tester

Table 3:OMNIA II Electrical Safety Tester

1	RESET BUTTON
2	TEST BUTTON
3	SCREEN
4	SOFT KEYS
5	NUMERIC DATA ENTRY
6	SCANNER STATUS LED's
7	POWER SWITCH
8	MY MENU KEY
9	EXIT KEY
10	UP, DOWN, LEFT, AND RIGHT, ARROW KEYS
11	ENTER KEY
12	SENSE + TERMINAL
13	CURRENT OUTPUT TERMINAL
14	HIGH VOLTAGE INDICATOR
15	RETURN OUTPUT TERMINAL
16	SENSE - TERMINAL
17	HIGH VOLTAGE OUTPUT TERMINAL

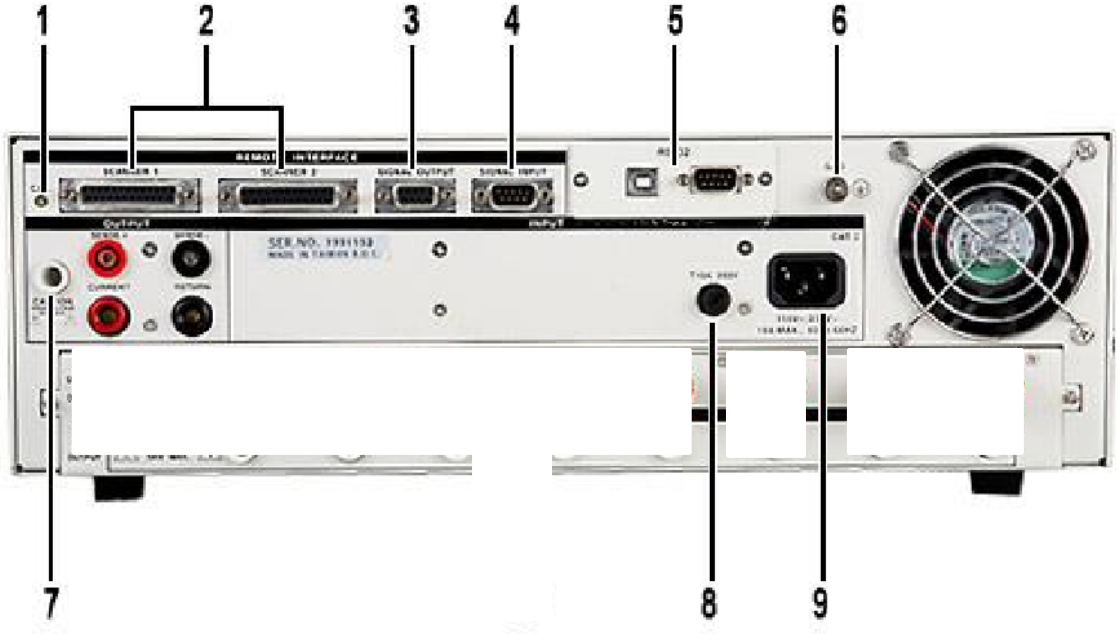


Figure 4: Back Panel - OMNIA II Electrical Safety Test

Table 4:Back Panel OMNIA II Electrical Safety Tester

1	CALIBRATION BUTTON
2	SCANNER CONNECTOR
3	REMOTE SIGNAL OUTPUT
4	REMOTE SIGNAL INPUT
5	BUS INTERFACE
6	CHASSIS GROUND (EARTH) CONNECTION
7	REAR PANEL OUTPUT TERMINALS
8	FUSE RECEPTACLE
9	INPUT POWER RECEPTACLE
10	SCANNER OUTPUTS

Figure 5: Front Panel Controls- High Voltage and High Current Modular Scanning Matrix (Master and Slave)

Table 5:Table 5: Front Panel Controls- High Voltage and High Current Modular Scanning Matrix

1	POWER INDICATOR
2	MODULE TYPE INDICATOR
3	MODULE B CHANNEL STATUS INDICATORS
4	MODULE A CHANNEL STATUS INDICATORS

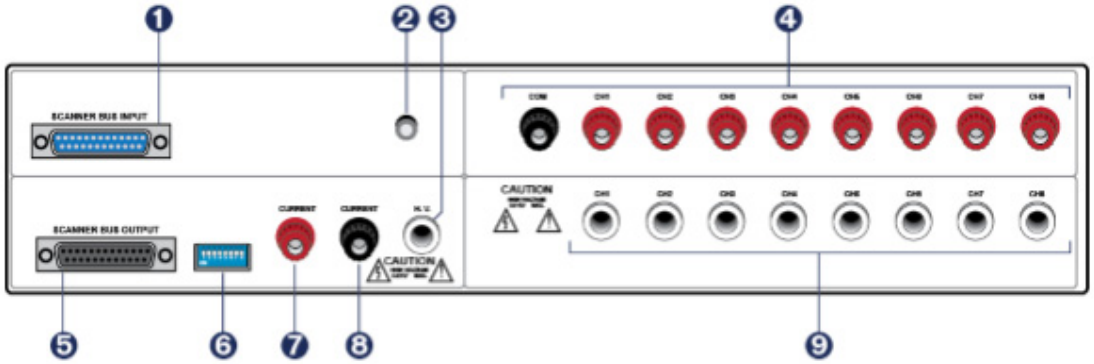


Figure 6: Back Panel- High Voltage and High Current Modular Scanning Matrix (Slave)

Table 6:Table 6: High Voltage and High Current Modular Scanning Matrix (Slave and Master)

Slave	
1	SCANNER BUS INPUT
2	SAFETY GROUND CONNECTOR
3	HIGH VOLTAGE INPUT

4	GROUND BOND OUTPUTS
5	SCANNER BUS OUTPUT
6	ADDRESS SWITCHES
7	CURRENT INPUT JACK
8	RETURN INPUT
9	HIGH VOLTAGE OUTPUTS
Master	
10	BUS INTERFACE
11	POWER SWITCH
12	FUSE RECEPTACLE
13	INPUT POWER RECEPTACLE
14	INPUT VOLTAGE SWITCH

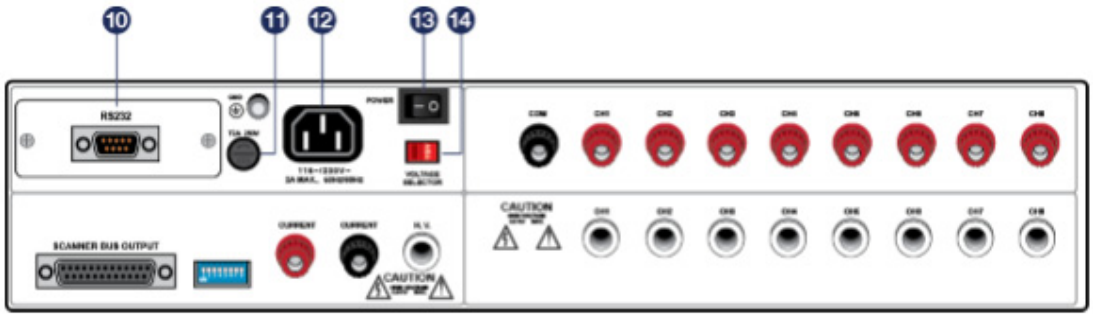


Figure 7: Back Panel- High Voltage and High Current Modular Scanning Matrix (Master)

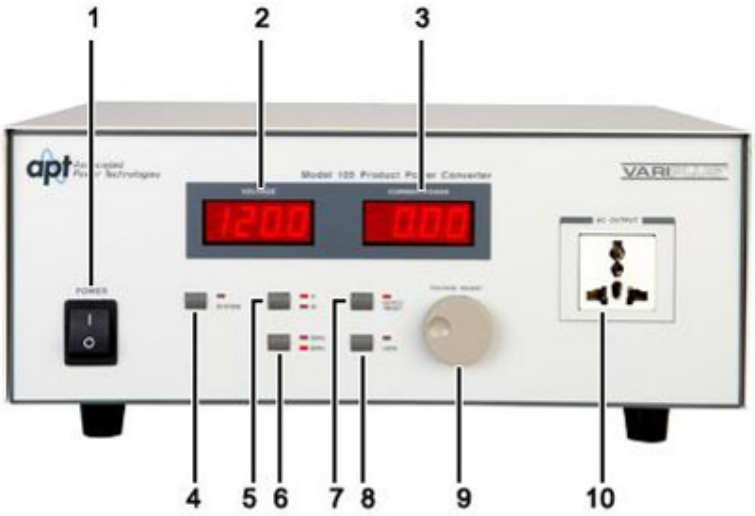


Figure 8: Front Panel - VariPlus Power Converter

Table 7:Table 7: Front Panel - VariPlus Power Converter

1	Power Switch
2	Voltage Display
3	Current/Power Display
4	System Key
5	Display Key
6	Frequency Key
7	Output/RESET Key
8	LOCK Key
9	Voltage Adjust Rotary Knob
10	Universal AC Output Socket

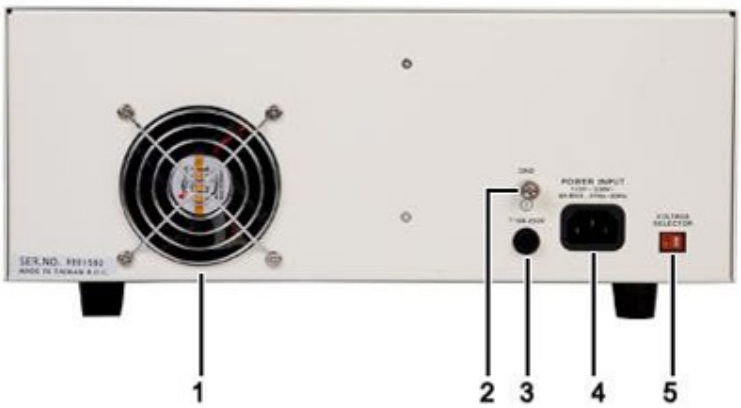


Figure 9: Back Panel - VariPlus Power Converter

Table 8:Table 8: Back Panel - VariPlus Power Converter

1	Thermal Fan
2	Ground Lug
3	Fuse Receptacle

4	Input Power Receptacle
5	Input Power Switch

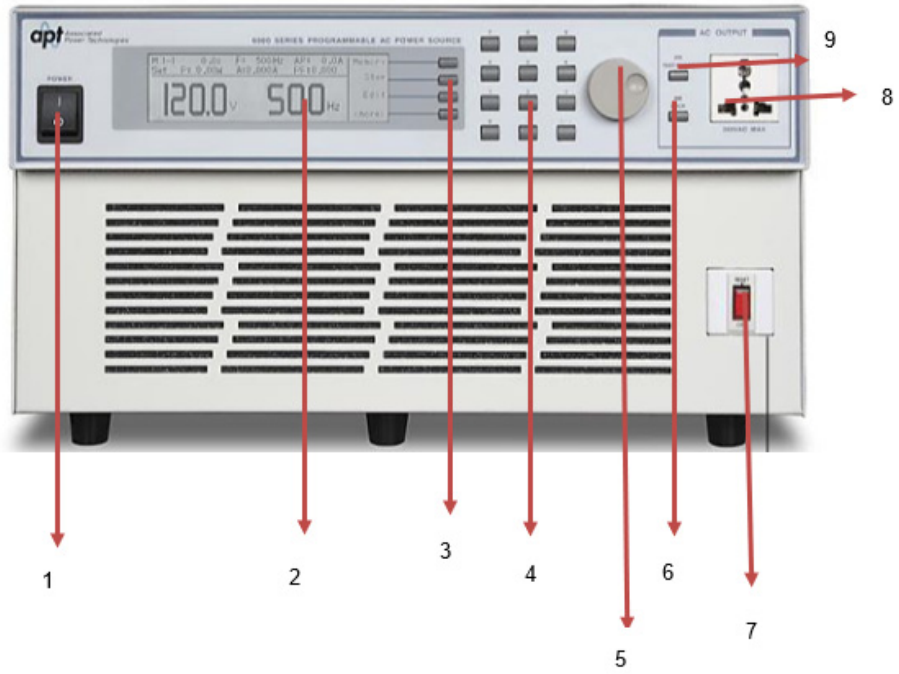


Figure 10: Front Panel - Automated AC Power Source

Table 9:Front Panel – Automated AC Power Source

1	Power Switch
2	Graphic LCD
3	Soft Keys
4	Number Keypad
5	Rotary Knob
6	Lock Key
7	Reset Switch
8	Universal AC Output Socket
9	Test/Reset Key

Figure 11: Back Panel – Automated AC Power Source

Table 10:Back Panel – Automated AC Power Source

11	Terminal Power Block
11a	Line Output Terminal
11b	Ground Output Terminal
11c	Neutral Output Terminal
11d	Line Input Terminal
11e	Ground Input Terminal
11f	Neutral Input Terminal
12	Input Breaker

1. DOCUMENT APPROVALS

Document approval reference document: CP0160

Ethicon Endo-Surgery

Function	Name	e-Signature / Wet Signature	Date
Originator	Bolakale Shekoni	eSig in EPICENTER	eSig in EPICENTER
Approvers			
Service Manager Service and Repair	Eric Smith,	eSig in EPICENTER	eSig in EPICENTER
Staff Service Engineer Service and Repair	Jason Stivers	eSig in EPICENTER	eSig in EPICENTER
Service Quality Representative Service and Repair	Robert Peters	eSig in EPICENTER	eSig in EPICENTER

2. PURPOSE

This protocol outlines the Performance Qualification for the 2nd electrical safety test station in the Ethicon Endo-Surgery Service and Repair Depot, Cincinnati, Ohio. PR-0000089 Franchise Procedure for Validation (Shared) defines the requirements & approach for Performance Qualification.

The purpose of this Performance Qualification is to establish by objective evidence that:

- The electrical safety test equipment consistently produces a valid test result that accurately reflects the electrical properties of the capital equipment being tested and establish confidence that the process is effective and reproducible.

3. SCOPE AND BACKGROUND

The scope of this Performance Qualification is to validate the electrical safety test equipment used to test the electrical properties of capital equipment serviced at the Ethicon Endo-Surgery Service and Repair Depot, Cincinnati, Ohio.

Table 11 lists the product families in the scope of this process.

Table 11 - Products Applicable to this Performance Qualification.

Product Code or Product Family Identifier	Description	Service Manual Document Numbers/Procedures

Product Code or Product Family Identifier	Description	Service Manual Document Numbers/Procedures
GEN11	GEN 11	P43566Pxx, Service Manual Revision 3
00482	Ethicon Versa point Generator	813272, Versa point Service Manual Revision AC
284580	DePuy Mitek FMS DUO Fluid Management System	109078, FMS DUO+ Instruction and Service Manual Revision A
284590	DePuy Mitek FMS SOLO Fluid Management System	109076, FMS SOLO Instruction Manual Revision A
PT-ASP-III-110	Mentor PSI-TEC III	21-OM-0002, PSI-TEC III™ Service Manual Revision E
AP II	Mentor Accelerator II	42-OM-0058, Mentor Accelerator II™ (110V or 220V) Instruction Manual Revision C
1000	Megadyne Mega Power 1000 Electrosurgical Generator	3000159-01 Megadyne Mega Power Electrosurgical Generator Service Manual Revision 003
242302	PURE Vue Camera Control System	103357358, PureVUE™ Autoclavable Camera Service Manual Revision 6
284004	FMS Vue II	103329712, FMS VUE II™ Service Manual (284004) Revision C
225024	VAPR VUE - Generator	Mitek# 110009 Gyrus#192058, VAPR VUE Radiofrequency System User Manual Revision 7
284002	FMS VUE - Fluid Management System	WI-8971, FMS VUE™ Service Manual (284002) Revision 10

Product Code or Product Family Identifier	Description	Service Manual Document Numbers/Procedures
283512	Micro Tornado Handpiece with Hand Control	103225136 Micro Handpiece for FMS VUE™ Fluid Management and Tissue Debridement Systems (283512) Service Manual Revision 1
0VB1: OVS1	Visualization - System	103185244, OVB1 Service Manual, Revision 5 103185252, OVS1 Service Manual, Revision 4
225021	VAPR3 - Electrosurgical Generator	837116: VAPR3 Service Manual Revision AB
ECVV120 and ECVV220	Megadyne MiniVac Smoke Plume Evacuator	ENG-WI-034, MiniVac Repair, and Test Instructions, Service and Repair Revision A

Table 12 lists all the Equipment associated with the process under the scope of this study.

Table 12 - Equipment Applicable to this Performance Qualification.

Equipment ID#	Equipment Description	Calibration Due Date & IMTE Number
Model Number-620L Serial Number-9610519	Line Leakage Tester-Line Check II	The unit has been calibrated, but the IMTE number is pending as the calibration form is pending approval. The IMTE number will be included in the completion report.
Model Number-SC6540 Serial Number-9531490 and 9531516	High Voltage and High Current Modular Scanning Matrix	ES3140 June 2, 2021 ES2958 June 9, 2021
Model Number-08204 Serial Number-9650581	OMNIA II Electrical Safety Tester	ES3142 June 2, 2021
Model Number-105 Serial Number-4150369	VariPlus Power Converter	ES3144 June 2,2021

Equipment ID#	Equipment Description	Calibration Due Date & IMTE Number
Model Number-6040 Serial Number-4080162	Automate AC Power Source	ES3143 June 2,2021

4. DEFINITIONS, TERMS, AND ABBREVIATIONS

Refer to the 100632965 Franchise Glossary for Validation (Shared) for terminology and abbreviations used in the validation program.

Table 3 - Definitions

Term/ Abbreviation	Definition
DUT	Device Under Test
PQ	Performance Qualification

5. ROLES & RESPONSIBILITIES

Responsibilities for the review and approval of this Installation Qualification are outlined in CP0160.

The Service Manager/Facilitator is responsible for the review and approval of this protocol and the associated completion report.

Service Engineer is responsible for the review and approval of this protocol and the associated completion report.

Service Quality Lead – is responsible for the review and approval of this protocol and the associated completion report.

Originator- is responsible for the creation, execution, and required before the performance of this protocol. This includes all associated activities and the completion report.

Service Repair Technician – is responsible for executing this protocol, assisting with the creation, requiring training prior, and implementing it. This includes the associated completion report. A second technician is responsible for the review of the scripts.

Document Management – is responsible for the maintenance and archival of this protocol.

6. PRE-REQUISITES

The Pre-Requisites that must be fulfilled before PQ execution are shown below.

Table 11 - Pre-Requisites

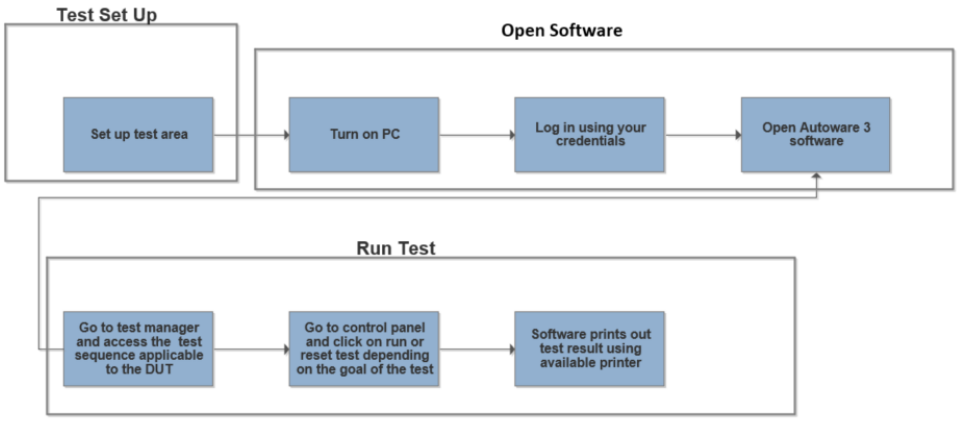
Pre-Requisite	Document Title	Reference Doc. # and Revision or Attachment
Installation Qualification Completion Report	Associated Research Electrical Safety Equipment Qualification Report	PRC089781, A
Training on the PQ protocol for the Electrical Safety tester	Performance Qualification Protocol for Electrical Safety Test Equipment	Evidence format detailed in section 11 of this protocol.

Pre-Requisite	Document Title	Reference Doc. # and Revision or Attachment

The above items pending completion will be verified for completion before PQ execution and documented in the completion report.

7. MANUFACTURING PROCESS FLOW

Table 12:Electrical Safety Test Process Map



8. REQUIREMENTS AND ACCEPTANCE CRITERIA / CTQ LIST

Table 13 - CTQ List

Attribute	Test Method	Specification	Acceptance Criteria
Line Leakage Current	Line Leakage Test	Refer to Attachment 1 for the specification of each capital equipment that will be tested during PQ execution	Leakage current is within the defined specification for each Device tested as defined in attachment 1 of this protocol
Electrical Integrity of the Ground connection	Ground Bond Test	Refer to Attachment 1 for the specification of each capital equipment that will be tested during PQ execution	The Resistance measured during the Ground Bond Test is within the defined specification limits for each Device tested, as defined in Attachment 1 of this protocol
Strength of the Insulation	HIPOT Test	Refer to Attachment 1 for the specification of each capital equipment that will be tested during PQ execution	The Current measured during the AC Withstand Test is within the defined specification limits for each Device tested, as defined in Attachment 1 of this protocol

9. PROCESS PARAMETERS

The design team established the process parameters during product development. The settings can be found in the applicable service manual for each product.

9.1 Process Parameters/ Inputs

The process parameters and ranges to be validated are attached (Attachment 1) to this protocol document.

10. OPERATING PROCEDURES

Product Code or Product Family Identifier	Description	Service Manual Document Numbers/Procedures
GEN11	GEN 11	Gen 11 Service Manual Revision 3
00482	Ethicon Versa point Generator	813272, Versa point Service Manual Revision AC
284580	DePuy Mitek FMS DUO Fluid Management System	109078, FMS DUO+ Instruction and Service Manual Revision A
284590	DePuy Mitek FMS SOLO Fluid Management System	109076, FMS SOLO Instruction Manual Revision A
PT-ASP-III-110	Mentor PSI-TEC III	21-OM-0002, PSI-TEC III™ Service Manual Revision E
AP II	Mentor Accelerator II	42-OM-0058, Mentor Accelerator II™ (110V or 220V) Instruction Manual Revision C
1000	Megadyne Mega Power 1000 Electrosurgical Generator	3000159-01 Megadyne Mega Power Electrosurgical Generator Service Manual Revision 003
242302	PURE Vue Camera Control System	103357358, PureVUE™ Autoclavable Camera Service Manual Revision 6
284004	FMS Vue II	103329712, FMS VUE II™ Service Manual (284004) Revision C
225024	VAPR VUE - Generator	Mitek# 110009 Gyrus#192058, VAPR VUE Radiofrequency System User Manual Revision 7
284002	FMS VUE - Fluid Management System	WI-8971, FMS VUE™ Service Manual (284002) Revision 10

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225021	VAPR3 – Electrosurgical Generator	837116: VAPR3 Service Manual Revision AB
ECVV120 and ECVV220	Megadyne MiniVac Smoke Plume Evacuator	ENG-WI-034, MiniVac Repair, and Test Instructions, Service and Repair Revision A

11. TRAINING REQUIREMENTS

Training of Service and Quality Assurance Technicians was conducted on the 8TH of August 2017. The training covered all Capital equipment serviced at the Ethicon Endo-Surgery Service and Repair Depot, Cincinnati, Ohio. Evidence of this training will be included in the Performance Qualification report.

Protocol training for the required personnel shall be done before protocol execution and will be documented on form FM-0000809 and attached to the protocol completion report, PRC089786. Training is not required for protocol approvers per WE0020.

12. TEST STRATEGY

A performance Qualification (PQ) will be executed by running a series of tests (ground-bound, leakage test, and insulation test) on all capital equipment serviced at the service center and then comparing the result to the results obtained by running the same test on the older QuadTech Electrical Safety Test Equipment. A piece of defective and non-defective capital equipment will be used to verify the accuracy of the test results generated by the test equipment. The list of all products in scope is listed in section 3 of this protocol.

13. SAMPLING PLAN AND RATIONALE

The PQ protocol will be completed by testing the capital equipment listed in Section 3. A Single capital equipment of each kind will be used to verify if the electrical safety equipment meets the service center's requirements since only a limited number of devices are available for testing. The test plan is listed in section 14 of this document. The product name and a serial number of the capital equipment will be attached to the completion report.

14. TEST PLAN

a) Equipment to be used is listed in Table 12

b) Turn on the workstation and open the Autoware 3 software

c) Load the appropriate test script for each of the capital equipment listed in table 11

d) The test script should include scripts required to run the HIPOT, Line Leakage, and Ground Bond test as applicable.

e) Select a known functional unit of each of the capital equipment listed in table 11

f) Run HIPOT, Line Leakage, and Ground Bond test on each Capital equipment, print, and save the results. The printout shall be attached to the completion report.

g) Record the results in the data collection form in appendix 2

h) Run the same test on the older QuadTech Electrical Safety Test Equipment to verify the accuracy of the results obtained from the Associated Research Electrical Safety Equipment. Record your observation in the data collection form in appendix 2. Attach the printout to the completion report.

i) For the second run, three failures -Leakage, HIPOT, and Ground Bond test failures will be induced in each of the units.

j) A description of the failures shall be recorded in the data collection form in appendix 2

k) Service technicians will follow the process steps described above to test each of the devices and print the test results. The printouts shall be attached to the completion report.

l) Record the results in the data collection form in appendix 2. The data collection form will be attached to the completion report.

m) The service technician will repeat the same test using the older QuadTech Electrical Safety Test Equipment and print the results. The printout shall be attached to the completion report.

n) A service technician will compare the results and verify the accuracy of the Advanced Research Electrical Safety Test Equipment. Record your observation in the data collection form in appendix 2

15. MATERIAL DISPOSITION

Capital equipment used to complete this protocol will be returned to the service line to be taken through the service process before being placed in a loaner/exchange pool.

16. DEVIATION HANDLING

If deviations occur during the performance qualification, they will be documented using the Validation Deviation Form 100646188. All deviations and corrective actions shall be recorded in the Performance Qualification Report. Any associated criteria for success changes, or process modifications will be assessed and revalidated if deemed necessary.

17. REFERENCE DOCUMENTS

The following documents are used to develop, support, or referenced within this Installation Qualification Protocol.

Document Number/Revision	Document Title
CP0190, BJ	Requirements for Control of Inspection, Measuring and Test Equipment
CP0160, GY	Change Control/Approval Matrix
FM-0000809,15	Franchise Qualification and Training Form

Document Number/Revision	Document Title
PR-0000089,14	Franchise Procedure for Validation (Shared)
100632965,3	Franchise Process Validation Glossary of Terms (Shared)
Manufacturer's Documentation	
Version 1.0	Associated Research Inc. Installation Qualification Documentation Installation Procedure- LINECHEK® II Model 620L
Version 1.24	Associated Research Inc. Operation Manual for MODEL 620L Line Leakage Tester
Version 2.0	Associated Research Inc. Installation Qualification Documentation Installation Procedure – OMNIA II 8204
Version 3.20	Associated Research Inc. Operation Manual for OMNIA II Electric Safety Tester
version 1.0	Associated Research Inc. Installation Qualification Documentation Installation Procedure - Autoware 3 software
version 1.0	Associated Research Inc. Installation Qualification Documentation Installation Procedure - Model SC6540 High voltage and High current scanning matrix
version 3.12	Associated Research Inc. Operation Manual for High Voltage and High Current Scanning Matrix
Version 1.13	Associated Power Technology VariPlus 105 Series Power Converter Operation Manual
Version 1.38	Associated Power Technology 6000 Series Automated AC Power Source Operation Manual
Version 3.20	Associated Research Inc. Operation Manual for OMNIA II Electric Safety Tester

18. APPENDIX

The following are appendices to this document.

Appendix Number	Appendix Name
1	Signature and Protocol Training Log
2	Data Collection forms

APPENDIX 1 – SIGNATURE and protocol training LOG

Training Log objective: to provide documented evidence of training to the protocol.

Training records are located within FM-0000809 and will be attached report.

Name	Job Title	Signature / Initials / Date
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____
		Signature: _____ Initials: _____ Date: _____

APPENDIX 2 - DATA COLLECTION FORMS

Run and State of the Unit	Test Type	Induced Failure Description	Associated Research Electrical Safety Test Result	Chroma Electrosurgical Analyzer Test result	Pass/Fail
1 Good Unit	Line Leakage Test	N/A			
2 Bad Unit					
1 Good Unit	Ground Bond Test	N/A			
2 Bad Unit					
1 Good Unit	HIPOT Test	N/A			
2 Bad Unit					
Product Name, Code and Serial Number					
Comments:					
Performed By:		Print Name:		Signature:	
Reviewed By:		Print Name:		Signature:	

PRC089785, A, Performance Qualification Protocol for Electrical Safety Test Equipment

19. ATTACHMENTS

Attachment Name	Attachment Number
Electrical Safety Parameter Specification	1