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Group: Fact Book
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Latest Released: YES
Implemented Date: 11/18/2019
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Johnson & Johnson Medical KK Sugakawa, Japan

Service and Repair Center for the Megapower 1000 Product Code

Factbook # FB003289

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Factbook Approval

We have reviewed and do approve Factbook #FB003289, Addendum to Factbook F-261 (EpiCenter document Number FB001103), for the service and repair of the MegaPower 1000 Generator at Johnson & Johnson Medical KK Sugakawa, Japan. We find that the documentation contained in this factbook meets the requirements as defined by WE001534, Rev F, Establishment and Certification of Service Depot, Field Service, and Parts Depot Centers. The signoff of this factbook represents the certification process and indicates the service center is to be considered authorized/qualified to perform service on the identified product(s).

E-Sig in EpiCenter

Shannon Gillespie
Manager, Service Center

E-Sig in EpiCenter

Date

E-Sig in EpiCenter

Robert Peters
Team Leader, Customer Quality
Worldwide Service and Repair

E-Sig in EpiCenter

Date

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FACTBOOK CHECKLIST

Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

Re: 1000

Activity	Complete	Not Applicable
Service System Quality Assessment	√	
Technical Training Program	√	
Documentation System	√	
Equipment Installation Qualification (EIQ)	√	
Physical Requirements	√	
Operating Agreement	√	
Start-Up Activities	√	
Supplier Approval	√	

Indicate Activity status with a single " √ " mark.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

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FACTBOOK STRATEGY

Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

Re: 1000

The support data establishing Johnson & Johnson Medical KK Sugakawa, Japan as an Ethicon Endo-Surgery authorized service center for the 1000 Megadyne capital equipment is contained in this Factbook.

The process follows WE001534 Rev F, Establishment and Certification of Service Depot, Field Service, and Parts Depot Centers. A Service and Repair Facility Qualification Record has been created which serves as the index for this factbook. Approval signatures will appear on each memorandum page as outlined by the Service and Repair Facility Qualification Record.

This information is an Addendum to the original Factbook F-261 that qualified Johnson & Johnson Medical KK Sugakawa, Japan as an authorized service center for the GEN04, SCM12, SCM23, and STHC1. This Factbook documents their training and qualification to repair the product codes 1000 generator. The original product codes SCM12, SCM23, and STHC1 were sold to another company and are not part of this factbook process. Johnson & Johnson Medical KK also services the RF60 generator approved in factbook number FB002269 and GEN11 approved in factbook number FB002911. Those factbooks and associated service of products are not affected by this factbook.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

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Service & Repair Facility Qualification Record

The table of contents of this Factbook is listed below. The documentation contained meets the intent of WE001534 Rev F, Establishment and Certification of Service Depot, Field Service, and Parts Depot Centers.

1.0 SERVICE SYSTEM QUALITY ASSESSMENT

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SERVICE SYSTEM QUALITY ASSESSMENT

Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

Re: 1000

Refer to section 1.0 of Factbook F-261 (EPI Center document number FB001103) for the support documentation that a servicing quality system assessment was conducted according to established procedures. Ongoing quality assessments of this facility will be maintained on file in EtQ per schedule.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

2.0 TECHNICAL TRAINING RESULTS

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TECHNICAL TRAINING RESULTS

Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

Re: 1000

On February 26-28, 2019, one service repair technician (Service Manager) from the J&J K.K. Medical Company Ltd. Japan Service and Repair Depot was provided training at Megadyne Medical Products, Draper, Utah for the following products:

- 1000, Mega Power Electrosurgical Generator

The training was conducted by Megadyne Service and Repair Trainers John Minuth and Tyler Skinner with assistance from Megadyne Repair Technician, Bruce Hevelone. Training began with a basic introduction to the product application and use, theory of operation of the system and a general product description and functional description. The attached training log contains the list of Megadyne forms, work instructions, software, and service bulletins required to be covered during the training for product codes. Additionally, procedures/manuals that included disassembly, reassembly, repair, testing, quality inspection, and product release were covered in the training. Troubleshooting information was also covered, which included identifying common causes of failure, hardware troubleshooting, and service testing. Afterward, standard service center processes, such as bench tests, electrical safely tests, and product release tests were demonstrated. To demonstrate the ability to repair the products the trainee was provided and passed a written test post training.

Finally, complaint awareness training is conducted on an annual basis and thus was not a needed deliverable for this specific training. Training records for complaint awareness are maintained within the training management system at the J&J KK Medical.

With this successful completion of the activities referenced above, the following individual(s) should now be considered trained as an authorized EES representative capable of the analysis, service, and repair of the Megadyne products listed above, and as a qualified and authorized trainer for the product.

1. Kohei Seki, Service Manager

Additionally, with this successful completion of the activities referenced above, the following individual(s) should now be considered trained as an authorized EES representative capable of the final release of product to inventory and authorized to train the quality release person(s) within their center.

1. Kohei Seki, Service Manager

Attached evidence of completion of these activities is:

- Franchise Qualification and Training Record Form (Shared)
- Training Agenda
- The Science of Electrosurgery – training presentation
- Megadyne Mega Power Service Center Repair Form, New Faceplate – objective evidence of completed device testing
- Mega Power Training Exam Results

- Certificate of Training

Note: Training Agenda and Training Record Form, include references to the Megadyne Mega Soft Patient Return Electrodes, and Mega Vac and Mega Vac Plus smoke evacuators. These references are not applicable for this factbook. The smoke evacuator products are not sold or serviced in the Japan market but were included in Megadyne training session. The Mega Soft products will be included in a future factbook.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Staff Service Engineer

Form Non-PPE
Quality System
Franchise Qualification and Training Record Form(Shared)

FM-0000809 / Rev: 11
CO: 100648063

FRANCHISE QUALIFICATION AND TRAINING RECORD FORM (Shared)

Page 1 of __2__

NOTE: COMPLETE THIS FORM IN BLUE OR BLACK INK ONLY.

Franchise/Site Impacted: ☐ Acclarent ☐ ASP ☐ Biosense Webster ☐ Ethicon ☒ Ethicon-Endo ☐ Mentor ☐ NeuWave ☐ Sterilmed

Method of Training: ☒ Instructor Led ☐ Self Training ☐ External Training ☐ Awareness

Instructor's Name/Signature/Date (Print {N/A if Self or External training}): John Minuth 2/28/19

Course, NR/CAPA, or Document Description: (*Description of content or course agenda/outline. Course description may include, but not limited to, the complete document title, version and sections/topic covered or brief description of reason for training)*

Megadyne Service & Repair Training – Mega Power 1000 Service & Repair, Mega Soft Pads Evaluation, Mega Vac Planned Maintenance, and Trainer Training

Training ID: Course Code, Title, NR/CAPA Number, or Document Number	Document Revision Number	Training Start Date	Training End Date	Training Duration	For Training Dept Use Only (or designee) Class Code (Optional)
CS-FRM-034	004	2/26/19	2/28/19	N/A	
CS-FRM-035	003	2/26/19	2/28/19	N/A	
ENG-FRM-013	003	2/26/19	2/28/19	N/A	
CS-FRM-027	001	2/26/19	2/28/19	N/A	
CS-FRM-028	001	2/26/19	2/28/19	N/A	
ENG-WI-037	001	2/26/19	2/28/19	N/A	
ENG-WI-036	001	2/26/19	2/28/19	N/A	
ENG-WI-035	002	2/26/19	2/28/19	N/A	
ENG-WI-053	004	2/26/19	2/28/19	N/A	
ICM-470-9024	H	2/26/19	2/28/19	N/A	
MKT-LBL-062	001	2/26/19	2/28/19	N/A	
MKT-LBL-063	002	2/26/19	2/28/19	N/A	
MKT-LBL-081	002	2/26/19	2/28/19	N/A	
MKT-LBL-101	002	2/26/19	2/28/19	N/A	

For Training Dept / Designee Use Only (Optional)

Form Non-PPE
Quality System
Franchise Qualification and Training Record Form(Shared)

FM-0000809 / Rev: 11
CO: 100648063

Printed Name of Data Entry Person: _____ Signature: _____ Date Entered: _____
The signature indicates that the training records are entered into ComplianceWire by the indicated person(s).

FRANCHISE QUALIFICATION AND TRAINING RECORD FORM (Shared)

IMS 9/18/19 Page 2 of 2 JH3 9/18/19

First Training ID: ~~N/A~~ CS-FRM-034	End Date: ~~N/A~~ 2/28/19
My signature below indicates I have self-trained / reviewed or participated in Instructor Led Training as described on page 1 and I understand the information or concepts covered.	

	TYPE / WRITE NAME	SIGNATURE	DATE	WWID #
1.	Kohei Seki	K. Seki	02/28/2019	152816107

Megadyne Medical Products
11506 S. State St. | Draper, UT 84020

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Megadyne, Mega Power 1000, Training Schedule, Salt Lake City: Feb 26 to Feb 28, 2018

Tuesday, Feb 26, 2019

9:00 am – 10:30 am	Principles to Electrosurgery
10:45 am – 12:00 pm	Anatomy and Troubleshooting,Mega Power 1000
12:00 pm – 1:00 pm	Lunch
1:00 pm – 2:00 pm	Disassembly of Mega Power 1000
2:00 pm – 4:00 pm	Assembly of Mega Power 1000

Wednesday, Feb 27, 2019

9:00 am – 10:00 am	Calibration, Mega Power 1000
10:00 am – 12:00 pm	Final Test
12:00 pm – 1:00 pm	Lunch
1:00 pm – 2:00 pm	Paperwork Overview

Thursday, Feb 28, 2019

9:00 am – 12:00 am	Preventive Maintenance Smoke Evacuator
12:00 am – 1:00 pm	Lunch
1:00 pm - 4:00pm	Pad Loaners

The Science of ELECTROSURGERY

February 26, 2019

John N. Minuth
Megadyne Medical Products, Inc.

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Electricity

Electricity flows in a closed path

1

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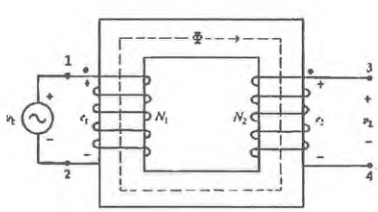
The Transformer

For Electrosurgery Current goes from Pin 3 back to Pin 4



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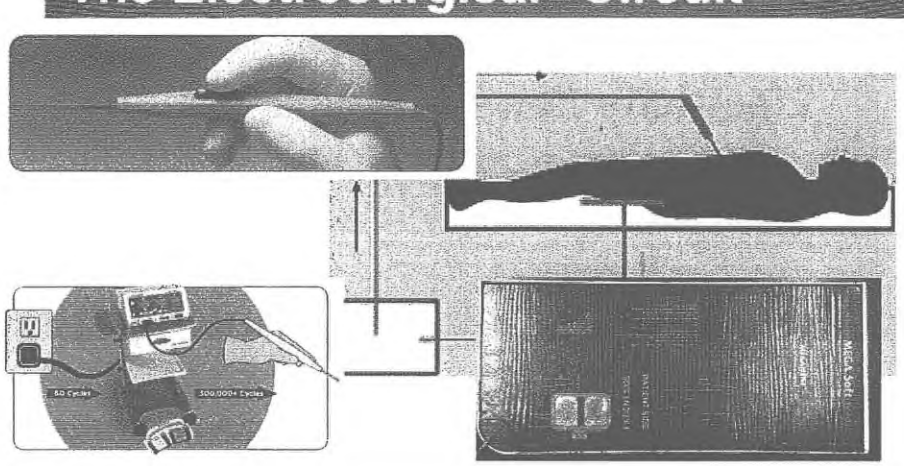
The Electrosurgical "Circuit"



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Basic Terms

- Voltage – Potential difference (Volts)
- Current – The time rate of flow of an electrical charge. (Amps)
- Power – The Rate that work is done. (Watts or Horsepower)

1 Horsepower = 746 Watts

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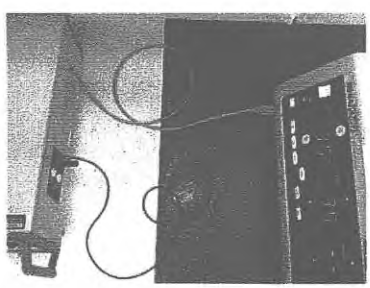
Basic Equations

- Ohm's Law: $V = I \cdot R$
- Power = $V \cdot I$ or V^2/R or $I^2 \cdot R$



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Generator Feedback Loop

- Generate a signal
- Measure Voltage and Current
- Calculate Power
- Change the voltage of the signal
- Start over.

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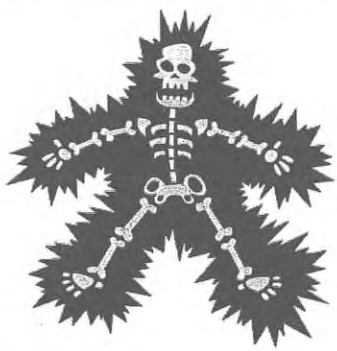
Electrocuted?

- Why doesn't electrosurgery shock people?



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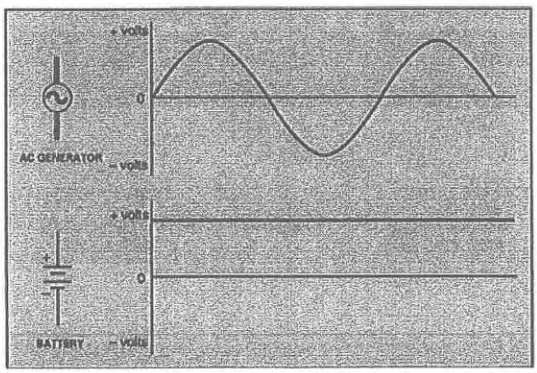
The Answer: Radio Freq AC

Alternating Current

AC

DC



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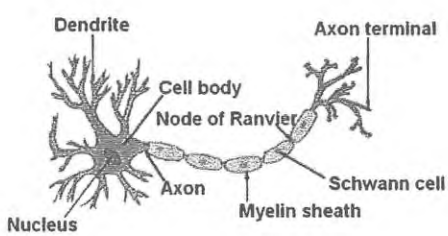
The Nervous System

Neurons (the copper wires of the body)

Structure of a Typical Neuron



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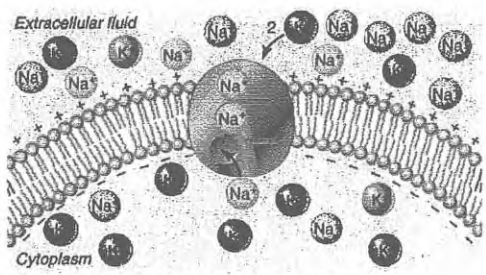
Sodium / Potassium Pump



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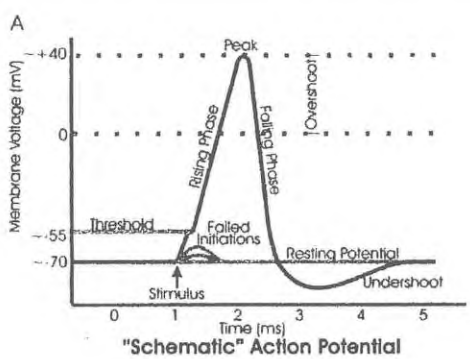
The Pump is Slow



"Schematic" Action Potential

Generator: 400 kHz
Each cycle = 2.5µS

Wall Plug: 60 Hz
Each cycle = 17mS

Neuron Cycle = 4mS

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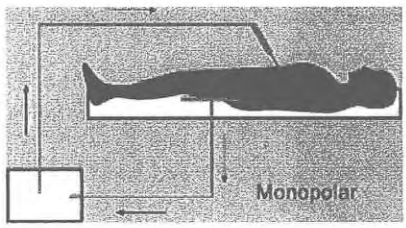
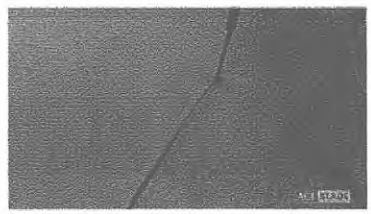
Cutting at the Surgical Site Only

- If current is travelling through the entire body, why does it only cut at the active electrode?





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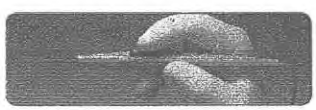
Current Density

- The current enters the body at one point, but travels out through a large pad.
- This is similar to a pressure washer.



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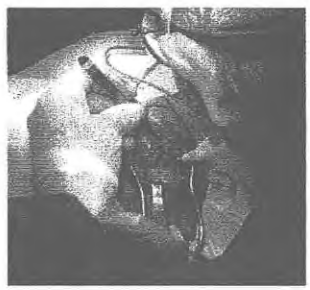
Current Density

- Increase the current density and you increase the surgical effect.



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What are the different modes?

- Ace
- Cut
- Coag
- Blend
- Bipolar

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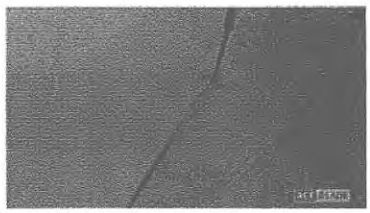
Cut

- The purpose of cut is to heat up cells so that their cytoplasm boils and the cell ruptures.



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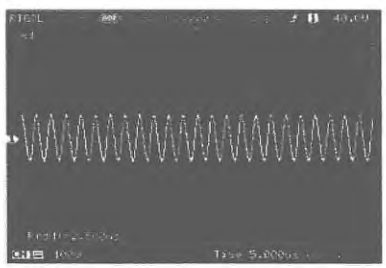
Cut Waveform

- The Cut Wave form is a sine wave. It continually applies power and ruptures cells.



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Cut Power Curves

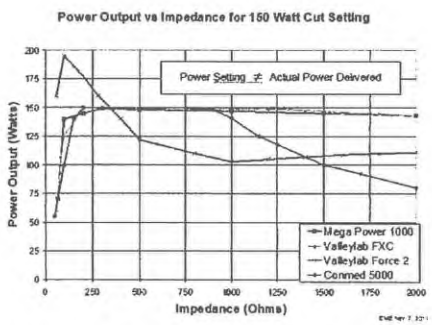

Figure 1 - Manufacturer Published Power Output versus Impedance Graphs

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Coag

- The purpose of Coag is to heat a large area and dry out blood.

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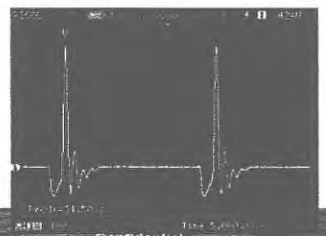
Coag Waveform

Coag bursts pulses for two reasons.

1. To let tissue cool and prevent penetration into the tissue.
2. To get larger voltages to encourage sparking



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Coag Power Curves

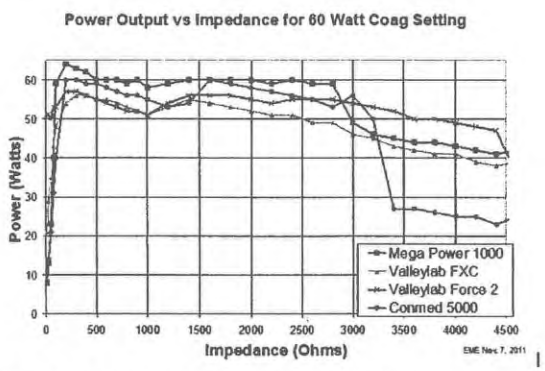

Figure 3 - Example of Actual Power Output versus Impedance Graphs

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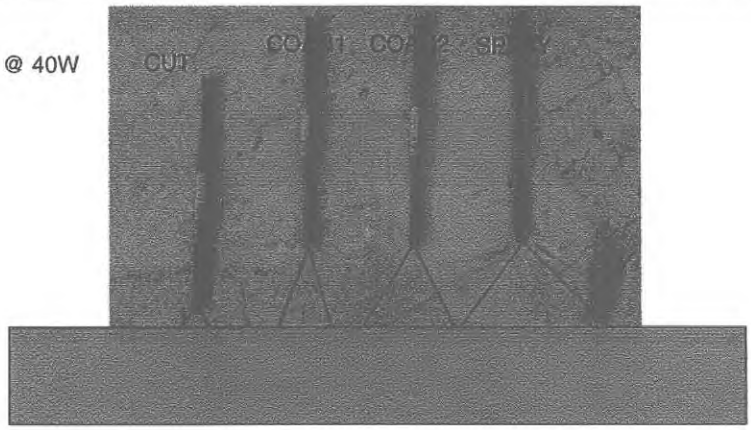
Cut Vs Coag

all @ 40W



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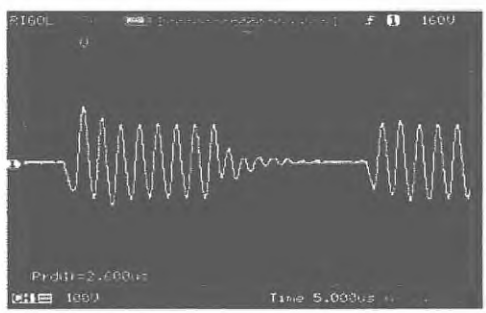
Blend

- Blend combines Cut and Coag.



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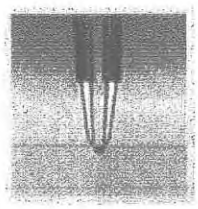
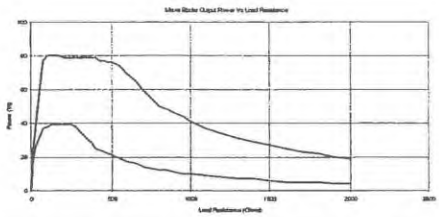
Bipolar

- Bipolar returns the current at the surgical site.
- Bipolar reduces power as the tissue dries.





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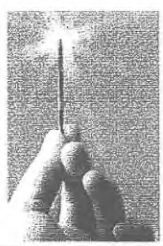
ACE (A better cut)

- Two requirements for ACE

1. A special blade
2. Special power algorithms



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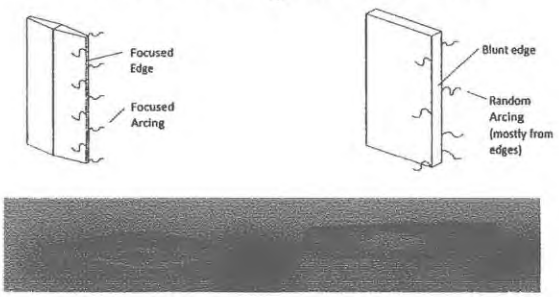
The ACE Blade

ACE blades have a patented geometry that naturally funnels (or focuses) the electrosurgical current



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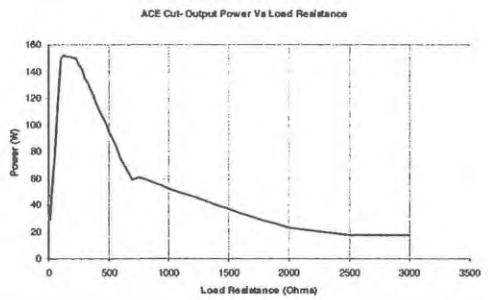
ACE Power Curves

- Power goes down once the tissue has been cut.



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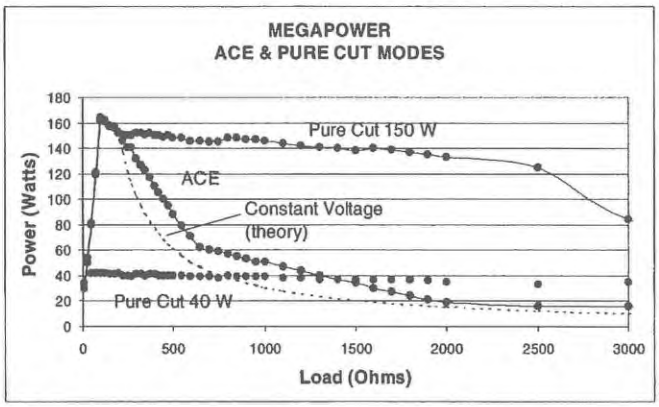
Power Curves (Cut and ACE)



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Generator Specifications

Output Power Characteristics

Mode	Power (Watts)	Output Tolerance * (Rated Load)	Rated Load (Ohms)	Maximum Open Circuit Voltage (Vp-p)	Operating Frequency (Rated Load)	Crest Factor Nominal @ (Rated Load)
Monopolar CUT						
ACE Cut	150	20%	200	1500	400kHz	1.6
Pure Cut	300	20%	300	3000	400kHz	1.6
Blend	200	20%	300	4000	400kHz	3.0
Monopolar COAG						
COAG 1	120	20%	500	5000	2.5µs Pulse @ 32kHz	6.9
COAG 2	120	20%	500	5000	2.5µs Pulse @ 30kHz	7.1
Spray	120	20%	500	6000	2.5µs Pulse @ 22kHz	8.0
Bipolar						
Micro	80	20%	100	360	400kHz	1.6
Macro	80	20%	100	760	400kHz	1.6

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Return Pads

Three Basic Kinds

1. Single Plate Pad Electrode
2. Dual Plate Pad Electrode
3. Mega Soft

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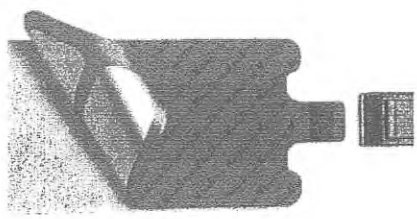
Dual Pads

- Dual Plate Pads are used to monitor the pad connection to the patient.



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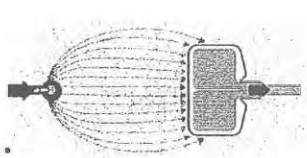
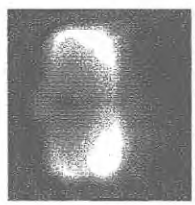
Pads and Edge Effects

When more current comes into a particular edge this is called an edge effect. This can lead to unbalanced heating and burns.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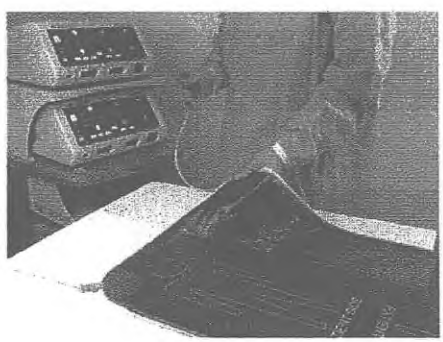
The Mega Soft

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Capacitively Coupled

- The Mega Soft connects the patient to the return through a capacitance.
- The capacitance is proportional to the area of the patient in contact with the pad.
- Prevents burns due to lack of contact.
- Prevents edge effects.

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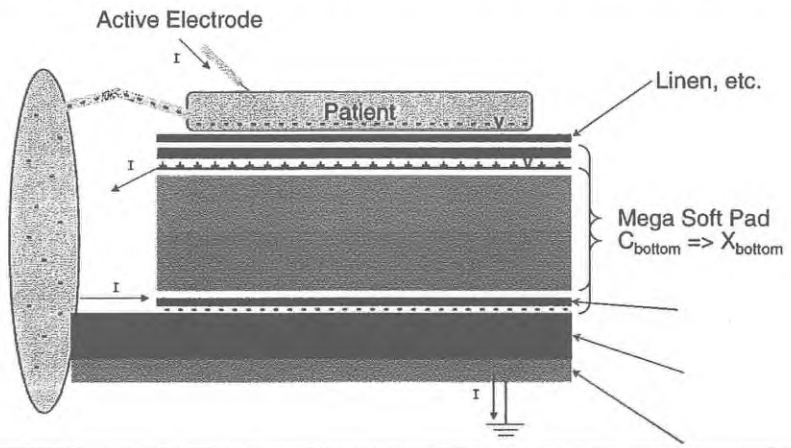
Mega Soft Setup



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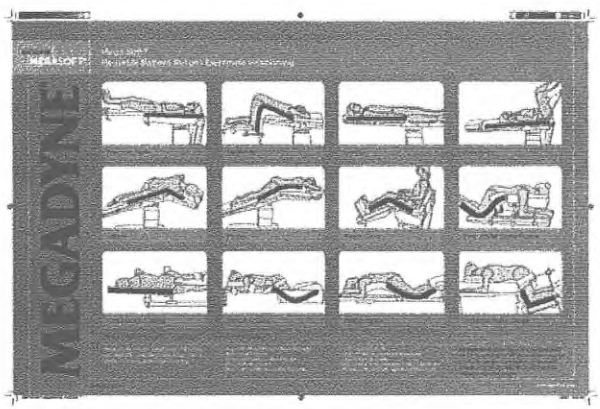
Mega Soft Positions



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Questions

- Any Questions?

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More Terms

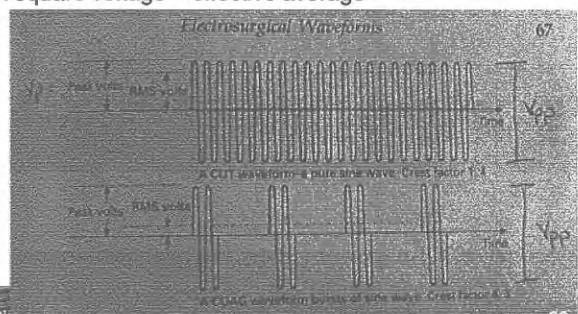
* Voltage

V_{pp} = peak-to-peak voltage – lowest negative to highest voltage

V_p = peak voltage – highest voltage away from zero (V_{pp} estimate = 2 x V_p)

V = V_{rms} = root mean square voltage – effective average

CF = V_p / V_{rms}



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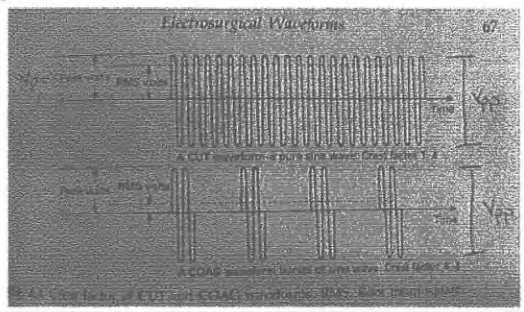
Electricity

* Voltage

(Example: home voltage)

120V = 120V_{rms} = 170Vp = 340Vpp

CF = 170/120 = 1.4)



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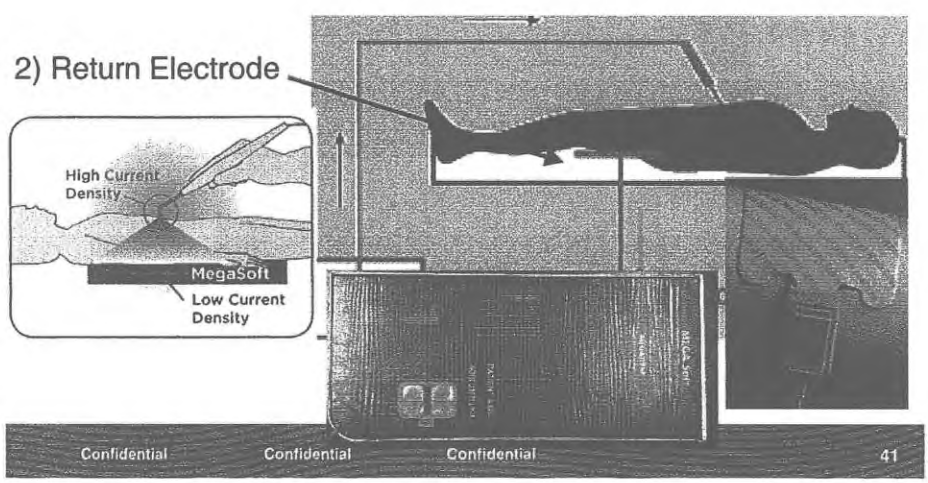
Electrosurgery - Overview



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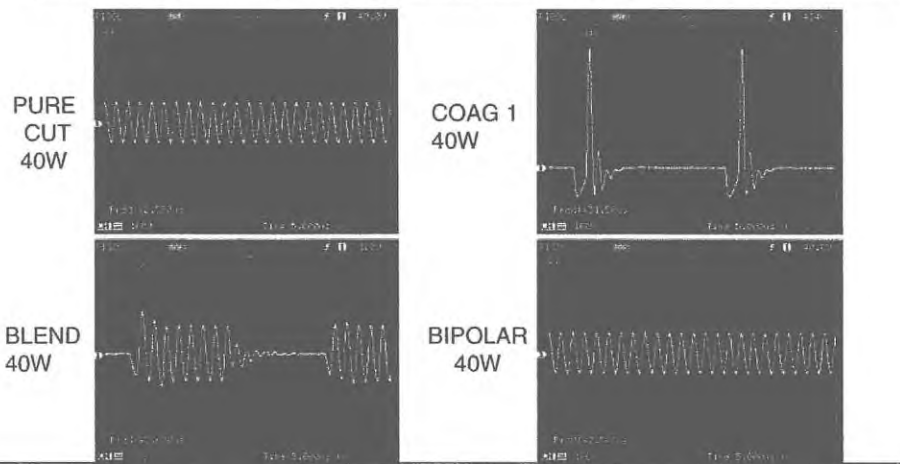
Waveforms



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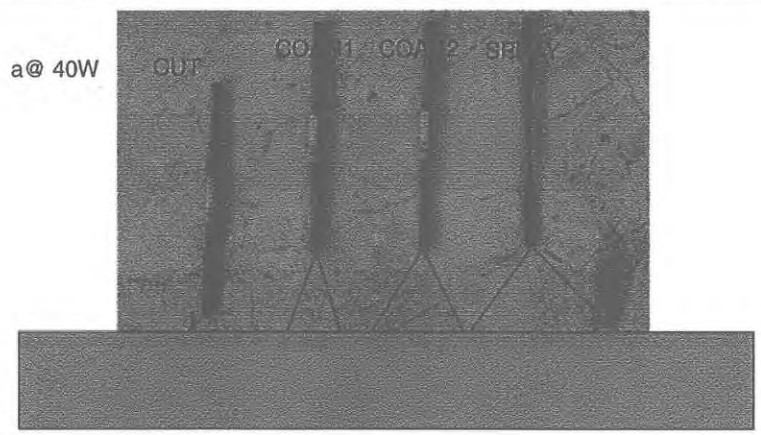
Waveforms



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Power Curves

ESU Output

Most ESUs (including the Mega Power) have modes that regulate power output:

1) Constant Power Output vs Resistive Load (e.g., Pure Cut or Standard Coag), or

2) Constant Voltage Output vs Resistive Load (e.g., ACE mode, some Erbe modes).

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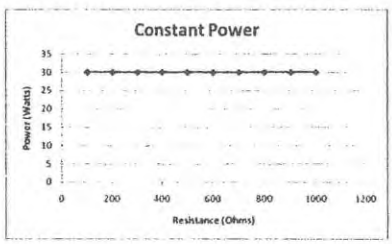
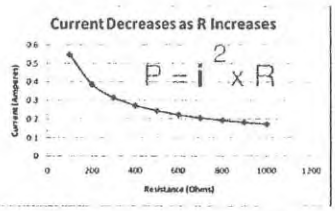
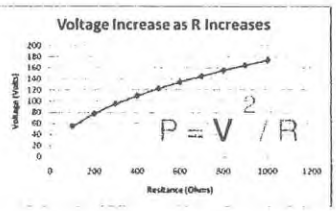
Power Curves

CONSTANT POWER







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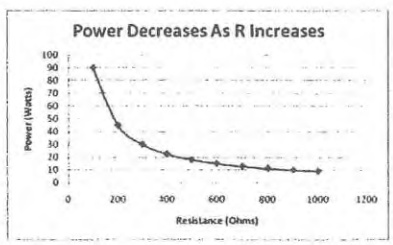
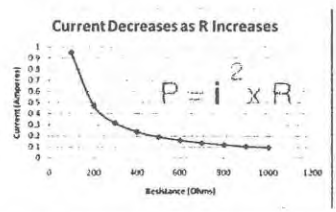
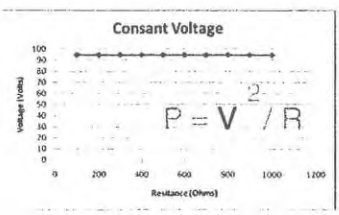
Power Curves

CONSTANT VOLTAGE







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Power Curves

Power Modes

As a safety feature to prevent unexpected power delivery spikes, simultaneous activation of multiple instruments is not possible on the ForceTriad energy platform.

Monopolar Modes

The ForceTriad energy platform produces five different modes of power output

Cut Modes

Pure cut provides a clean, precise cut in any tissue with little or no hemostasis

Blend cut is a conventional blended wave form that provides slower cutting and additional hemostasis

ValleyLab Mode

ValleyLab mode is a unique combination of hemostasis and dissection and allows the user to slow down for more hemostasis and speed up for faster dissection. Thermal spread is equal or superior to Cut or Blend modes

Coag Modes

Fulgurate coagulation is made by sparking from the active electrode through air to the patient tissue. Since sparks may spray unpredictably from the electrode during fulguration, extra vigilance for delicate tissue or in confined areas can complicate surgery. Accidental sparking to adjacent areas can occur as tissue at the surgical site dries and becomes more resistant to current flow

1-8 *ForceTriad™ User's Guide*

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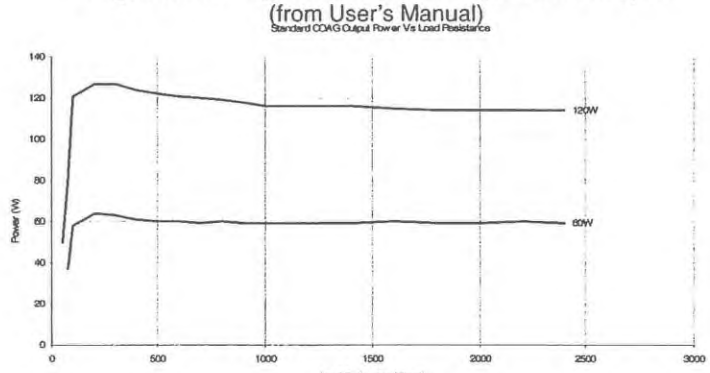
ESU Technical Background

Mega Power Coagulation Standard Output Power Graphs
(from User's Manual)



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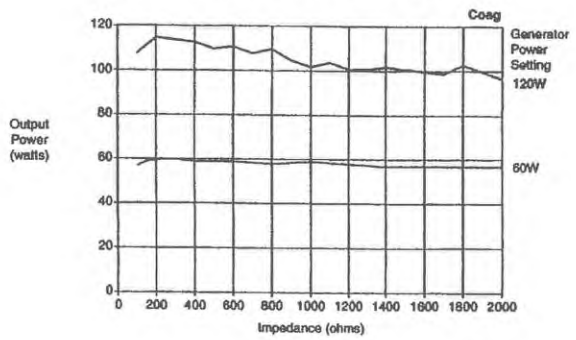
ESU Technical Background

Competitive Generator - Coagulation Standard Output Power Graphs
(from their User's Manual – Force FX C)



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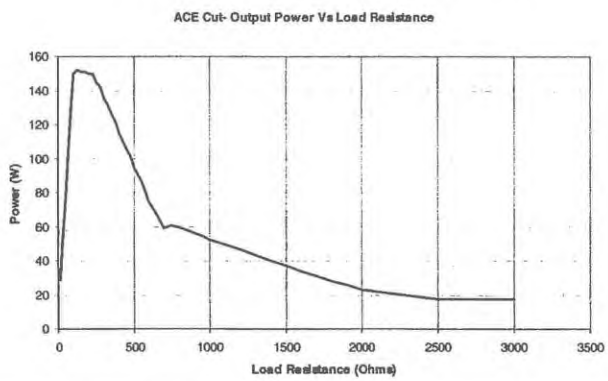
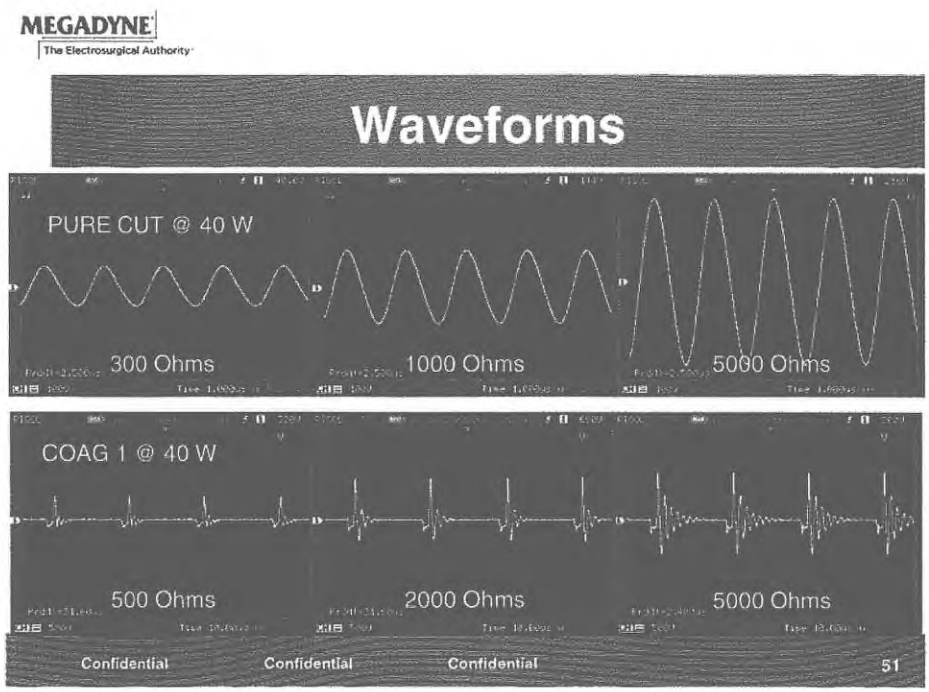
ESU Technical Background

ACE Power Graphs (from User's Manual)

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Waveforms
PURE CUT @ 40 W
300 Ohms
1000 Ohms
5000 Ohms
COAG 1 @ 40 W
500 Ohms
2000 Ohms
5000 Ohms
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Confidential
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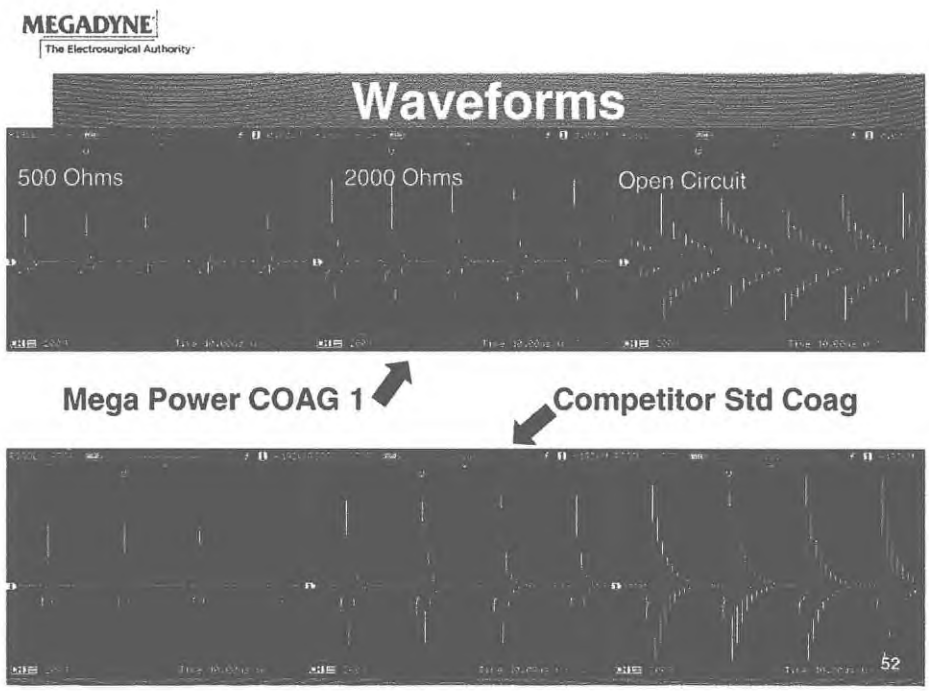
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The Electrosurgical Authority
Waveforms
500 Ohms
2000 Ohms
Open Circuit
Mega Power COAG 1
Competitor Std Coag
52

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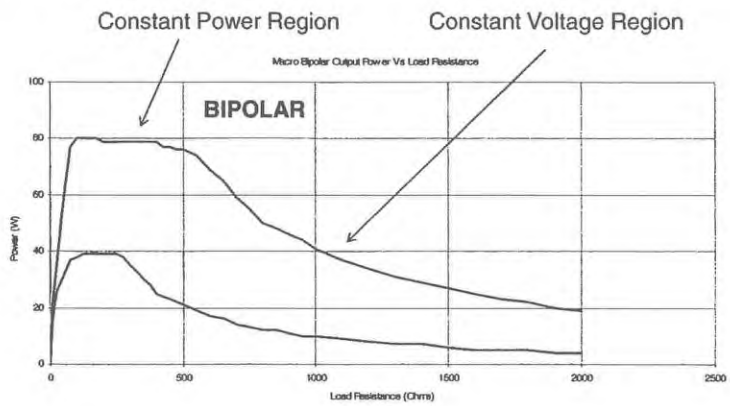
ESU Technical Background



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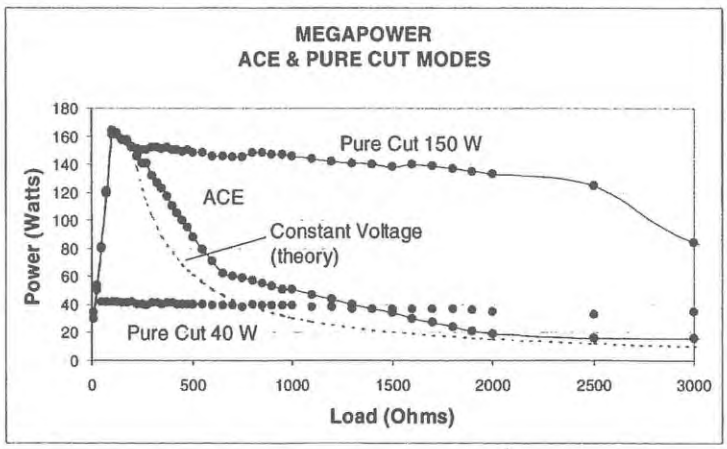
Mega Power Specifications



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Mega Power Specifications

Output Power Characteristics

Mode	Power (Watts)	Output Tolerance * (Rated Load)	Rated Load (Ohms)	Maximum Open Circuit Voltage (Vp-p)	Operating Frequency (Rated Load)	Crest Factor Nominal @ (Rated Load)
Monopolar CUT						
ACE Cut	150	20%	200	1500	400kHz	1.6
Pure Cut	300	20%	300	3000	400kHz	1.6
Blend	200	20%	300	4000	400kHz	3.0
Monopolar COAG						
COAG 1	120	20%	500	5000	2.5µs Pulse @ 32kHz	6.9
COAG 2	120	20%	500	5000	2.5µs Pulse @ 30kHz	7.1
Spray	120	20%	500	6000	2.5µs Pulse @ 22kHz	8.0
Bipolar						
Micro	80	20%	100	360	400kHz	1.6
Macro	80	20%	100	760	400kHz	1.6

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Mega Power Specifications

Power Output vs Impedance for 160 Watt Cut Setting

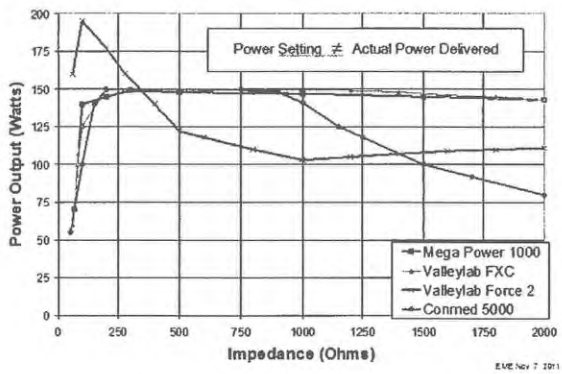

Figure 1 - Manufacturer Published Power Output versus Impedance Graphs

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Mega Power Specifications

Power Output vs Impedance for 60 Watt Coag Setting

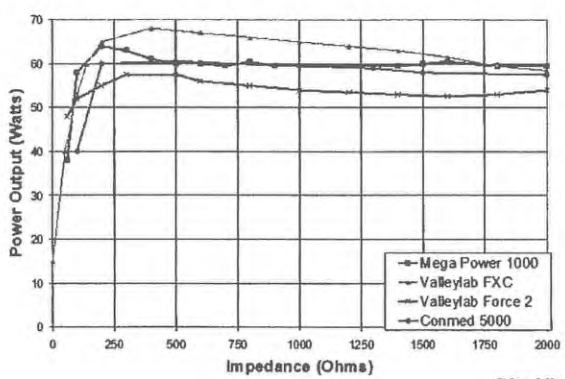

Figure 2 - Manufacturer Published Power Output versus Impedance Graphs

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Mega Power Specifications

Power Output vs Impedance for 60 Watt Coag Setting

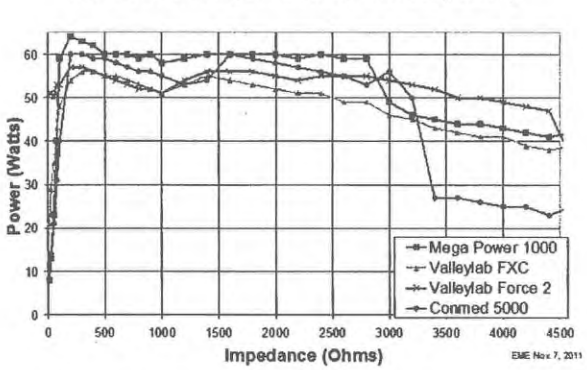

Figure 3 - Example of Actual Power Output versus Impedance Graphs

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Mega Power Specifications

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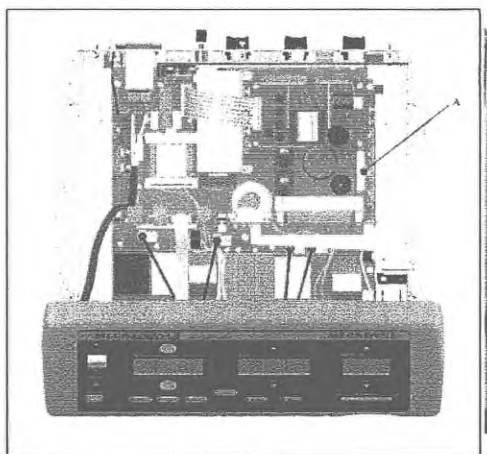
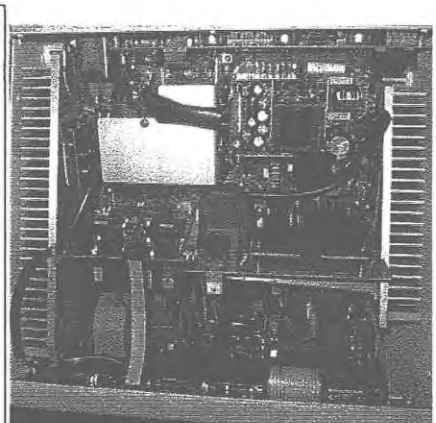
Let's Take a Peek Inside





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Mega Power – what is inside?

1) General Purpose Generator
- CUT Modes
- COAG Modes
- BIPOLAR Modes

2) Advanced Cutting Effect
- Smart Cutting Mode

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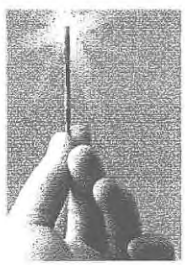
Advanced Cutting Effect

ACE BLADE



Special Mode

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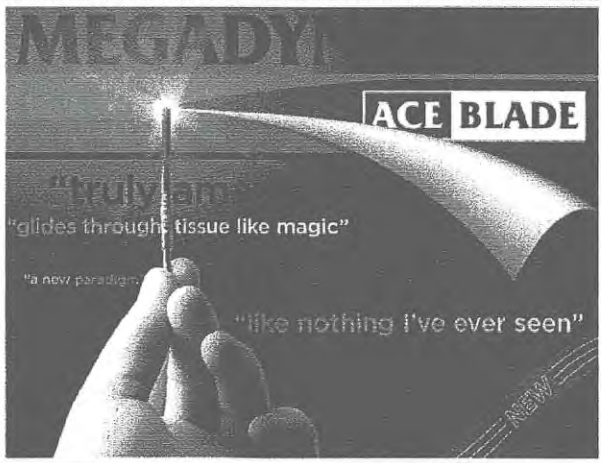
Advanced Cutting Effect



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Advanced Cutting Effect

How Does ACE Work?

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Advanced Cutting Effect

How Does ACE Work?

Two Keys

1) ACE Mode (generator)

+

2) ACE Blade (blade shape)

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Let's Look at ACE Mode

Background ....

Most Modern Day Generators try and maintain Constant Power Output

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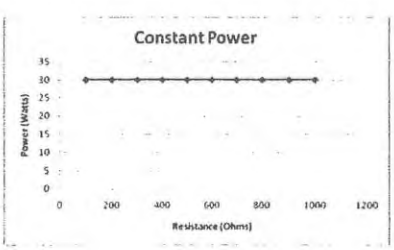
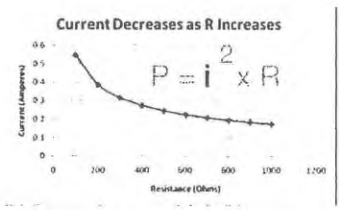
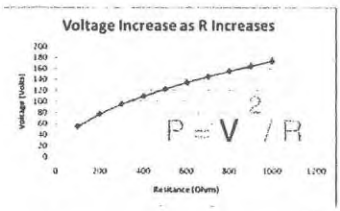
ESU Technical Background

CONSTANT POWER







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Advanced Cutting Effect

ACE Mode is DIFFERENT!

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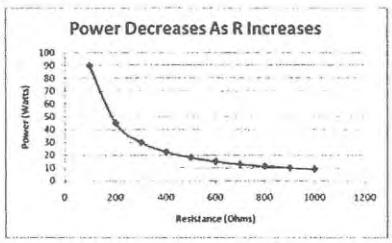
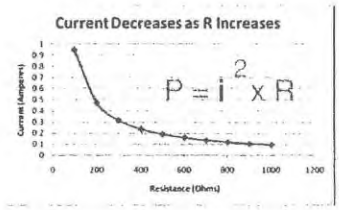
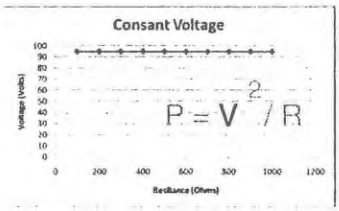
ESU Technical Background

CONSTANT VOLTAGE







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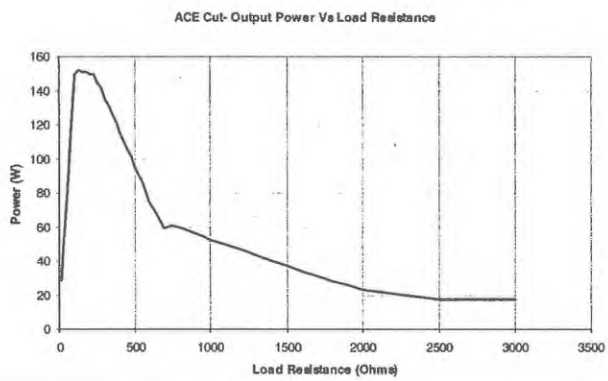
ESU Technical Background

ACE Power Graphs (from User's Manual)



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Advanced Cutting Effect

Thought Experiment

How do we measure Power?

(what units are used)

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For Electrosurgical Generators

Power is measured in WATTS

(metric units)

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For Electrosurgical Generators

Power is measured in WATTS

(metric units)

How about Power in automobiles – what units?

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Power is measured in

Horse Power

1 Horse Power = 746 Watts

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Thought Experiment

What if we have an auto putting out 100 HP – how fast will it go?

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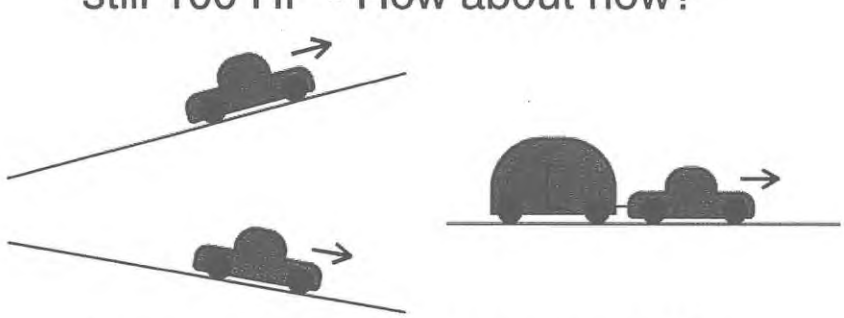
Advanced Cutting Effect

still 100 HP - How about now?



Constant Power = Different Effect

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Advanced Cutting Effect

for ACE

the only effect we want is

*** CLEAN CUTTING ***
(no thermal damage, no drag)

regardless of Load!

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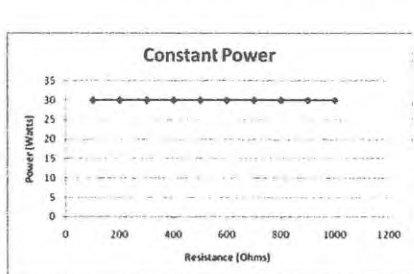
Advanced Cutting Effect

Back to Thought Experiment:



Using a Constant Power Mode, would one expect the same surgical effect if you changed blade depth or tissue type?

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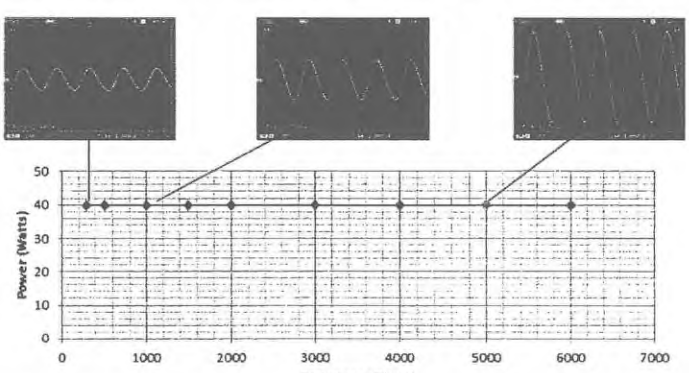
Advanced Cutting Effect

With Constant Power, Voltage Increases as Resistance Increases



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Advanced Cutting Effect

Only EFFECT we want with ACE

by
nes,
This
a GI

riod
the
the
final
) + 0
12-1

hemostasis.

Electrosurgical generators may deliver monopolar current to produce electrosurgical cutting and/or coagulation. Electrosurgical cutting is achieved by a high voltage (>200 V) continuous current. This cutting effect begins with micro-electric arcs that are concentrated at the area of application via an active electrode (accessory device). This produces a rapid rise in the internal temperature of cells, causing intracellular water to boil and the cells to burst. This path of disrupted cells creates an electrosurgical cut. Dissipation of heat to the tissue at the margins of the cut produces a zone of coagulation along the cut edge.

VOLUME 58, NO. 5, 2003

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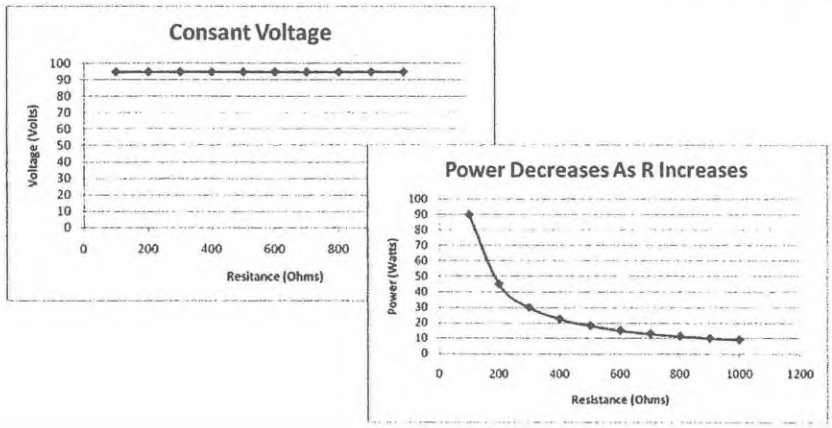
Advanced Cutting Effect



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Advanced Cutting Effect

- ACE mode is actually not as simple as Constant Voltage.
- As the resistive load increases, there are other losses in the electrosurgical circuit that rob voltage from the surgical site.
- The ACE mode uses a propriety feedback algorithm to adjust the Mega Power to maintain constant voltage at the surgical site, thus compensating the output for other voltage losses in the system as impedance dynamically changes.

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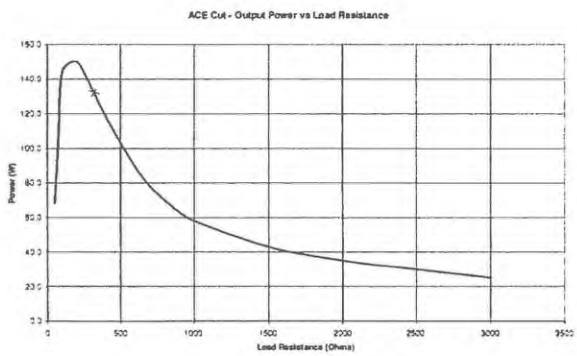
Advanced Cutting Effect

Ace Power Curve Graphs



ACE - Power Output vs Power Max

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Advanced Cutting Effect

If you do not get it right –

- Too much Voltage = thermal damage
- Not enough Voltage = drag
- Right amount of Voltage = ACE effect

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Advanced Cutting Effect

Two Keys to ACE

The other Half of the

ACE Effect

comes from the blade geometry

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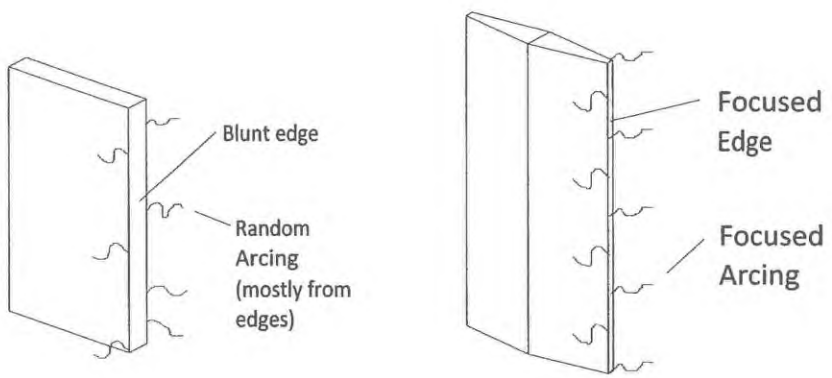
Advanced Cutting Effect



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Advanced Cutting Effect

ACE blades have a patented geometry that naturally funnels (or focuses) the electrosurgical current

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Advanced Cutting Effect

Competitive Advanced Surgical Cutters

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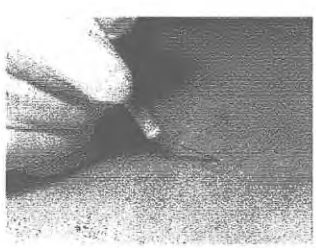
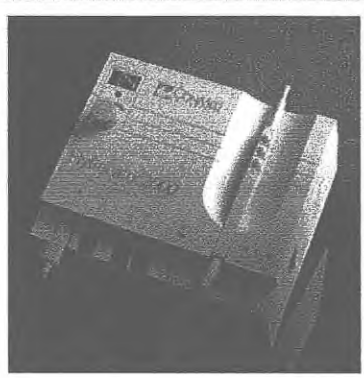
Other RF-based Generators

Hyfrecators





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QUESTIONS?

TRIAL LAKE, UTAH AUG 2012

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Mega Power Service Center Repair Form, New Faceplate

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Mega Power Information	
RGA	16780
Serial Number	17502700 1
RoHS	☐ Leaded ☑ RoHS

PART A: Equipment Calibration

Record calibration data:

Table A1: Calibration Data

Equipment	Brand	Model Number	Serial Number	Cal. Due Date
ESU Analyzer	FLUKE	9A-ESII	202407	18 Jun 19
Digital Multi-meter	FLUKE	179	37220327	1/31/2020
Safety Analyzer	FLUKE	ESA 620	2543060	11/30/2019

*All testing must be performed with calibrated equipment. Do not proceed with final testing if any piece of equipment is not current with calibration schedule.

Part B: Investigation and Repair

Section 1: Before the Mega Power is disassembled

1) With the ESU analyzer set to 300 Ohms, measure the output power with the Mega Power set to PURE CUT and the power set to 30 W, 75 W, and 300 W. Record the results in Table B1.
2) With the ESU analyzer set to 500 Ohms, measure the output power with the Mega Power set to COAG 1 and the power set to 30 W, 50 W, and 120 W. Record the results in Table B2.
3) Using Field Calibration Software, 1410010-01, download, print, and attach the error logs from the master processor and watch dog processor.

Table B1: PURE CUT

Setting		Power Output
300 Ω	30 W	30 W
300 Ω	75 W	75 W
300 Ω	300 W	298 W

Table B2: COAG 1

Setting		Power Output
500 Ω	30 W	30 W
500 Ω	50 W	50 W
500 Ω	120 W	120 W

Section 2: Investigation

Table B3: Investigation

The Unit is good working. Loaner return

Initial/Date: KS 02/27/19

Document Number	Revision	Previous Number	Page
CS-FRM-034	004	N/A	1 of 11

Mega Power Service Center Repair Form, New Faceplate

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Section 3: Repair Actions

Table B4: Repair Actions	
None	
	Initial/Date: lcs 02/27/2019

Table B5: Replacement Parts (Confirm all replacement parts with CS-FRM-038)				
Part Number	Description	PCB Number	Lot Number	QTY

lcs 02/27/2019

Ship Printed Circuit Boards to Megadyne	
Ship replaced parts to Megadyne for evaluation. Please note the RGA on the outside of the shipping box.	Megadyne Medical Product, Inc. Attn: Service and Repair 11506 South State St. Draper, Utah 84020 USA

Table B6: Shipped to Megadyne		
Part Number	Description	PCB Number (Where Applicable)

lcs 02/27/2019

Shipped By:	lcs 02/27/2019	Date:	
Tracking Number:			

Mega Power Service Center Repair Form, New Faceplate

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Once the repair work has been completed and the Mega Power has been reassembled, test per Part C through Part G.

PART C: Display Test

Section 1: Power-Up Test

Turn on the Mega Power. Once the Mega Power has completed the POST test check the appropriate boxes in Table C1.

Table C1: Power-Up Test

Pass	Fail	Criteria
☑	☐	Power Switch is illuminated
☑	☐	PURE CUT LED is illuminated
☑	☐	COAG 1 LED is illuminated
☑	☐	MICRO LED is illuminated
☑	☐	No errors are displayed
☑	☐	All display segments show dashes.
☑	☐	CQM Alarm LED is red and alarm tone sounded (Without a return pad connected to the Mega Power)

Section 2: Display Functionality

Table C2: Display Functionality

Pass	Fail	Criteria
☑	☐	Press each mode button and verify that the appropriate LED button lights up.
☑	☐	Press the up arrow button on each of the three channels and verify power goes up.
☑	☐	Press the down arrow button on each of the three channels and verify power goes down.
☑	☐	Press the Bipolar Tone button and verify the LED lights up.
☑	☐	Plug in the Monopolar Return Test Cable and verify CQM alarm LED turns green.
☑	☐	Set all power settings to 1. Turn power off. Turn power on. Press recall and verify power setting of 1 is displayed for each mode.

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PART D: Monopolar Output Tests

Section 1: **Monopolar A**, Power Outputs and Crest Factors

Procedure:

1) Set the ESU analyzer to the loads called out in Table D1.
2) Set the Mega Power to the power settings (PSET) and modes called out in Table D1.
3) Measure and record the appropriate output wattage and crest factors where indicated.
4) Verify Mega Power Tones.

Table D1: Monopolar A, Power Outputs and Crest Factors

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)	Crest Factor	Criteria
300	Pure	1	2	0 - 5		
300	Pure	10	9	5 - 15		
300	Pure	150	149	120 - 180		
300	Pure	300	299	240 - 360	1.5	1.3 – 1.9
300	Blend	1	2	0 - 5		
300	Blend	10	10	5 - 15		
300	Blend	100	103	80 - 120		
300	Blend	200	209	160 - 240	2.8	2.5 – 3.5
300	ACE		131	108 - 162	1.5	1.3 – 1.9
Verify Tone for CUT: ☑Pass ☐Fail				Verify volume can be adjusted: ☑ Pass ☐Fail		
500	Coag 1	1	2	0 - 5		
500	Coag 1	10	10	5 - 15		
500	Coag 1	60	60	48 - 72		
500	Coag 1	120	120	96 - 144	6.5	6.4 – 7.4
500	Coag 2	1	1	0 - 5		
500	Coag 2	10	9	5 - 15		
500	Coag 2	60	60	48 - 72		
500	Coag 2	120	121	96 - 144	6.7	6.6 – 7.6
500	Spray	1	1	0 - 5		
500	Spray	10	9	5 - 15		
500	Spray	60	60	48 - 72		
500	Spray	120	122	96 - 144	7.8	7.7 – 8.7
Verify Tone for COAG: ☑Pass ☐Fail						

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Section 2: **Monopolar B,** Power Outputs and Crest Factors

Procedure:

1) Set the Mega Power up so that Monopolar B is connected to the ESU Analyzer
2) Ensure that the activation button activates the Monopolar B electrode.
3) Set the ESU analyzer to the loads called out in Table D2.
4) Set the Mega Power to the power settings (PSET) and modes called out in Table D2.
5) Measure and record the appropriate output wattage and crest factors where indicated.
6) Verify Mega Power tones.

Table D2: Monopolar B, Power Outputs and Crest Factors

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)	Crest Factor	Criteria
300	Pure	1	2	0 - 5		
300	Pure	10	9	5 - 15		
300	Pure	150	150	120 - 180		
300	Pure	300	300	240 - 360	1.5	1.3 – 1.9
300	Blend	1	2	0 - 5		
300	Blend	10	10	5 - 15		
300	Blend	100	104	80 - 120		
300	Blend	200	210	160 - 240	2.8	2.5 – 3.5
300	Ace		131	108 - 162	1.5	1.3 – 1.9
		Verify Tone for Cut:	☑Pass	☐Fail		
500	Coag 1	1	2	0 - 5		
500	Coag 1	10	10	5 - 15		
500	Coag 1	60	56	48 - 72		
500	Coag 1	120	120	96 - 144	6.5	6.4 – 7.4
500	Coag 2	1	1	0 - 5		
500	Coag 2	10	9	5 - 15		
500	Coag 2	60	57	48 - 72		
500	Coag 2	120	121	96 - 144	6.6	6.6 – 7.6
500	Spray	1	1	0 - 5		
500	Spray	10	9	5 - 15		
500	Spray	60	60	48 - 72		
500	Spray	120	117	96 - 144	7.8	7.7 – 8.7
		Verify Tone for COAG:	☑Pass	☐Fail		

Mega Power Service Center Repair Form, New Faceplate

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Section 3: **Monopolar B** Power Curves

Procedure:

1) Set the ESU analyzer to the loads called out in Table D3 and Table D4.
2) Set the Mega Power to the power settings and modes called out in Table D3 and Table D4.
3) Measure and record the appropriate output wattage where indicated.

Table D3: CUT Power Curves

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)
100	ACE		159	120 – 180
200	ACE		151	120 – 180
300	ACE		See Table D2	108 – 162
500	ACE		92	76 – 114
1,000	ACE		50	42 – 64
2,000	ACE		22	18 – 28
100	Pure	300	155	105 – 175
200	Pure	300	269	240 – 360
300	Pure	300	See Table D2	240 – 360
500	Pure	300	295	240 – 360
1,000	Pure	300	286	240 – 360
2,000	Pure	300	195	160 – 240
100	Blend	200	96	75 – 125
200	Blend	200	204	160 – 240
300	Blend	200	See Table D2	160 – 240
500	Blend	200	203	160 – 240
1,000	Blend	200	190	160 – 240
2,000	Blend	200	166	130 – 190

Table D4: COAG Power Curves

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)
100	COAG 1	120	117	96 – 144
200	COAG 1	120	129	96 – 144
500	COAG 1	120	See Table D2	96 – 144
1,000	COAG 1	120	107	92 – 140
2,000	COAG 1	120	118	90 – 135
100	COAG 2	120	121	96 – 144
200	COAG 2	120	129	96 – 144
500	COAG 2	120	See Table D2	96 – 144
1,000	COAG 2	120	113	92 – 138
2,000	COAG 2	120	110	86 – 129
100	Spray	120	123	96 – 144
200	Spray	120	128	96 – 144
500	Spray	120	See Table D2	96 – 144
1,000	Spray	120	103	90 – 135
2,000	Spray	120	101	80 – 120

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PART E: Bipolar Output Tests

Section 1: **Bipolar** Power Outputs and Crest Factors

Procedure:

1) Set the Mega Power up so that Bipolar is connected to the ESU Analyzer
2) Ensure that footswitch activates the Bipolar electrodes.
3) Set the ESU analyzer to the loads called out in Table E1.
4) Set the Mega Power to the power settings (PSET) and modes called out in Table E1.
5) Measure and record the appropriate output wattage and crest factors where indicated.
6) Verify Mega Power Tones.

Table E1: Bipolar, Power Outputs and Crest Factors

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)	Crest Factor	Criteria
100	Micro	1	1	0 - 5		
100	Micro	10	10	5 - 15		
100	Micro	40	39	32 - 48		
100	Micro	80	82	64 - 96	1.5	1.4 – 2.0
100	Macro	1	1	0 - 5		
100	Macro	10	9	5 - 15		
100	Macro	40	39	32 - 48		
100	Macro	80	81	64 - 96	1.5	1.4 – 2.0
Verify normal tone*: ☑Pass ☐Fail			Verify pulsing tone*: ☑Pass ☐Fail			

* When bipolar is activated the Mega Power displays the estimated current flow in the current flow indicator window. In addition to the current flow indicator, the Mega Power can be set to indicate the current with an audio alarm. The current is proportional to the pulsing rate of the audio tone. By pressing the bipolar tone button (the button to the right of the current flow window) the bipolar alarm will toggle between a continuous tone and a pulsing tone. Verify that both the continuous and the pulsing tones are operational in the Macro Mode with a 100 Ω load, and the Mega Power set to 80 W.

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Section 2: **Bipolar** Power Curves

Procedure:

1) Set the ESU analyzer to the loads called out in Table E2.
2) Set the Mega Power to the power settings (PSET) and modes called out in Table E2.
3) Measure and record the appropriate output wattage where indicated.

Table E2: BIPOLAR Power Curves

Load (Ω)	Mode	PSET (watts)	Output (Watts)	Criteria (Watts)
50	Micro	80	66	46 – 68
75	Micro	80	81	60 – 90
100	Micro	80	See Table E1	64 – 96
200	Micro	80	96	64 – 96
650	Micro	80	8	5 – 15
1000	Micro	80	5	0 – 10
50	Macro	80	66	46 – 68
75	Macro	80	81	60 – 90
100	Macro	80	See Table E1	64 – 96
200	Macro	80	96	64 – 96
500	Macro	80	42	38 – 58
1000	Macro	80	28	20 – 32

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PART F: Isolation Voltages and Contact Quality Monitor (CQM) Test

Section 1: Isolation Voltages

Table F1: Isolation Voltages

Channel	Directions	Voltage (V)	Criteria (V)
Monopolar A	With a digital multi-meter measure the voltage across the active electrode and one of the hand switching inputs.	11.5	> 10.5
Monopolar B	With a digital multi-meter measure the voltage across the active electrode and one of the hand switching inputs.	11.7	> 10.5
Bipolar	With a digital multi-meter measure the voltage across the active electrode and the ground output.	12.05	> 10.5

Section 2: Verify Potentiometer, PN: 2010127-02, Calibration

Procedure:

1) Set the potentiometer to resistances called out in Table F2.
2) With a digital multi-meter measure the voltages across the potentiometer.

Table F2: Verify Potentiometer Calibration

Potentiometer Setting	Measured Resistance (Ω)	Criteria (Ω)
10 Ω	10.1	9 - 11
50 Ω	49.9	49 – 51
200 Ω	199.1	196 - 204

Section 3: CQM Test

Table F3: CQM Test

Start up		
With the Mega Power off, connect and set the potentiometer to 50 Ω.	CQM is green when power up is complete:	☑Pass ☐Fail
Lower CQM Alarm Trip Point		
Set the potentiometer to 0 Ω and connect to Mega Power. Raise the resistance until CQM turns red.	CQM turns green:	☑Pass ☐Fail
	Resistance: 16	< 20 Ω
Midlevel CQM Trip Point		
Unplug the potentiometer. Set the potentiometer to 50 Ω and reconnect. Raise the resistance until CQM turns red.	CQM turns green:	☑Pass ☐Fail
	Resistance: 65	58 – 72 Ω
Upper CQM Alarm Trip Point		
Unplug the potentiometer. Set the potentiometer to 200Ω and reconnect. Lower the resistance until CQM turns green.	CQM stays red:	☑Pass ☐Fail
	Resistance: 136	122 – 148 Ω

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Mega Power Information	
RGA	16080
Serial Number	~~1608~~ 17502700 1

Keiki 02/27/19

PART G: Electrical Safety Test

Table G1: Protective Earth Connection to Chassis		
Protective Earth ground to outlet.		
Current Applied: 25 A	Impedance: 54	Criteria: < 200m Ω

Table G2: Enclosure Leakage Test 1		
Protective earth ground to power entry: ground open.		
Voltage applied: Mains	Current: 101	Criteria: 50 – 300 µA

Table G3: Enclosure Leakage Test 2		
Protective earth ground to power entry: neutral open, and ground open.		
Voltage applied: Mains	Current: 180.8	Criteria: < 1000 µA

Table G4: Enclosure Leakage Test 3		
Protective earth ground to power entry: neutral open, reverse polarity, and ground open.		
Voltage applied: Mains	Current: 190.7	Criteria: < 1000 µA

Table G5: Enclosure Leakage Test 4		
Protective earth ground to power entry: reverse polarity, and ground open.		
Voltage applied: Mains	Current: 101.5	Criteria: <1000 µA

Table G6: Patient Leakage		
All patient connections to power entry.		
Voltage applied: Mains	Current: 4.3	Criteria: < 10 µA

Technician Performing Electrical Safety Test	
The Mega Power has passed all tests stated in Sections G.	
Print: KOHEI SEKI	
Signature: K. Seki	Date: 02/27/2019

Mega Power Service Center Repair Form, New Faceplate

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PART H: Signatures

Technician Performing Tests	
All equipment used to perform final test was calibrated. The Mega Power has passed all tests stated in Sections C through Section G and packaged per ENG-WI-035.	
Print: CONTROL SYSTEM	
Signature: C. SEGL	Date: 02/20/2019

Megadyne Review	
The document has been reviewed. The test data is within the stated criteria.	
Print: BRUCE HEVELONE	
Signature: Bruce Hevelone	Date: 2-27-19

Megadyne Medical Products
11506 S. State St | Draper, UT 84020

Score: 9 . 10
Passing: 8/10 or better

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Mega Power 1000 Service Center Test

1) Rated load is the resistance at which ESU is tested. What is the rated load for:
   a. Pure Cut: 300
   b. Coag: 500
   c. Bipolar: 100

2) Mega Power Preventive Maintenance is performed with what form numbers:
   a. New Face Plate: CS-FRM-034
   b. Original Face Plate: CS-FRM-035

3) The CQM measures the Resistance between the two pads of a dual plate return electrode.

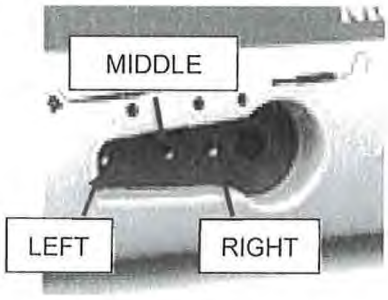
4) The power curves test measures power at different load(s) by means of an ESU analyzer

5) Crest Factor is calculated by the ESU analyzer by dividing the Peak Voltage by the RMS Voltage.

6) What two modes are found on the new face plate ESU, but not the old face plate ESU? MICRO and MACRO

Legal Entity
123 Street Address | Town, State, Zip

7) When connecting to the ESU Analyzer, which Monopolar Pin do you plug the red lead into (Left, Middle, or Right)? RIGHT



8) True or False: The Potentiometer 2010127-02 calibration needs to be verified before each use. YES

9) The ESU needs to be electrical safety tested to which test standard? IEC 60601-1

10) True or False: Fields can be left blank on the form if the information is unknown or does not apply. False

Print Technician Name: KOHEI SEKI

Signature: Kseki Date: 02/27/2019

Megadyne Review: [signature] Date: 2/27/2019

Certificate of Training

This certificate is presented to:

Kohei Seki

Johnson and Johnson, Service Center

In recognition for completing service training on Mega Power 1000

Trainer (Tyler Skinner) — Date: Aug. 19, 2019

Trainer (John Minuth) — Date: Aug. 19, 2019

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3.0 DOCUMENTATION SYSTEM

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DOCUMENTATION SYSTEM

Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

Re: 1000

Procedures, work instructions, and items that are non-product specific to 1000 already reside in the J&J Medical KK documentation system as they were previously qualified as a service center. Refer to section 3.0 of Factbook F-261 (EpiCenter document Number FB001103). Procedures, work instructions, and items that are product specific to the 1000 have been created and implemented into the J&J Medical KK service process and are listed below.

Megadyne Reference Documents

- 3000144-01 Megadyne Mega Power Field Calibration Manual
- MKT-LBL-063Megadyne Mega Power Trouble Shooting Guide
- 3000158-01 Megadyne Mega Power Electrosurgical Generator Operators Manual ~ *www.e-ifu.com*
- 3000159-01 Megadyne Mega Power Electrosurgical Generator Service Manual ~ *www.e-ifu.com*
- ENG-WI-035 Mega Power 1000 Packaging Instructions, Service and Repair
- ENG-WI-036 Mega Power 1000 Disassembly Instructions, Service and Repair
- ENG-WI-037 Mega Power 1000 Assembly Instructions, Service and Repair
- CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

4.0 EQUIPMENT INSTALLATION QUALIFICATION RESULTS

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EIQ RESULTS

Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

Re: 1000

All equipment necessary to perform service and repair activities on the Megadyne Mega Power 1000 Electrosurgical Generator have been installed at the J&J K.K. Medical Products Service and Repair Depot, Sukagawa, Japan location. Equipment Installation was conducted per Megadyne Protocol ENG-PRT-437 revision 001 and ENG-PRT-502 revision 001 (see attached).

As described in the service procedures, the product specific test equipment used for the repair and testing of the Megadyne Mega Power 1000 Electrosurgical Generator are as follows:

Custom
Mega Power 1900 Software Calibration Kit
Monopolar Footswitch (1400 or 1400J)
Bipolar Footswitch (1450 or 1450J)
Potentiometer (PN: 2010127-02)

Standard
Fluke QA-ESII Electrosurgery Analyzer (Reference F-124)
Yokogawa Digital Multimeter 733 (Reference F-07)
Kikusuiu Ground Bond Tester TOS6100 (Reference F-09)
Hioki Leak Current HiTester 3156 (Reference F-56)

The J&J K.K. Medical Products Service and Repair Depot personnel were trained and qualified to use the above-mentioned equipment as referenced in the training section of this Factbook.

The equipment can be found within the J&J K.K. Medical Products Service and Repair Depot calibration system where appropriate and custom tooling or equipment identified has been documented as installed for use. Installation Qualification (IQ) and Performance Qualification (PQ) of equipment was performed. The IQ/PQ stored in local J&J K.K. document control system represents the successful execution of test procedures which qualifies the test equipment being used as properly installed and in good working order.

Specification Sheets and calibration certificates for Standard Equipment listed above are attached to this Factbook.

Part of product testing includes performing electrical safety testing according to appropriate standards as outlined in the service documentation. The equipment used at J&J K.K. meets all applicable standards.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number ENG-PRT-473
	Installation Qualification for Mega Power 1000 Controlled by Service Centers	Revision: 001
		Page 1 of 2

Authored By: John Minuth

Table of Contents

1.0 References

1000 Mega Power Assembly

2.0 Attachments

Appendix A Protocol Results

3.0 Scope

This protocol is intended to be used with Mega Power 1000's used by service centers as a known good unit.

4.0 Purpose

Service Centers will receive a working Mega Power 1000 that can be used during the investigation of a failure. This installation protocol will be performed upon initial receipt of the Mega Power. It will also be performed if the Mega Power 1000 is disassembled and then reassembled.

5.0 Equipment

ESU Analyzer	Fluke, QA-ESII or equivalent
Digital Multi-meter	Fluke 289 or equivalent
Safety Analyzer	Fluke ESA620 or equivalent

6.0 Passing Criteria

All data acquired from Appendix A is required to be within the listed specification

7.0 Procedure

See Appendix A for Procedure

8.0 Results and Conclusions

Once Appendix A is completed, the document will be scanned and sent to SRINTL@Megadyne.com. They will be entered into the Service Center Fact Book.

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ENG-PRT-473: Appendix A

PART A: Equipment Calibration

Record calibration data:

Table A1: Calibration Data

Equipment	Brand	Model Number	Serial Number	Cal. Due Date
ESU Analyzer	Fluke	QA-ESII	300091	09/30/2020
Digital Multi-meter	Yokogawa	73302	1501471	03/31/2020
Safety Analyzer	Hioki	3156	151238345	11/30/2019

*All testing must be performed with calibrated equipment. Do not proceed with final testing if any piece of equipment is not current with calibration schedule.

PART A: Display Test

Section 1: Power-Up Test

Turn on the Mega Power. Once the Mega Power has completed the POST test check the appropriate boxes in Table A1.

Table A1: Power-Up Test

Pass	Fail	Criteria
☑	☐	Power Switch is illuminated
☑	☐	PURE CUT LED is illuminated
☑	☐	COAG 1 LED is illuminated
☑	☐	MICRO LED is illuminated
☑	☐	No errors are displayed
☑	☐	All display segments show dashes.
☑	☐	CQM Alarm LED is red and alarm tone sounded (Without a return pad connected to the Mega Power)

Section 2: Display Functionality

Table A2: Display Functionality

Pass	Fail	Criteria
☑	☐	Press each mode button and verify that the appropriate LED button lights up.
☑	☐	Press the up arrow button on each of the three channels and verify power goes up.
☑	☐	Press the down arrow button on each of the three channels and verify power goes down.
☑	☐	Press the Bipolar Tone button and verify the LED lights up.
☑	☐	Plug in the Monopolar Return Test Cable and verify CQM alarm LED turns green.
☑	☐	Set all power settings to 1. Turn power off. Turn power on. Press recall and verify power setting of 1 is displayed for each mode.

PART B: Monopolar Output Tests

Section 1: **Monopolar A**, Power Outputs and Crest Factors

Procedure:

1) Set the ESU analyzer to the loads called out in Table B1.
2) Set the Mega Power to the power settings (PSET) and modes called out in Table B1.
3) Measure and record the appropriate output wattage and crest factors where indicated.
4) Verify Mega Power Tones.
5) Verify that Error 219 does not get displayed.

Table B1: Monopolar A, Power Outputs and Crest Factors

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)	Crest Factor	Criteria
300	Pure	1	2	0 - 5		
300	Pure	10	10	5 - 15		
300	Pure	150	152	120 - 180		
300	Pure	300	306	240 - 360	1.6	1.3 – 1.9
300	Blend	1	2	0 - 5		
300	Blend	10	10	5 - 15		
300	Blend	100	104	80 - 120		
300	Blend	200	212	160 - 240	2.9	2.5 – 3.5
300	ACE		133	108 - 162	1.6	1.3 – 1.9
Verify Tone for CUT: ☑Pass ☐Fail			Verify volume can be adjusted: ☑Pass ☐Fail			
500	Coag 1	1	2	0 - 5		
500	Coag 1	10	10	5 - 15		
500	Coag 1	60	62	48 - 72		
500	Coag 1	120	124	96 - 144	6.8	6.4 – 7.4
500	Coag 2	1	2	0 - 5		
500	Coag 2	10	10	5 - 15		
500	Coag 2	60	62	48 - 72		
500	Coag 2	120	125	96 - 144	7.0	6.6 – 7.6
500	Spray	1	1	0 - 5		
500	Spray	10	9	5 - 15		
500	Spray	60	61	48 - 72		
500	Spray	120	123	96 - 144	8.1	7.7 – 8.7
Verify Tone for COAG: ☑Pass ☐Fail						
Error 219: Set generator to Coag 1, 30 Watts. With the Generator unloaded (Disconnected from the ESU Analyzer), activate the generator for 10 to 20 seconds. Verify that an error 219 was not displayed.					☑Pass ☐Fail	

Section 2: **Monopolar B,** Power Outputs and Crest Factors

Procedure:

1) Set the Mega Power up so that Monopolar B is connected to the ESU Analyzer
2) Ensure that the activation button activates the Monopolar B electrode.
3) Set the ESU analyzer to the loads called out in Table B2.
4) Set the Mega Power to the power settings (PSET) and modes called out in Table B2.
5) Measure and record the appropriate output wattage and crest factors where indicated.
6) Verify Mega Power tones.
7) Verify Error 219 does not get displayed

Table B2: Monopolar B, Power Outputs and Crest Factors

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)	Crest Factor	Criteria
300	Pure	1	2	0 - 5		
300	Pure	10	10	5 - 15		
300	Pure	150	155	120 - 180		
300	Pure	300	309	240 - 360	1.6	1.3 – 1.9
300	Blend	1	2	0 - 5		
300	Blend	10	10	5 - 15		
300	Blend	100	105	80 - 120		
300	Blend	200	213	160 - 240	2.9	2.5 – 3.5
300	Ace		155	108 - 162	1.6	1.3 – 1.9
		Verify Tone for Cut: ☑Pass ☐Fail				
500	Coag 1	1	2	0 - 5		
500	Coag 1	10	10	5 - 15		
500	Coag 1	60	62	48 - 72		
500	Coag 1	120	124	96 - 144	6.8	6.4 – 7.4
500	Coag 2	1	2	0 - 5		
500	Coag 2	10	10	5 - 15		
500	Coag 2	60	62	48 - 72		
500	Coag 2	120	125	96 - 144	7.0	6.6 – 7.6
500	Spray	1	1	0 - 5		
500	Spray	10	9	5 - 15		
500	Spray	60	61	48 - 72		
500	Spray	120	123	96 - 144	8.1	7.7 – 8.7
		Verify Tone for COAG: ☑Pass ☐Fail				
Error 219: Set generator to Coag 1, 20 Watts. With the Generator unloaded (Disconnected from the ESU Analyzer), activate the generator for 10 to 20 seconds. Verify that an error 219 was not displayed.					☑Pass ☐Fail	

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Section 3: Monopolar B Power Curves

Procedure:

1) Set the ESU analyzer to the loads called out in Table D3 and Table B4.
2) Set the Mega Power to the power settings and modes called out in Table D3 and Table B4.
3) Measure and record the appropriate output wattage where indicated.

Table B3: CUT Power Curves

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)
100	ACE		163	120 – 180
200	ACE		155	120 – 180
300	ACE		See Table B2	108 – 162
500	ACE		93	76 – 114
1,000	ACE		53	42 – 64
2,000	ACE		23	18 – 28
100	Pure	300	168	105 – 175
200	Pure	300	281	240 – 360
300	Pure	300	See Table B2	240 – 360
500	Pure	300	303	240 – 360
1,000	Pure	300	295	240 – 360
2,000	Pure	300	202	160 – 240
100	Blend	200	99	75 – 125
200	Blend	200	206	160 – 240
300	Blend	200	See Table B2	160 – 240
500	Blend	200	206	160 – 240
1,000	Blend	200	194	160 – 240
2,000	Blend	200	169	130 – 190

Table B4: COAG Power Curves

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)
100	COAG 1	120	120	96 – 144
200	COAG 1	120	129	96 – 144
500	COAG 1	120	See Table B2	96 – 144
1,000	COAG 1	120	122	92 – 140
2,000	COAG 1	120	120	90 – 135
100	COAG 2	120	124	96 – 144
200	COAG 2	120	131	96 – 144
500	COAG 2	120	See Table B2	96 – 144
1,000	COAG 2	120	119	92 – 138
2,000	COAG 2	120	113	86 – 129
100	Spray	120	126	96 – 144
200	Spray	120	129	96 – 144
500	Spray	120	See Table B2	96 – 144
1,000	Spray	120	114	90 – 135
2,000	Spray	120	104	80 – 120

PART C: Bipolar Output Tests

Section 1: **Bipolar** Power Outputs and Crest Factors

Procedure:

1) Set the Mega Power up so that Bipolar is connected to the ESU Analyzer
2) Ensure that footswitch activates the Bipolar electrodes.
3) Set the ESU analyzer to the loads called out in Table C1.
4) Set the Mega Power to the power settings (PSET) and modes called out in Table C1.
5) Measure and record the appropriate output wattage and crest factors where indicated.
6) Verify Mega Power Tones.

Table C1: Bipolar, Power Outputs and Crest Factors

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)	Crest Factor	Criteria
100	Micro	1	1	0 - 5		
100	Micro	10	10	5 - 15		
100	Micro	40	38	32 - 48		
100	Micro	80	79	64 - 96	1.6	1.4 – 2.0
100	Macro	1	1	0 - 5		
100	Macro	10	8	5 - 15		
100	Macro	40	38	32 - 48		
100	Macro	80	76	64 - 96	1.6	1.4 – 2.0

Verify normal tone*: ☑Pass ☐Fail Verify pulsing tone*: ☑Pass ☐Fail

* When bipolar is activated the Mega Power displays the estimated current flow in the current flow indicator window. In addition to the current flow indicator, the Mega Power can be set to indicate the current with an audio alarm. The current is proportional to the pulsing rate of the audio tone. By pressing the bipolar tone button (the button to the right of the current flow window) the bipolar alarm will toggle between a continuous tone and a pulsing tone. Verify that both the continuous and the pulsing tones are operational in the Macro Mode with a 100 Ω load, and the Mega Power set to 80 W.

Section 2: **Bipolar** Power Curves

Procedure:

1) Set the ESU analyzer to the loads called out in Table C2.
2) Set the Mega Power to the power settings (PSET) and modes called out in Table C2.
3) Measure and record the appropriate output wattage where indicated.

Table C2: BIPOLAR Power Curves

Load (Ω)	Mode	PSET (watts)	Output (Watts)	Criteria (Watts)
50	Micro	80	62	46 – 68
75	Micro	80	78	60 – 90
100	Micro	80	See Table C1	64 – 96
200	Micro	80	75	64 – 96
650	Micro	80	8	5 – 15
1000	Micro	80	6	0 – 10
50	Macro	80	62	46 – 68
75	Macro	80	78	60 – 90
100	Macro	80	See Table C1	64 – 96
200	Macro	80	75	64 – 96
500	Macro	80	54	38 – 58
1000	Macro	80	29	20 – 32

PART D: Isolation Voltages and Contact Quality Monitor (CQM) Test

Section 1: Isolation Voltages

Table D1: Isolation Voltages

Channel	Directions	Voltage (V)	Criteria (V)
Monopolar A	With a digital multi-meter measure the voltage across the active electrode and one of the hand switching inputs.	12.61	> 10.5
Monopolar B	With a digital multi-meter measure the voltage across the active electrode and one of the hand switching inputs.	12.29	> 10.5
Bipolar	With a digital multi-meter measure the voltage across the active electrode and the ground output.	15.02	> 10.5

Section 2: Verify Potentiometer, PN: 2010127-02, Calibration

Procedure:

1) Set the potentiometer to resistances called out in Table D2.
2) With a digital multi-meter measure the voltages across the potentiometer.

Table D2: Verify Potentiometer Calibration

Potentiometer Setting	Measured Resistance (Ω)	Criteria (Ω)
10 Ω	9.2	9 - 11
50 Ω	50.3	49 – 51
200 Ω	201.6	196 - 204

Section 3: CQM Test

Table D3: CQM Test

Start up			
With the Mega Power off, connect and set the potentiometer to 50 Ω.	CQM is green when power up is complete:	☑Pass ☐Fail	
Lower CQM Alarm Trip Point			
Set the potentiometer to 0 Ω and connect to Mega Power. Raise the resistance until CQM turns red.	CQM turns green:	☑Pass ☐Fail	
	Resistance: 17		< 20 Ω
Midlevel CQM Trip Point			
Unplug the potentiometer. Set the potentiometer to 50 Ω and reconnect. Raise the resistance until CQM turns red.	CQM turns green:	☑Pass ☐Fail	
	Resistance: 69		58 – 72 Ω
Upper CQM Alarm Trip Point			
Unplug the potentiometer. Set the potentiometer to 200Ω and reconnect. Lower the resistance until CQM turns green.	CQM stays red:	☑Pass ☐Fail	
	Resistance: 143		122 – 148 Ω

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PART E: Electrical Safety Test

Table E1: Protective Earth Connection to Chassis		
Protective Earth ground to outlet.		
Current Applied: 25 A	Impedance: 10	Criteria: < 200m Ω

Table E2: Enclosure Leakage Test 1		
Protective earth ground to power entry: ground open.		
Voltage applied: Mains	Current: 88	Criteria: 50 – 300 µA

Table E3: Enclosure Leakage Test 2		
Protective earth ground to power entry: neutral open, and ground open.		
Voltage applied: Mains	Current: 163	Criteria: < 1000 µA

Table E4: Enclosure Leakage Test 3		
Protective earth ground to power entry: neutral open, reverse polarity, and ground open.		
Voltage applied: Mains	Current: 184	Criteria: < 1000 µA

Table E5: Enclosure Leakage Test 4		
Protective earth ground to power entry: reverse polarity, and ground open.		
Voltage applied: Mains	Current: 87	Criteria: <1000 µA

Table E6: Patient Leakage		
All patient connections to power entry.		
Voltage applied: Mains	Current: 3	Criteria: < 10 µA

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PART F: Signatures

Technician Performing Tests	
All equipment used to perform final test was calibrated. The Mega Power has passed all tests stated in Sections B through Section F.	
Print: KOHEI SEKI	
Signature: K. seki	Date: 10/09/2019

Megadyne Review	
The document has been reviewed. The test data is within the stated criteria.	
Print: JASON STIVERS	
Signature:	Date: 10/25/2019

SIGNING AS SERVICE ENGINEER FOR MEGA POWER 1000 AT ETHICON ENDO-SURGERY

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number ENG-PRT-502
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Authored By: John Minuth

1.0 Purpose

This document is intended to qualify a service center to repair the Mega Power 1000. The service center will have to be able to disassemble, reassemble, and final test a generator.

2.0 References

1000	Mega Power 1000
CS-SOP-001	Service and Repair SOP
ENG-WI-036	Mega Power 1000 Disassembly Instructions, Service and Repair
ENG-WI-037	Mega Power 1000 Assembly Instructions, Service and Repair
CS-FRM-034	Mega Power Service Center Repair Form, New Faceplate

3.0 Attachments

None

4.0 Scope

The scope of this protocol is any J&J Service Center that will repair the Mega Power 1000 both old and new faceplates.

5.0 Strategies/Assumption

5.1 A technician from each service center will follow the instructions in section 6 for one (1) unit.

5.2 Each service center to be qualified will conduct this protocol separately.

5.3 Although the old faceplate and new faceplates are different and there is a different Mega Power Service Center Repair form for the old faceplate, the process for disassembly, re-assembly, packaging and repair of the Mega Power is the same so the qualification will only be performed on a Mega Power with new faceplate.

5.4 Each of the service centers receiving this protocol have been trained.

5.5 Although no repair is planned to be performed as part of this qualification it is assumed that a full disassembly and re-assembly of the unit per the referenced work instructions is representative of the repair process.

6.0 Procedural Steps

6.1 Steps to be conducted by J&J Service Center

6.1.1 Complete Part A on CS-FRM-034

6.1.2 Part B of CS-FRM-034 is not applicable to this protocol since no repair is planned. Mark each table with an N/A.

6.1.3 Disassemble a Mega Power 1000 per ENG-WI-036

6.1.4 Reassemble a Mega Power 1000 per ENG-WI-037

6.1.5 Test the Mega Power 1000 per CS-FRM-034, Part C through H. Complete all required fields except for the Megadyne Review of Section H.

6.1.6 Scan and send completed CS-FRM-034 to Megadyne.
SRINTL@megadyne.com
Attn: Carly Rasband

6.2 Steps to be conducted by Megadyne

6.2.1 Review completed form CS-FRM-034 sent by the service center and complete the Megadyne Review of Section H.

6.2.2 Document results of each J&J Service Center qualification within a report.

6.2.3 Send completed form CS-FRM-034 to Ethicon for inclusion in the factbook
Attn: Jamie Best
4545 Creek Road
Mail Location 120A
Cincinnati, Ohio 45242

7.0 Acceptance Criteria

The acceptance criterion is that after disassembly and re-assembly, the unit under test passes all the test requirements called out in CS-FRM-034.

Mega Power Service Center Repair Form, New Faceplate

MEGADYNE
The Electrosurgical Authority

Mega Power Information	
RGA	K.Seki 11/09/2019
Serial Number	18295500
RoHS	☐ Leaded ☑ RoHS

PART A: Equipment Calibration

Record calibration data:

Table A1: Calibration Data

Equipment	Brand	Model Number	Serial Number	Cal. Due Date
ESU Analyzer	Fluke	QA-ESII	300091	09/30/2020
Digital Multi-meter	Yokogawa	73302	1501491	03/31/2020
Safety Analyzer	Hioki	3156	051238345	11/30/2019

*All testing must be performed with calibrated equipment. Do not proceed with final testing if any piece of equipment is not current with calibration schedule.

Part B: Investigation and Repair

Section 1: Before the Mega Power is disassembled

1) With the ESU analyzer set to 300 Ohms, measure the output power with the Mega Power set to PURE CUT and the power set to 30 W, 75 W, and 300 W. Record the results in Table B1.
2) With the ESU analyzer set to 500 Ohms, measure the output power with the Mega Power set to COAG 1 and the power set to 30 W, 50 W, and 120 W. Record the results in Table B2.
3) Using Field Calibration Software, 1410010-01, download, print, and attach the error logs from the master processor and watch dog processor.

Table B1: PURE CUT

Setting		Power Output
300 Ω	30 W	31w
300 Ω	75 W	76w
300 Ω	300 W	305w

Table B2: COAG 1

Setting		Power Output
500 Ω	30 W	32w
500 Ω	50 W	54w
500 Ω	120 W	129w

Section 2: Investigation

Table B3: Investigation

The Unit is good working. KGV

K.Seki 11/09/2019

Initial/Date: K.S 11/09/2019

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Section 3: Repair Actions

Table B4: Repair Actions

None
K.Sekiguchi 10/08/2019
Initial/Date: K.S 10/08/2019

Table B5: Replacement Parts (Confirm all replacement parts with CS-FRM-038)

Part Number	Description	PCB Number	Lot Number	QTY

K.Sekiguchi 10/08/2019

Ship Printed Circuit Boards to Megadyne

Ship replaced parts to Megadyne for evaluation. Please note the RGA on the outside of the shipping box.	Megadyne Medical Product, Inc. Attn: Service and Repair 11506 South State St. Draper, Utah 84020 USA

Table B6: Shipped to Megadyne

Part Number	Description	PCB Number (Where Applicable)

K.Sekiguchi 10/08/2019

Shipped By:		Date:	
Tracking Number:			

K.Sekiguchi 10/08/2019

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Once the repair work has been completed and the Mega Power has been reassembled, test per Part C through Part G.

PART C: Display Test

Section 1: Power-Up Test

Turn on the Mega Power. Once the Mega Power has completed the POST test check the appropriate boxes in Table C1.

Table C1: Power-Up Test

Pass	Fail	Criteria
☑	☐	Power Switch is illuminated
☑	☐	PURE CUT LED is illuminated
☑	☐	COAG 1 LED is illuminated
☑	☐	MICRO LED is illuminated
☑	☐	No errors are displayed
☑	☐	All display segments show dashes.
☑	☐	CQM Alarm LED is red and alarm tone sounded (Without a return pad connected to the Mega Power)

Section 2: Display Functionality

Table C2: Display Functionality

Pass	Fail	Criteria
☑	☐	Press each mode button and verify that the appropriate LED button lights up.
☑	☐	Press the up arrow button on each of the three channels and verify power goes up.
☑	☐	Press the down arrow button on each of the three channels and verify power goes down.
☑	☐	Press the Bipolar Tone button and verify the LED lights up.
☑	☐	Plug in the Monopolar Return Test Cable and verify CQM alarm LED turns green.
☑	☐	Set all power settings to 1. Turn power off. Turn power on. Press recall and verify power setting of 1 is displayed for each mode.

Mega Power Service Center Repair Form, New Faceplate

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PART D: Monopolar Output Tests

Section 1: **Monopolar A**, Power Outputs and Crest Factors

Procedure:

1) Set the ESU analyzer to the loads called out in Table D1.
2) Set the Mega Power to the power settings (PSET) and modes called out in Table D1.
3) Measure and record the appropriate output wattage and crest factors where indicated.
4) Verify Mega Power Tones.

Table D1: Monopolar A, Power Outputs and Crest Factors

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)	Crest Factor	Criteria
300	Pure	1	2	0 - 5		
300	Pure	10	10	5 - 15		
300	Pure	150	152	120 - 180		
300	Pure	300	306	240 - 360	1.6	1.3 – 1.9
300	Blend	1	2	0 - 5		
300	Blend	10	10	5 - 15		
300	Blend	100	104	80 - 120		
300	Blend	200	212	160 - 240	2.9	2.5 – 3.5
300	ACE		133	108 - 162	1.6	1.3 – 1.9
Verify Tone for CUT: ☑Pass ☐Fail			Verify volume can be adjusted: ☑Pass ☐Fail			
500	Coag 1	1	2	0 - 5		
500	Coag 1	10	10	5 - 15		
500	Coag 1	60	62	48 - 72		
500	Coag 1	120	124	96 - 144	6.8	6.4 – 7.4
500	Coag 2	1	2	0 - 5		
500	Coag 2	10	10	5 - 15		
500	Coag 2	60	62	48 - 72		
500	Coag 2	120	125	96 - 144	7.0	6.6 – 7.6
500	Spray	1	1	0 - 5		
500	Spray	10	9	5 - 15		
500	Spray	60	61	48 - 72		
500	Spray	120	123	96 - 144	8.1	7.7 – 8.7
Verify Tone for COAG: ☑Pass ☐Fail						

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MEGADYNE The Electrosurgical Authority

Section 2: **Monopolar B**, Power Outputs and Crest Factors

Procedure:

1) Set the Mega Power up so that Monopolar B is connected to the ESU Analyzer
2) Ensure that the activation button activates the Monopolar B electrode.
3) Set the ESU analyzer to the loads called out in Table D2.
4) Set the Mega Power to the power settings (PSET) and modes called out in Table D2.
5) Measure and record the appropriate output wattage and crest factors where indicated.
6) Verify Mega Power tones.

Table D2: Monopolar B, Power Outputs and Crest Factors

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)	Crest Factor	Criteria
300	Pure	1	2	0 - 5		
300	Pure	10	10	5 - 15		
300	Pure	150	155	120 - 180		
300	Pure	300	309	240 - 360	1.6	1.3 – 1.9
300	Blend	1	2	0 - 5		
300	Blend	10	10	5 - 15		
300	Blend	100	105	80 - 120		
300	Blend	200	213	160 - 240	2.9	2.5 – 3.5
300	Ace		135	108 - 162	1.6	1.3 – 1.9
		Verify Tone for Cut:	☑Pass	☐Fail		
500	Coag 1	1	2	0 - 5		
500	Coag 1	10	10	5 - 15		
500	Coag 1	60	62	48 - 72		
500	Coag 1	120	124	96 - 144	6.8	6.4 – 7.4
500	Coag 2	1	2	0 - 5		
500	Coag 2	10	10	5 - 15		
500	Coag 2	60	62	48 - 72		
500	Coag 2	120	125	96 - 144	7.0	6.6 – 7.6
500	Spray	1	1	0 - 5		
500	Spray	10	9	5 - 15		
500	Spray	60	61	48 - 72		
500	Spray	120	123	96 - 144	8.1	7.7 – 8.7
		Verify Tone for COAG:	☑Pass	☐Fail		

Mega Power Service Center Repair Form, New Faceplate

MEGADYNE
The Electrosurgical Authority

Section 3: **Monopolar B** Power Curves

Procedure:

1) Set the ESU analyzer to the loads called out in Table D3 and Table D4.
2) Set the Mega Power to the power settings and modes called out in Table D3 and Table D4.
3) Measure and record the appropriate output wattage where indicated.

Table D3: CUT Power Curves

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)
100	ACE		163	120 – 180
200	ACE		155	120 – 180
300	ACE		See Table D2	108 – 162
500	ACE		93	76 – 114
1,000	ACE		53	42 – 64
2,000	ACE		23	18 – 28
100	Pure	300	168	105 – 175
200	Pure	300	281	240 – 360
300	Pure	300	See Table D2	240 – 360
500	Pure	300	303	240 – 360
1,000	Pure	300	295	240 – 360
2,000	Pure	300	202	160 – 240
100	Blend	200	99	75 – 125
200	Blend	200	206	160 – 240
300	Blend	200	See Table D2	160 – 240
500	Blend	200	206	160 – 240
1,000	Blend	200	194	160 – 240
2,000	Blend	200	169	130 – 190

Table D4: COAG Power Curves

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)
100	COAG 1	120	120	96 – 144
200	COAG 1	120	129	96 – 144
500	COAG 1	120	See Table D2	96 – 144
1,000	COAG 1	120	122	92 – 140
2,000	COAG 1	120	120	90 – 135
100	COAG 2	120	124	96 – 144
200	COAG 2	120	131	96 – 144
500	COAG 2	120	See Table D2	96 – 144
1,000	COAG 2	120	119	92 – 138
2,000	COAG 2	120	113	86 – 129
100	Spray	120	126	96 – 144
200	Spray	120	129	96 – 144
500	Spray	120	See Table D2	96 – 144
1,000	Spray	120	114	90 – 135
2,000	Spray	120	109	80 – 120

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PART E: Bipolar Output Tests

Section 1: **Bipolar** Power Outputs and Crest Factors

Procedure:

1) Set the Mega Power up so that Bipolar is connected to the ESU Analyzer
2) Ensure that footswitch activates the Bipolar electrodes.
3) Set the ESU analyzer to the loads called out in Table E1.
4) Set the Mega Power to the power settings (PSET) and modes called out in Table E1.
5) Measure and record the appropriate output wattage and crest factors where indicated.
6) Verify Mega Power Tones.

Table E1: Bipolar, Power Outputs and Crest Factors

Load (Ω)	Mode	PSET (Watts)	Output (Watts)	Criteria (Watts)	Crest Factor	Criteria
100	Micro	1	1	0 - 5		
100	Micro	10	10	5 - 15		
100	Micro	40	38	32 - 48		
100	Micro	80	79	64 - 96	1.6	1.4 – 2.0
100	Macro	1	1	0 - 5		
100	Macro	10	8	5 - 15		
100	Macro	40	38	32 - 48		
100	Macro	80	76	64 - 96	1.6	1.4 – 2.0

Verify normal tone*: ☑Pass ☐Fail Verify pulsing tone*: ☑Pass ☐Fail

* When bipolar is activated the Mega Power displays the estimated current flow in the current flow indicator window. In addition to the current flow indicator, the Mega Power can be set to indicate the current with an audio alarm. The current is proportional to the pulsing rate of the audio tone. By pressing the bipolar tone button (the button to the right of the current flow window) the bipolar alarm will toggle between a continuous tone and a pulsing tone. Verify that both the continuous and the pulsing tones are operational in the Macro Mode with a 100 Ω load, and the Mega Power set to 80 W.

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Section 2: **Bipolar** Power Curves

Procedure:

1) Set the ESU analyzer to the loads called out in Table E2.
2) Set the Mega Power to the power settings (PSET) and modes called out in Table E2.
3) Measure and record the appropriate output wattage where indicated.

Table E2: BIPOLAR Power Curves

Load (Ω)	Mode	PSET (watts)	Output (Watts)	Criteria (Watts)
50	Micro	80	62	46 – 68
75	Micro	80	78	60 – 90
100	Micro	80	See Table E1	64 – 96
200	Micro	80	75	64 – 96
650	Micro	80	8	5 – 15
1000	Micro	80	6	0 – 10
50	Macro	80	62	46 – 68
75	Macro	80	78	60 – 90
100	Macro	80	See Table E1	64 – 96
200	Macro	80	75	64 – 96
500	Macro	80	54	38 – 58
1000	Macro	80	29	20 – 32

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PART F: Isolation Voltages and Contact Quality Monitor (CQM) Test

Section 1: Isolation Voltages

Table F1: Isolation Voltages

Channel	Directions	Voltage (V)	Criteria (V)
Monopolar A	With a digital multi-meter measure the voltage across the active electrode and one of the hand switching inputs.	12.61	> 10.5
Monopolar B	With a digital multi-meter measure the voltage across the active electrode and one of the hand switching inputs.	12.29	> 10.5
Bipolar	With a digital multi-meter measure the voltage across the active electrode and the ground output.	13.02	> 10.5

Section 2: Verify Potentiometer, PN: 2010127-02, Calibration

Procedure:

1) Set the potentiometer to resistances called out in Table F2.
2) With a digital multi-meter measure the voltages across the potentiometer.

Table F2: Verify Potentiometer Calibration

Potentiometer Setting	Measured Resistance (Ω)	Criteria (Ω)
10 Ω	9.2	9 - 11
50 Ω	50.3	49 – 51
200 Ω	201.6	196 - 204

Section 3: CQM Test

Table F3: CQM Test

Start up			
With the Mega Power off, connect and set the potentiometer to 50 Ω.	CQM is green when power up is complete:	☑Pass ☐Fail	
Lower CQM Alarm Trip Point			
Set the potentiometer to 0 Ω and connect to Mega Power. Raise the resistance until CQM turns red.	CQM turns green:	☑Pass ☐Fail	
	Resistance: 17		< 20 Ω
Midlevel CQM Trip Point			
Unplug the potentiometer. Set the potentiometer to 50 Ω and reconnect. Raise the resistance until CQM turns red.	CQM turns green:	☑Pass ☐Fail	
	Resistance: 69		58 – 72 Ω
Upper CQM Alarm Trip Point			
Unplug the potentiometer. Set the potentiometer to 200Ω and reconnect. Lower the resistance until CQM turns green.	CQM stays red:	☑Pass ☐Fail	
	Resistance: 143		122 – 148 Ω

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Mega Power Information	
RGA	kseki 11/8/19
Serial Number	18295501

PART G: Electrical Safety Test

Table G1: Protective Earth Connection to Chassis			
Protective Earth ground to outlet.			
Current Applied: 25 A	Impedance:	70	Criteria: < 200m Ω

Table G2: Enclosure Leakage Test 1			
Protective earth ground to power entry: ground open.			
Voltage applied: Mains	Current:	88	Criteria: 50 – 300 µA

Table G3: Enclosure Leakage Test 2			
Protective earth ground to power entry: neutral open, and ground open.			
Voltage applied: Mains	Current:	7.63	Criteria: < 1000 µA

Table G4: Enclosure Leakage Test 3			
Protective earth ground to power entry: neutral open, reverse polarity, and ground open.			
Voltage applied: Mains	Current:	7.84	Criteria: < 1000 µA

Table G5: Enclosure Leakage Test 4			
Protective earth ground to power entry: reverse polarity, and ground open.			
Voltage applied: Mains	Current:	89	Criteria: <1000 µA

Table G6: Patient Leakage			
All patient connections to power entry.			
Voltage applied: Mains	Current:	3	Criteria: < 10 µA

Technician Performing Electrical Safety Test	
The Mega Power has passed all tests stated in Sections G.	
Print: KOHEI SEKI	
Signature: K. Seki	Date: 11/08/2019

Mega Power Service Center Repair Form, New Faceplate

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PART H: Signatures

Technician Performing Tests	
All equipment used to perform final test was calibrated. The Mega Power has passed all tests stated in Sections C through Section G and packaged per ENG-WI-035.	
Print: KOHEI SEKI	
Signature: K-Seki	Date: 10/08/2019

Megadyne Review	
The document has been reviewed. The test data is within the stated criteria.	
Print: JASON STINERS	
Signature:	Date: 10/25/2019

SIGNING AS
SERVICE ENGINEER
FOR MEGA POWER 1000
AT ETHICON ENDO-SURGERY

Document Number	Revision	Previous Number	Page
CS-FRM-034	004	N/A	11 of 11

Title : Error Log

Kuroki 08/01/2019

Page 1 Thursday, May 30, 2019

Master Error Log
Start Index = 0

#	Err	Mode	VSI	VSV	MP	Pset	DAC	Vout	Iout	Z	Pmeas
00	255	.....	000	000	000	000	000	0.000	0.000	0	0
41	255	.....	255	255	255	255	255	0.000	0.000	0	0
40	255	.....	255	255	255	255	255	0.000	0.000	0	0
39	255	.....	255	255	255	255	255	0.000	0.000	0	0
38	255	.....	255	255	255	255	255	0.000	0.000	0	0
37	255	.....	255	255	255	255	255	0.000	0.000	0	0
36	255	.....	255	255	255	255	255	0.000	0.000	0	0
35	255	.....	255	255	255	255	255	0.000	0.000	0	0
34	255	.....	255	255	255	255	255	0.000	0.000	0	0
33	255	.....	255	255	255	255	255	0.000	0.000	0	0
32	255	.....	255	255	255	255	255	0.000	0.000	0	0
31	255	.....	255	255	255	255	255	0.000	0.000	0	0
30	255	.....	255	255	255	255	255	0.000	0.000	0	0
29	255	.....	255	255	255	255	255	0.000	0.000	0	0
28	255	.....	255	255	255	255	255	0.000	0.000	0	0
27	255	.....	255	255	255	255	255	0.000	0.000	0	0
26	255	.....	255	255	255	255	255	0.000	0.000	0	0
25	255	.....	255	255	255	255	255	0.000	0.000	0	0
24	255	.....	255	255	255	255	255	0.000	0.000	0	0
23	255	.....	255	255	255	255	255	0.000	0.000	0	0
22	255	.....	255	255	255	255	255	0.000	0.000	0	0
21	255	.....	255	255	255	255	255	0.000	0.000	0	0
20	255	.....	255	255	255	255	255	0.000	0.000	0	0
19	255	.....	255	255	255	255	255	0.000	0.000	0	0
18	255	.....	255	255	255	255	255	0.000	0.000	0	0
17	255	.....	255	255	255	255	255	0.000	0.000	0	0
16	255	.....	255	255	255	255	255	0.000	0.000	0	0
15	255	.....	255	255	255	255	255	0.000	0.000	0	0
14	255	.....	255	255	255	255	255	0.000	0.000	0	0
13	255	.....	255	255	255	255	255	0.000	0.000	0	0
12	255	.....	255	255	255	255	255	0.000	0.000	0	0
11	255	.....	255	255	255	255	255	0.000	0.000	0	0
10	255	.....	255	255	255	255	255	0.000	0.000	0	0
09	255	.....	255	255	255	255	255	0.000	0.000	0	0
08	255	.....	255	255	255	255	255	0.000	0.000	0	0
07	255	.....	255	255	255	255	255	0.000	0.000	0	0
06	255	.....	255	255	255	255	255	0.000	0.000	0	0
05	255	.....	255	255	255	255	255	0.000	0.000	0	0
04	255	.....	255	255	255	255	255	0.000	0.000	0	0
03	255	.....	255	255	255	255	255	0.000	0.000	0	0
02	255	.....	255	255	255	255	255	0.000	0.000	0	0
01	255	.....	255	255	255	255	255	0.000	0.000	0	0

SN: 18295500 1

1/1

Title : ESU Test Results from lock Station

k.seki 08/01/2019

Thursday, May 30, 2019

Date = 05-30-2019 Time = 23:09:41
User ID: k.s
SN: 18295001

Monopolar A measurements:
132.58 ;ACE cut power measurement PASS
1.60 ;ACE Crest Factor PASS
307.26 ;PURE cut 300 Watts measurement PASS
1.60 ;PURE Cut Crest Factor PASS
210.72 ;BLEND cut 200 Watts measurement PASS
2.90 ;BLEND Cut Crest Factor PASS
124.10 ;Standard Coag 120 Watts measurement PASS
6.80 ;COAG Standard Crest Factor PASS
123.60 ;Spray Coag 120 Watts measurement PASS
8.20 ;COAG Spray Crest Factor PASS
124.70 ;CWC Coag 120 Watts measurement PASS
7.00 ;COAG CWC Crest Factor PASS

Monopolar B ACE measurements:
134.50 ;ACE cut power measurement PASS
1.60 ;ACE Crest Factor PASS
308.88 ;PURE cut 300 Watts measurement PASS
1.60 ;PURE Cut Crest Factor PASS
212.60 ;BLEND cut 200 Watts measurement PASS
2.90 ;BLEND Cut Crest Factor PASS
123.86 ;Standard Coag 120 Watts measurement PASS
6.78 ;COAG Standard Crest Factor PASS
123.30 ;Spray Coag 120 Watts measurement PASS
8.16 ;COAG Spray Crest Factor PASS
124.42 ;CWC Coag 120 Watts measurement PASS
7.00 ;COAG CWC Crest Factor PASS

78.70 ;Macro Bipolar 80 Watts measurement PASS
1.60 ;Bipolar Macro Crest Factor PASS

78.78 ;Standard Bipolar 80 Watts measurement PASS
1.60 ;Bipolar Standard Crest Factor PASS

51 ;CQM Reading (ohms) PASS

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FLUKE®
Biomedical

QA-ES Series II
Electrosurgery Analyzer

Technical Data

QA-ES Series II analyzes electrosurgical units quickly and accurately.

A wide load-resistance range provides 128 user-selectable loads, including very low loads for testing many of today's ESUs.

An accuracy of ± 2 % of reading down to 20 mA guarantees reliable high-frequency leakage results. With capability to run an automatic-power-distribution test in as little as 1 minute, the QA-ES works fast so technicians save time.

An Ansur QA-ES software plug-in allows users to create and automatically run tests, capture data, and produce easy-to-read reports with a PC.

Key features

- Automatic power distribution measurement, including power, current, peak-to-peak voltage (closed load only), and crest factor
- Oscilloscope output
- High-frequency leakage measurements with accuracy of ± 2 % of reading
- 128 internal user-selectable test loads from 10 Ω to 5200 Ω
- Foot-switch output for triggering the ESU under test
- Ansur QA-ES software plug-in for automated test protocols
- Large display
- RS-232 and Centronic-Printer interface

Technical specifications

Generator output

Continuous operation
Continuous measurement of power, current, peak-to-peak voltage (closed load only), and crest factor

Single operation
Single measurement after the set delay time of the ESU output of power, current, peak-to-peak voltage (closed load only), and crest factor

Power distribution
Automatic measurement of power, current, peak-to-peak voltage (closed load only), and crest factor through a user-selectable load range

RF leakage current
Provides connections and load configurations to measure HF leakage from both grounded and isolated equipment

RECQM
Test the "return electrode control quality monitoring" using the QA-ES internal loads

Modes of operation
Manual or remote controlled (via Ansur)

Measurement
True-rms value of applied waveform

RMS bandwidth
30 Hz to 10 MHz (-3 dB) for instrumentation only
30 Hz to 2.5 MHz (-3 dB) with loads

Low frequency filter
100 Hz filter to avoid low-frequency disturbance or interference

Current
20 mA to 2200 mA

Current accuracy
20 mA to 2200 mA ± 2 % of reading

Load resistance
10 Ω to 2500 Ω in step of 25 Ω (@ dc)
2500 Ω to 5200 Ω in step of 100 Ω (@ dc)

Additional fixed load
200 Ω 400 W for 30 s; max 15 % duty cycle

Crest factor
The higher of the two peak voltage measurements is used for computation

Range
1.4 to 16 (V peak/V rms)

Foot-switch output
The foot switch output can be used to trigger the electrosurgical unit

Peak-to-peak voltage
0 kV to 10 kV (closed load only)
accuracy: ± 10 %

Note: Measurement is taken between the active and dispersive electrodes with closed load only.

Oscilloscope output
5 V/A uncalibrated, 100 mA RF current minimum input

Ansur QA-ES Plug-In

Remote control
All functions and tests in QA-ES may be performed from the PC

User-programmable test sequences
Allows unlimited numbers of test sequences with user-programmable templates and test limits. These tests include power distribution test, output test, HF leakage, and RECQM verification

Storage and recall
Protocol formats and data may be stored, recalled, printed out, or transferred

FLUKE Biomedical

Temperature

Operating
15 °C to 35 °C (59 °F to 95 °F)

Storage
0 °C to 50 °C (32 °F to 122 °F)

Display
LCD graphic display

Alphanumeric format
8 lines x 40 characters

Graphic mode
240 x 64 pixel matrix

Display control
5 F-keys, enter, cancel, control knob, and an encoder

Data input/outputs
Parallel printer port and bidirectional RS-232

Power
115/230 V ac; 48 Hz to 66 Hz, 35 VA

Housing
Metal case

Dimensions (WxDxH)
39.5 cm x 34.2 cm x 13.2 cm
(15.6 in x 13.5 in x 5.2 in)

Weight
9.8 kg (21.6 lb)

Ordering Information

Models
2649769 QA-ES Series II 115 V Electrosurgery Analyzer (US)
2651725 QA-ES Series II 230 V Electrosurgery Analyzer (Schuko)
2770445 QA-ES Series II 230 V Electrosurgery Analyzer (UK)
2770450 QA-ES Series II 230 V Electrosurgery Analyzer (Australia)
3096390 QA-ES Series II 100 V Electrosurgery Analyzer (Japan)

Standard accessories
2716044 Manual on CD
2716032 Manual Hard Copy
2772171 ESU-Dispersive Safety Lead
2772180 ESU-CQM Safety Lead
2772209 ESU-Jumper Safety Lead
Power Cord (country specific)
2826194 Test Lead with stackable plugs
1903307 Test Lead Set with retractable sheaths
1610159 Sure-Grip Large Alligator Clip Set

Optional accessories
2461794 Carrying Case
2461802 Ansur Test Software, QA-ES Plug-in License
2461993 Data Transfer Cable, RS-232
2716059 Calibration Manual
2523266 Clamp, crocodile style, grip C, black
2523275 Clamp, crocodile style, grip C, red

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About Fluke Biomedical

Fluke Biomedical is the world's leading manufacturer of quality biomedical test and simulation products. In addition, Fluke Biomedical provides the latest medical imaging and oncology quality-assurance solutions for regulatory compliance.

Today, biomedical personnel must meet the increasing regulatory pressures, higher quality standards, and rapid technological growth, while performing their work faster and more efficiently than ever. Fluke Biomedical provides a diverse range of software and hardware tools to meet today's challenges.

Fluke Biomedical Regulatory Commitment

As a medical test device manufacturer, we recognize and follow certain quality standards and certifications when developing our products. We are ISO 9001 certified and our products are:

- CE Certified, where required
- NIST Traceable and Calibrated
- UL, CSA, ETL Certified, where required
- NRC Compliant, where required

Fluke Biomedical.
Better products. More choices. One company.

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1/2017 2839598 D-EN-N Rev D

SG032(3) 様式4

計測装置社外校正記録書

管理番号 Control Number	F-124	管理部門 Division	リペアサービス Repair Service
計測装置名称 Product	Electrosurgical Analyzer QA-ES II 300091		
依頼先供給者名 Supplier	大正医科器械 株式会社 Taisho Biomed Instruments co. ltd		
校正実施日/期間 Date of Calibration	2018年9月28日　09/28/2018		
校正証明書の文書番号 ※受取った校正証明書の全ての文書番号を転記	・サービス報告書　報告書番号:180928 Y2 ・Calibration Report Found -Left-300091-9/28/2018 ・2018年4月11日発行　校正体系図（電気メステスタトレーサビリティ体系図）		
校正結果の確認	①校正担当者は校正結果の校正項目、公称値、測定値をレビューのうえ、許容範囲(合格範囲)内であることを確認し、校正結果にレ点チェックにより記録する。 (レ点チェックは、赤、青、緑などの色つきのペンを使用すること。)		
	②校正担当者は①の確認の結果、問題がなければ下記にチェックを記載する。 □　校正項目、公称値、測定値をレビューし、許容範囲(合格範囲)内であることを確認しました。		
合否判定 Result	pass 合格 / 不合格 fail		
次回校正実施期限*1 Due Date	2019年9月　09/2019		

*1 次回校正実施期限は、前回校正実施年月に校正周期を加えた年月の月末までとする。

【作成】校正担当者　署名: Yuki Akuma 10/15/2018

【レビュー】計測装置管理責任者　署名: 10/16/2018

【承認】QO　署名: 10/17/2018

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FLUKE Biomedical

Calibration Report
Found-Left - 300091 - 9/28/2018

Model # QA-ES-J
Mfr. Fluke Biomedical
S/N: 300091
Customer Name: ジョンソン・エンド・ジョンソン株式会社
Customer P.O. #: N/A
Date Received: 2018/9/28
Condition as Received: Operable
WO #: N/A
Calibration Date: 2018/9/28
Calibration Data: Found-Left
Temperature (C): 24
Pressure (mm Hg): 761.4
Relative Humidity: 55
Notes: N/A

Calibration Standards

2000 or Equiv DMM IRM#: 1586027
2000 or Equiv DMM Cal Due Date: 2019/4/16
Oscilloscope IRM#: DM8480044
Oscilloscope Cal Due Date: 2019/4/16
RF Voltmeter #: 16856
RF Voltmeter Cal Due Date: 2018/12/28
Pearson 411 IRM#: 167612
Pearson 411 Cal Due Date: 2019/3/15

Calibration Description

* The calibration of this instrument is traceable to the National Institute of Standards and Technology.
* The uncertainty ratio for this calibration is better than 4:1 except the Current Tests which are 2.3:1
* The results in this report relate only to the item being tested
* This calibration report cannot be reproduced except in full, without written approval from the laboratory

Calibration Data

Preliminary Checks	Version	Pass/Fail
Power Up Routine Works Properly		Pass
Firmware Version	2.26	
User Interface and Display Operates Normally		Pass
Cooling Fan Operates Normally		Pass
Serial and Parallel Interface Operates Normally		Pass
Foot Switch Operates Normally		Pass
Housing and Measuring Inputs Isolated		Pass

	Spec (Ohms)	Reading (Ohms)		Pass/Fail
Fixed Load	180 - 220	200.18		Pass
Load Tests	**Spec (Ohms)**	**Measured (Ohms)**	**Tolerance**	**Pass/Fail**
10 Ohm Load	9.8	9.97	+/-5%	Pass
25 Ohm Load	24.8	25.1	+/-5%	Pass
50 Ohm Load	49	49.82	+/-5%	Pass
75 Ohm Load	71.8	72.57	+/-5%	Pass
100 Ohm Load	102	102.61	+/-5%	Pass
200 Ohm Load	202	201.89	+/-5%	Pass
300 Ohm Load	302	302.11	+/-5%	Pass
400 Ohm Load	402	405.37	+/-5%	Pass
500 Ohm Load	502	505.6	+/-5%	Pass
700 Ohm Load	702	705.12	+/-5%	Pass
800 Ohm Load	802	798.68	+/-5%	Pass
1500 Ohm Load	1502	1502.88	+/-5%	Pass
1575 Ohm Load	1571.8	1572.7	+/-5%	Pass
1600 Ohm Load	1622	1619.6	+/-5%	Pass
3000 Ohm Load	3002	2992.3	+/-5%	Pass
5200 Ohm Load	5222	5210.3	+/-5%	Pass

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Internet http://www.taishobiomed.com/

FLUKE Biomedical

Current Test Monopolar Cut	Measured mA	Tolerance	UUT mA	%Error	Pass/Fail
500 Ohm load @ 50W Cut	316	+/-5%	317	0.41	Pass
300 Ohm load @ 50W Cut	404.9	+/-5%	407	0.52	Pass
300 Ohm load @ 100W Cut	572.6	+/-5%	576	0.59	Pass
1500 Ohm load @ 100W Cut	202	+/-5%	198	-1.98	Pass
300 Ohm load @ 150W Cut	702	+/-5%	705	0.43	Pass
300 Ohm load @ 200W Cut	810.8	+/-5%	812	0.15	Pass
300 Ohm load @ 300W Cut	911.7	+/-5%	913	0.14	Pass
700 Ohm load @ 300 W Cut	650.5	+/-5%	649	-0.23	Pass
200 Ohm load @ 300 W Cut	949	+/-5%	948	-0.05	Pass
100 Ohm load @ 300 W Cut	987	+/-5%	986	-0.09	Pass

Power Tests	Calculated Power Watts	UUT Power Watts	%Error
500 Ohm load @ 50W	50.4	51	1.21
300 Ohm load @ 50W	49.5	50	0.95
300 Ohm load @ 100W	99.1	100	0.96
1500 Ohm load @ 100W	61.3	59	-3.79
300 Ohm load @ 150W	148.9	150	0.75
300 Ohm load @ 200W	198.6	199	0.20
300 Ohm load @ 300W	251.1	252	0.35
700 Ohm load @ 300 W	298.4	298	-0.12
200 Ohm load @ 300 W	181.6	181	-0.35
100 Ohm load @ 300 W	99.9	100	0.06

Output Waveform Test — Pass

Current Test Monopolar Coag	Measured mA	Tolerance Percent	Offset (mA)	UUT mA	Pass/Fail
2000 Ohm @ 1W Coag	22.0	5%	2	20	Pass
1000 Ohm @ 1W Coag	30.0	5%	2	29	Pass
600 Ohm @ 1W Coag	37.2	5%	2	36	Pass
400 Ohm @ 1W Coag	45.1	5%	2	45	Pass
300 Ohm @ 3W Coag	96.0	5%	2	97	Pass
300 Ohm @ 7W Coag	148.5	5%	2	150	Pass
300 Ohm @ 12W Coag	194.6	5%	2	196	Pass
300 Ohm @ 27W Coag	292.0	5%	2	294	Pass
300 Ohm @ 75W Coag	497.2	5%	2	490	Pass
200 Ohm @ 110W Coag	616.7	5%	2	604	Pass
75 Ohm @ 110W Coag	638.8	5%	2	636	Pass
50 Ohm @ 110W Coag	642.6	5%	2	638	Pass

Span Tests Bipolar Coag	Measured mA	Tolerance Percent	Offset (mA)	UUT mA	Pass/Fail
600 Ohm @ 1W Coag	35.6	5%	2	34	Pass
400 Ohm @ 1W Coag	43.7	5%	2	43	Pass
300 Ohm @ 3W Coag	97.4	5%	2	98	Pass
300 Ohm @ 7W Coag	149.9	5%	2	150	Pass
300 Ohm @ 12W Coag	197.4	5%	2	198	Pass
300 Ohm @ 27W Coag	296.9	5%	2	299	Pass
275 Ohm @ 70W Coag	503.5	5%	2	507	Pass
125 Ohm @ 70W Coag	749.1	5%	2	753	Pass
50 Ohm @ 70W Coag	1153.0	5%	2	1150	Pass
25 Ohm @ 70W Coag	1539.0	5%	2	1523	Pass

Calibration Performed by : 天下良治 Date: 2018.9.28

Technical Check by : 橋本敏仁 Date: 2018.10.1

The suggested re-calibration date is: 2019/9/28

大正医科器械株式会社
大阪市大正区三軒家東 2-2-22
TEL. 06-6553-9666
FAX. 06-6553-9305
Internet http://www.taishobiomed.com/

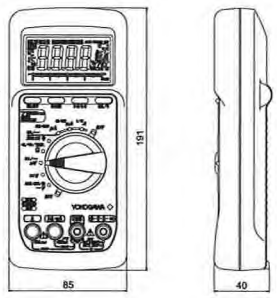
Test Equipment Depot
1-800-517-8431
99 Washington Street
Melrose, MA 02176
Fax 781-665-0780
TestEquipmentDepot.com

General Specifications of 73301 / 02 / 03

Additional Functions	Relative and percentage value computation, data / auto hold, overvoltage warning
Display	Digital display: 4,000-count digital reading; 40-segment bar graph
Measuring Rate	Digital display: 2.3 times/sec Bar graph display: 23 times/sec
Operating Temp. and Humidity	-10˚C to 50˚C; 80% RH or less at -10˚C to 40˚C, or 70% RH or less at 40˚C to 50˚C (no condensation)
Storage Temp. and Humidity	-20˚C to 60˚C, 70 RH or less (no condensation)
Temperature Coefficient	Add the accuracy (0.1/˚C to the basic accuracy at a temperature within -10˚C to 18˚C and 28˚C to 50˚C
Withstanding Voltage	5.55 kV AC for 1 minute (between input terminals and casing)
Power Supply	Two AA (R6) dry cells
Battery Life	73301: Approx. 1000 hours (for continuous DC voltage measurement with alkaline cells) 73302/03: Approx. 350 hours
Auto Power Off	The power is automatically turned off when no operation is made for approx. 20 minutes (can be disabled).
Dimensions	85 (W) x 191 (H) x 40 (D) mm
Weight	Approximately 450 g (including batteries)
Compliance with Standards	Safety EN61010-1 (1995); EN61010-2-031 (1995) (AC/DC 1000 V, CAT II; AC/DC 600 V, CAT III) EMC EMI: EN55011 (1998); EN61326-1 (1998) + A1(Class B, Group 1) EMS: EN50082-1 (1997); EN61326-1 (1998) + A1
Standard Accessories	Instruction manual:1, Test lead set (RD031):1, AA (R6) dry cells(built in):2

Optional Accessories

Name	Model	Specification
Fuse	A1518EF	500 mA/600 V
	A1519EF	15 A/600 V
Test leads	RD031	Red / black (1 set)
Thermistor probe	234901	-50˚C to 150˚C
Carrying case (hard)	B9646HH	Houses the DMM and test leads



Performance

Test conditions: Temperature and humidity = 23˚C ± 5˚C, 80% RH or less;Accuracy = ±(% rdg + dgt).
Note: A response time is the time required for achieving the accuracy specified for the corresponding range.

• DC Voltage Measurement (⎓ V)

Range	Accuracy 73301	Accuracy 73302/03	Input Resistance	Maximum Input Voltage
400.0 mV fixed	0.3% + 1	0.2% + 1	10 MΩ	1000 Vrms AC, 1000 V DC
4.000 V			11 MΩ	
40.00 V			10 MΩ	
400.0 V				
1000 V				

Response time: 1 second or less

• AC Voltage Measurement (~V)

Model 73301 — Mean-value detection and RMS-value calibration

Range	Accuracy 50/60 Hz	Accuracy 50 – 500 Hz	Accuracy 500 Hz – 1 kHz	Input Impedance	Maximum Input Voltage
400.0 mV fixed	0.5% + 2	1% + 2	1.5% + 4	10 MΩ, <50 pF	1000 Vrms AC, 1000 V DC
4.000 V				11 MΩ, <50 pF	
40.00 V				10 MΩ, <50 pF	
400.0 V					
1000 V			——		

Response time: 2 seconds or less

Model 73302 — Mean-value detection and RMS-value calibration

Range	Accuracy 50/60 Hz	Accuracy 50 – 500 Hz	Accuracy 500 Hz – 1 kHz	Input Impedance	Maximum Input Voltage
400.0 mV fixed	0.5% + 2	0.75% + 2	1.5% + 4	10 MΩ, <50 pF	1000 Vrms AC, 1000 V DC
4.000 V				11 MΩ, <50 pF	
40.00 V				10 MΩ, <50 pF	
400.0 V					
1000 V			——		

Response time: 2 seconds or less

Model 73303 — RMS detection, and mean-value detection and RMS-value calibration(except 400 mV range)

Range	Accuracy 50/60 Hz	Accuracy 50 – 500 Hz	Accuracy 500 Hz – 1 kHz	Input Impedance	Maximum Input Voltage
400.0 mV fixed	0.5% + 5 *1	1% + 5 *1	1.5% + 5 *1	10 MΩ, <50 pF	1000 Vrms AC, 1000 V DC
4.000 V				11 MΩ, <50 pF	
40.00 V				10 MΩ, <50 pF	
400.0 V					
1000 V			——		

Response time: 2 seconds or less; crest factor: <3
*1: 5 to 100% of F.S., or 200 to 1000 V for 1000 V range:

• DC Current Measurement (⎓ A)

Range	Accuracy 73301	Accuracy 73302/03	Voltage Drop	Maximum Input Current
400.0 µA	1% + 2	0.5% + 2	<0.11 mV/µA	400 mA (500 mA/600 V fuse-protected)
4000 µA			<2.5 mV/mA	
40.00 mA				
400.0 mA				
4.000 A	1.2% + 2		<0.1 V/A	10 A (15 A/600 V fuse-protected)
10.00 A				

Response time: 1 second or less

• AC Current Measurement (~A)

Model 73301 — Mean-value detection and RMS calibration

Range	Accuracy 50/60 Hz	Accuracy 40 Hz – 1 kHz	Voltage Drop	Maximum Input Current
400.0 µA	1% + 5	1.5% + 5	<0.11 mV/µA	400 mA (500 mA/600 V fuse-protected)
4000 µA			<2.5 mV/mA	
40.00 mA				
400.0 mA				
4.000 A	1.2% + 5		<0.1 V/A	10 A (15 A/600 V fuse-protected)
10.00 A				

Response time: 2 seconds or less

• AC Current Measurement (~AC)

Models 73302/03 — RMS-value detection (73303 only), and mean-value detection and RMS calibration

Range	Accuracy 50/60 Hz	Accuracy 40 Hz – 1 kHz	Voltage Drop	Maximum Input Current
400.0 µA	0.75% + 5 *1	1.5% + 5 *1	<0.11 mV/µA	400 mA (500 mA/600 V fuse-protected)
4000 µA			<2.5 mV/mA	
40.00 mA				
400.0 mA				
4.000 A	1% + 5 *1		<0.1 V/A	10 A (15 A/600 V fuse-protected)
10.00 A				

Response time: 3 sec or less; crest factor: <3 (73303 only)
*1: 5 to 100% of F.S., 2 – 10 A for 10 A range (73303 only)

• Resistance Measurement (Ω)

Range	Accuracy 73301	Accuracy 73302/03	Maximum Testing Current	Open-circuit Voltage	Input Protection Voltage
400.0 Ω	0.5% + 1*	0.4% + 1*	<1.4 mA	<2.5 V	600 Vrms
4.000 kΩ			<120 µA	<1.3 V	
40.00 kΩ			<13 µA		
400.0 kΩ			<1.3 µA		
4.000 MΩ		0.5% + 1	<130 nA		
40.00 MΩ	1% + 2				

Response time: 2 seconds or less for 400 Ω range, 10 seconds or less for 4 MΩ range or greater
*: Accuracy after zero calibration for 400 Ω range

• Continuity Check ( ))

Range	Continuity Beeper	Maximum Testing Current	Open-circuit Voltage	Input Protection Voltage
400.0 Ω	Buzzer sounds at 20 Ω or less.	0.8 mA	<3.4 V	600 Vrms

• Diode Test (→|←)

Range	Accuracy	Testing Current (Vf = 0.6 V)	Open-circuit Voltage	Input Protection Voltage
2.000 V	1% + 2	Approximately 0.5 mA	<3.4 V	600 Vrms

• Temperature Measurement (TEMP)

Range	Accuracy	Input Protection Voltage
-50.0˚C to 150.0˚C	0˚C to 70.0˚C: ± 1˚C -30.0˚C to 0˚C or 70.0˚C to 150.0˚C: ± 2˚C	600 Vrms

Accuracy when used in combination with optional thermistor probe (234901)

• Capacitor Check (⊣⊢)

Models 73302/03 (function not available with 73301)

Range	Accuracy	Input Protection Voltage
10.00 nF	2% + 10 (after zero calibration)	600 Vrms
100.0 nF	2% + 5	
1000 nF		
10.00 µF		
100.0 µF	3% + 5	
1000 µF		

• Frequency Measurement (Hz)

Models 73302/03 (function not available with 73301)

Range	Accuracy 73302/03	Input Voltage Range	Maximum Input Voltage
10.00 – 99.99 Hz	0.02% + 1	0.2 – 400 Vrms	600 Vrms
90.0 – 999.9 Hz			
900 – 9999 Hz		0.4 – 400 Vrms	
9.00 – 99.99 kHz		0.8 – 100 Vrms	100 Vrms

Coupling type: AC coupling

SG032(3) 様式4

計測装置社外校正記録書

管理番号 Control Number	F-07	管理部門 Division	リペアサービス Repair Service
計測装置名称 Product	YOKOGAWA デジタルマルチメーター Digital Multi Meter		
依頼先供給者名 Supplier	日本電計株式会社 Denkei		
校正実施日/期間 Date of Calibration	2018年3月14日 03/14/2018		
校正証明書の文書番号 ※受取った校正証明書の全ての文書番号を転記	・校正証明書 発行番号:UI-4428409 ・試験成績書 YEW-5251-01-S206-01 / 100209B02 ・トレーサビリティ体系図 UTM-006-1-068-18		
校正結果の確認	①校正担当者は校正結果の校正項目、公称値、測定値をレビューのうえ、許容範囲(合格範囲)内であることを確認し、校正結果にレ点チェックにより記録する。 (レ点チェックは、赤、青、緑などの色つきのペンを使用すること。)		
	②校正担当者は①の確認の結果、問題がなければ下記にチェックを記載する。 ☑ 校正項目、公称値、測定値をレビューし、許容範囲(合格範囲)内であることを確認しました。		
合否判定 Result	pass (合格) / 不合格 fail		
次回校正実施期限*1 Due Date	2020年3月 03/2020		

*1 次回校正実施期限は、前回校正実施年月に校正周期を加えた年月の月末までとする。

【作成】校正担当者 署名: Kazuhiro Ishimura 3/26/2018

【レビュー】計測装置管理責任者 署名: Yuki Ishimura 3/26/2018

【承認】QO 署名: E-Ota 03/26/2018

1/1

Date of Issue 03/14/2018
発行日：2018年3月14日
Control Number
発行番号：UI-4428409

校正証明書

Calibration Certification

顧客名：ジョンソン・エンド・ジョンソン株式会社 御中
Custome Johnson and Johnson K.K.

事業所名：
Plant

部門名：
Division

製品名：デジタルマルチメータ
Product Digital Multi Meter

型番：733 02
Product Code

製造者名：横河電機
Manufactured Yokogawa

製造番号：1501471
Manufacturing Number

管理番号：F-07
Control Number

校正日：2018年3月14日
Date of Calibration 03/14/2018

上記の製品は、当社の管理規定にもとづき校正されています。
使用した基準器は国際度量衡委員会（CIPM）/国際度量衡局（BIPM）に加盟する、国立研究開発法人産業技術総合研究所（AIST）等の国家、国際標準にトレーサブルである事を証明します。

ISO／IEC17025（RCL00030）認定校正機関
（直流電圧・電流／交流電圧・電流／直流抵抗）
ISO9001（JQA-QMA15393）、ISO14001（JQA-EM7241）認証取得
ユウアイ電子株式会社
埼玉県川越市かし野台2-16-
TEL:049-243-4703 FAX:049-243-470
E-mail:calroom@yuai.co.jp

試験成績書

顧客名 ジョンソン・エンド・ジョンソン株式会社 御中
Customer Johnson and Johnson K.K.

校正日 Date of Calibration 2018年3月14日 03/14/2018
温度 Temperature 21 ℃ 湿度 Humidity 41 %

製品名 デジタルマルチメータ
Product : Digital Multi Meter
型番 Product Code 733 02
製造者名 横河電機
Manufactured : Yokogawa
製造番号 Manufacturing Number 1501471
管理番号 F-07

校正者 Tester 矢内和宏
承認者 Approved
判定 Result

埼玉県川越市かし野台2-13-2
ユウアイ電子株式会社

上記の製品は、当社の管理規定にもとづき校正されています。使用した基準器は国際度量衡委員会(CIPM)/国際度量衡局(BIPM)に加盟する、国立研究開発法人産業技術総合研究所(AIST)等の国家、国際標準にトレーサブルです。

試験項目 Test Contents

直流電圧測定 DC Current

レンジ Range	分解能 Resolution	試験点 Test Point	確度 Spec	下限値 Lower	測定値 Measured	上限値 Upper	結果 Result
400 mV	0.1	100 mV	0.2 + 1	99.7 mV	100.0 mV	100.3 mV	合 格 ✓pass
4 V	0.001	1 V	0.2 + 1	0.997 V	1.000 V	1.003 V	合 格 ✓pass
40 V	0.01	10 V	0.2 + 1	9.97 V	10.00 V	10.03 V	合 格 ✓pass
400 V	0.1	100 V	0.2 + 1	99.7 V	100.0 V	100.3 V	合 格 ✓pass
1000 V	1	1000 V	0.2 + 1	997 V	999 V	1003 V	合 格 ✓pass

確度 Spec ±(% rdg+dgt)

交流電圧測定 AC Current f=400Hz

レンジ	分解能	試験点	確度	下限値	測定値	上限値	結果
400 mV	0.1	100 mV	0.75 + 2	99.1 mV	100.0 mV	100.9 mV	合 格 ✓pass
4 V	0.001	1 V	0.75 + 2	0.991 V	1.000 V	1.009 V	合 格 ✓pass
40 V	0.01	10 V	0.75 + 2	9.91 V	10.00 V	10.09 V	合 格 ✓pass
400 V	0.1	100 V	0.75 + 2	99.1 V	100.0 V	100.9 V	合 格 ✓pass
1000 V	1	1000 V	0.75 + 2	991 V	1000 V	1009 V	合 格 ✓pass

確度 ±(% rdg+dgt)

直流電流測定 DC Current

レンジ	分解能	試験点	確度	下限値	測定値	上限値	結果
400 μA	0.1	100 μA	0.5 + 2	99.3 μA	99.6 μA	100.7 μA	合 格 ✓pass
4000 μA	1	1000 μA	0.5 + 2	993 μA	999 μA	1007 μA	合 格 ✓pass
40 mA	0.01	10 mA	0.5 + 2	9.93 mA	9.96 mA	10.07 mA	合 格 ✓pass
400 mA	0.1	100 mA	0.5 + 2	99.3 mA	99.9 mA	100.7 mA	合 格 ✓pass
4 A	0.001	1 A	0.5 + 2	0.993 A	0.994 A	1.007 A	合 格 ✓pass
10 A	0.01	10 A	0.5 + 2	9.93 A	9.98 A	10.07 A	合 格 ✓pass

確度 ±(% rdg+dgt)

試験成績書

製品名 デジタルマルチメータ (Product: Digital Multi Meter)
型番 733 02 (Product Code)
製造者名 横河電機 (Product: Yokogawa)
製造番号 1501471 (Manufacturing Number)
管理番号 F-07 (Control Number)

交流電流測定 AC Current f=400Hz

レンジ Range	分解能 Resolution	試験点 Test Point	確度 Spec.	下限値 Lower	測定値 Measured	上限値 Upper	結果 Result
400 μA	0.1	100 μA	1.5 + 5	98.0 μA	99.9 μA	102.0 μA	合 格 ✓pass
4000 μA	1	1000 μA	1.5 + 5	980 μA	999 μA	1020 μA	合 格 ✓pass
40 mA	0.01	10 mA	1.5 + 5	9.80 mA	9.98 mA	10.20 mA	合 格 ✓pass
400 mA	0.1	100 mA	1.5 + 5	98.0 mA	99.7 mA	102.0 mA	合 格 ✓pass
4 A	0.001	1 A	1.5 + 5	0.980 A	0.996 A	1.020 A	合 格 ✓pass
10 A	0.01	10 A	1.5 + 5	9.80 A	9.97 A	10.20 A	合 格 ✓pass

確度 Spec ±(% rdg+dgt)

抵抗測定 Resistance

レンジ	分解能	試験点	確度	下限値	測定値	上限値	結果
400 Ω	0.1	100 Ω	0.4 + 1	99.5 Ω	100.0 Ω	100.5 Ω	合 格 ✓pass
4 kΩ	0.001	1 kΩ	0.4 + 1	0.995 kΩ	1.000 kΩ	1.005 kΩ	合 格 ✓pass
40 kΩ	0.01	10 kΩ	0.4 + 1	9.95 kΩ	9.99 kΩ	10.05 kΩ	合 格 ✓pass
400 kΩ	0.1	100 kΩ	0.4 + 1	99.5 kΩ	99.8 kΩ	100.5 kΩ	合 格 ✓pass
4 MΩ	0.001	1 MΩ	0.5 + 1	0.994 MΩ	1.000 MΩ	1.006 MΩ	合 格 ✓pass
40 MΩ	0.01	10 MΩ	1.0 + 2	9.88 MΩ	9.99 MΩ	10.12 MΩ	合 格 ✓pass

確度 Spec ±(% rdg+dgt)

data end

特記 : 顧客仕様

使用基準器 Reference Equipment

No	基準器名 Name of Equipment	製造番号 Manufacturing Number	管理番号 Control Number	基準器の有効期限 Due Date
1	マルチプロダクトキャリブレータ Multi Product Calibrator 5522A/SC600	2625904	U-1-068	19年02月

全ての測定値が許容範囲内であることを確認いたしました。

担当者	~~部門長~~ 計測標準管理責任者
Kyohiro Ishimura 3/26/2018	3/26/2018 YA Yuko Ohnuma 3/26/2018

TOS6100

AC LOW OHM TESTER

Specifications

■ Resistance Measured Values: 0 to 0.12Ω/0 to 0.6Ω, 2 ranges
Accuracy: ±10% of full scale (3 to 5 A)
±5% of full scale (5 to 30 A)

■ Test Current Output: 3 to 30 A AC, adjusted by dial on panel
Max. current 30 A AC, max. voltage: 8 V (when line voltage is at the central value of each input voltage range)
☛These values cannot be obtained at the same time.

■ Output Ammeter
Scale: 3 to 30 A AC
Accuracy: ±5% of full scale
Indication: Mean value response/rms value scale graduation

■ Pass/fail Judgement
Judgement Method:
- A FAIL judgement is made and output is cut off if the measured value is greater than the reference value.
- A PASS judgement is made and a PASS signal is output if there are no abnormalities after the set time has elapsed.

Limit Value Setting Range: Set as desired between 5 to 100% of the measuring range

Judgement Accuracy: ±15% of full scale for reference value (3 to 5 A)
±10% of full scale for reference value (5 to 30 A)

■ Subtraction Function:
- A predetermined value can be subtracted from the measured value and the result of subtraction can be displayed
- The result of subtraction can be compared with the judgement reference value and the result of comparison can be used for PASS/FAIL judgement

Subtraction Range: 0 to 0.1Ω
Subtraction Error: Max. ±5 of full scale (added to measuring accuracy or PASS/FAIL judgement accuracy)

■ Test Current Monitoring Function:
- Test current can be monitored during testing
- A warning alarm is generated when the test current value deviates from the range of approximately 10% of the monitoring reference value
- Reference values can be set as desired within a range of 3 to 30 A
- Continuation or stopping of testing when a warning has occurred can be selected

■ Test Time: 0.5 seconds to 10 minutes (with 4-range timer)

■ Remote Control
Start/Stop Operation:
- Low active control
- Input conditions:
  - ◆High level input voltage: 11 to 15 V
  - ◆Low level input voltage: 0 to 4 V
  - ◆Low level sweepout current: Max. 2 mA
  - ◆Input signal time width: Min. 20 ms
- ☛Since the input terminal is pulled up to a +15V power supply by a resistor, input becomes equal to high level input if the input terminal is open.

■ Signal Outputs

Signal Type	Conditions for Signal Output	Signal Contents
TEST	Testing in progress	Make contact signal, amp
PASS	Approx. 50 ms when PASS judgement is made	Make contact signal, amp, buzzer
FAIL	Continuous when FAIL judgement is made	Make contact signal, amp, buzzer
WARNING	See test current monitoring function	Make contact signal, amp
READY	During standby	Make contact signal
MONITOR	Normal	DC 0 to 10 V

☛(1) The contact rating of the contact signal is 100 V AC, 1 A/30V DC, 1
☛(2) Buzzer volume can be adjusted with a single dial for the PASS signal and FAIL alarm.
☛(3) The MONITOR output consists of an output of direct current voltage proportional to the angle of deflection of the pointer on the ohmmeter. The scale is as indicated below.
- ●0.5 Ω range: 10V/0.5Ω
- ●0.1 Ω range: 10V/0.1Ω

The absolute value of output voltage error is either 5% of the output value or 50 mV, whichever is larger.

■ Environment
Specification temperature and humidity ranges: 5 to 35°C/20 to 85% RH
Operating temperature and humidity ranges: 0 to 40°C/20 to 90% RH
Storage temperature: -20 to 70°C/Max. 90% RH

■ Power Requirements
Allowable Line Voltage: A: 90 to 110V, B: 104 to 125V, C: 194 to 236V, D: 207 to 250V
Frequency: 50/60 Hz
Power Consumption: Max. 20 VA under no-load conditions (READY state)
Approx. 280 VA during 30 A output (RM ≒ 0.22Ω)
Insulation Resistance: Min. 30 MΩ at 500V DC
Withstanding Voltage: 1000V AC for 1 minute

■ Dimensions (MAX): 430W × 149H × 370Dmm (430W × 164H × 435Dmm)

■ Weight: Approx. 16 kg

■ Accessories:
- ●Short bars (to be attached to the tester):2
- ●Power cable set: 1
- ●Operation manual: 1
- ●Fuse 3 A (S.B): 1
- ●Fuse 1.6 A (S.B): 2

■ Options:
- ●Model RC01-TOS/RC02-TOS remote control box
- ●Model LTP-2 low resistance test probe
- ●Model BZ01-TOS buzzer unit
- ●Model PL01-TOS warning light unit
- ●Model BH3M-TOS rack mount bracket for JIS
- ●Model BH4-TOS rack mount bracket for EIA

SG032(2) 様式4

計測装置社外校正記録書

管理番号 Control Number	F-09	管理部門 Division	リペアサービス Repair Service
計測装置名称 Product	交流低抵抗試験器 TOS6100 S/N:29070206 Ground Bond Tester		
依頼先供給者名 Supplier	日本電計株式会社 Denkei		
校正実施日/期間 Date of Calibration	08/03/2017		
校正証明書の文書番号 ※受取った校正証明書の全ての文書番号を転記	校正証明書 発行番号:UI-4410258 試験成績書 KIK-0008-01 040422T07 トレーサビリティ体系図 UTM-006-1-0163-03 トレーサビリティ体系図 UTM-006-1-197-19		
校正結果の確認	①校正担当者は校正結果の校正項目、公称値、測定値をレビューのうえ、許容範囲(合格範囲)内であることを確認し、校正結果にレ点チェックにより記録する。 (レ点チェックは、赤、青、緑などの色つきのペンを使用すること。)		
	②校正担当者は①の確認の結果、問題がなければ下記にチェックを記載する。 ☑ 校正項目、公称値、測定値をレビューし、許容範囲(合格範囲)内であることを確認しました。		
合否判定 Result	pass 合格 / 不合格 fail		
次回校正実施期限*1 Due Date	8/2019		

*1 次回校正実施期限は、前回校正実施年月に校正周期を加えた年月の月末までとする。

【作成】校正担当者 署名: 結城紀昭 8/4/2017

【レビュー】計測装置管理責任者 署名: Yuki Shimura 8/4/2017

【承認】QRC 署名: 08/07/2017

1/1

Date of Issue 08/03/2017
発行日：2017年8月3日
Control Number
発行番号：UI-4410258

校正証明書

Calibration Certification

顧客名：ジョンソン・エンド・ジョンソン株式会社 御中
Customer : Johnson and Johnson K.K.

事業所名 ：
Plant

部門名 ：
Division

製品名：交流低抵抗試験器
Product : Ground Bond Tester

型番：TOS6100
Product Code : TOS6100

製造者名：菊水電子工業
Manufatured : Kikusui Electronic Corp.

製造番号：29070206
Manufacturing Number : 29070206

管理番号：F-09
Control Number : F-09

校正日：2017年8月3日
Date of Calibration : 08/03/2017

上記の製品は、当社の管理規定にもとづき校正されています。
使用した基準器は国際度量衡委員会（CIPM）/国際度量衡局（BIPM）に加盟する、国立研究開発法人産業技術総合研究所（AIST）等の国家、国際標準にトレーサブルである事を証明します。

ISO／IEC17025（RCL00030）認定校正機関
（直流電圧・電流／交流電圧・電流／直流抵抗）
ISO9001（JQA-QMA15393）、ISO14001（JQA-EM7241）認証取得
ユウアイ電子株式会社
埼玉県川越市かし野台2-16-
TEL:049-243-4703 FAX:049-243-470
E-mail:calroom@yuai.co.jp

試験成績書 Test Report

顧客名 ジョンソン・エンド・ジョンソン株式会社 御中
Customer : Johnson and Johnson K.K.

校正日 Date of Calibration 2017年8月3日 08/03/2017
温度 21 ℃ 湿度 42 %
temperature 21°C humidity 42%

製品名 交流低抵抗試験器
Product : Ground Bond Tester
型番 TOS6100
Product Code : TOS6100
製造者名 菊水電子工業
Manufactured : Kikusui Electronic Corp
製造番号 29070206
Manufacturing Number 29070206
管理番号 F-09
Control Number

校正者 矢内和宏
Tester : Kazuhiro Yauchi
承認者
Approved : Suzuki
判定 Result 合格 PASS
埼玉県川越市かし野台2-13-2
ユウアイ電子株式会社

上記の製品は、当社の管理規定にもとづき校正されています。使用した基準器は国際度量衡委員会(CIPM)/国際度量衡局(BIPM)に加盟する、国立研究開発法人産業技術総合研究所(AIST)等の国家、国際標準にトレーサブルです。

試験項目 Test Contents

抵抗測定 Resistance 10A

レンジ Range	試験点 Test point	確度 Spec	下限値 lower	測定値 measured	上限値 upper	結果 Result
0.10 Ω	0.02 Ω	5	0.015 Ω	0.019 Ω	0.025 Ω	合 格 ✓ PASS
0.10 Ω	0.06 Ω	5	0.055 Ω	0.060 Ω	0.065 Ω	合 格 ✓ PASS
0.10 Ω	0.10 Ω	5	0.095 Ω	0.100 Ω	0.105 Ω	合 格 ✓ PASS
0.50 Ω	0.10 Ω	5	0.075 Ω	0.100 Ω	0.125 Ω	合 格 ✓ PASS
0.50 Ω	0.30 Ω	5	0.275 Ω	0.296 Ω	0.325 Ω	合 格 ✓ PASS
0.50 Ω	0.50 Ω	5	0.475 Ω	0.500 Ω	0.525 Ω	合 格 ✓ PASS
			確度 ±(% fs) Spec			

電流計 Current

試験点	確度	下限値	測定値	上限値	結果
10 A	5	8.50 A	9.95 A	11.50 A	合 格 ✓ PASS
20 A	5	18.50 A	19.88 A	21.50 A	合 格 ✓ PASS
30 A	5	28.50 A	29.76 A	31.50 A	合 格 ✓ PASS
fs= 30 A			確度 ±(% fs)		

data end

使用基準器 Reference Equipment

No	基準器名 Name of Equipment	製造番号 Manufacturing Number	管理番号 Control Number	基準器の有効期限 Due Date
1	マルチプロダクトキャリブレータ Multi Product Calibrator 5502A	2927802	U-1-163	17年10月 ✓
2	デジタルマルチメータ DMM 34410A	MY45001069	U-1-197	18年04月 ✓

全ての値が良好であることを確認しました。

担当者	~~部門長~~
結城 8/4/2017	計測装置管理責任者 Yuki Hamura 8/4/2017

8/4/2017 矢内

KIK-0008-01 ユウアイ電子株式会社 040422T07

3156 Specifications

■ Leak current measurement

Measurement mode : Earth leakage current / Leakage current between enclosure and earth / Leakage current between enclosure and enclosure / Leakage current between enclosure and line / Patient leakage current I / Patient leakage current II / Patient leakage current III / Patient auxiliary current

Target current : DC, AC, AC+DC, AC peak

Allowable value measurement current : 25 mA max. (DC/AC/AC+DC mode)
75 mA max. (ACpeak mode)

Measurement range : DC/AC/AC+DC mode:
50 μA/500 μA/5 mA/25 mA
AC peak mode:
500 μA/1 mA /10 mA/75 mA

Range switch : Auto range/Hold range

Trigger system : Manual: Automatic generation of internal trigger, and free-run measurement
Automatic: measurement started by external start signal
1. Started by pressing Start key on the operation screen.
2. Asserted by the START terminal on the EXT I/O connector.
3. Started by the :START interface command.

Measurement speed : Trigger-system manual measurement: 100 ±1 ms (indication of moving average of 16 measurements)
Trigger-system automatic measurement:
100 ±1 ms (min.) - measurement setting time

Measurement terminals : Terminal T1, terminal T2 (with built-in fuse holder)
Terminal T3 (110% voltage application terminal)

Measurement system : Indication of a current value calculated based the measured drop in voltage caused by simulated resistance of the human body.
Measurement of true effective value.
The measurement section: chassis-grounded and floating.

A/D conversion system : Δ Σ system (20 bits)

Input resistance : 1 MΩ ±1% (single-ended input)
Excluding voltmeter section, simulated resistance of the human body (current detection circuit)

Input capacity : 200 pF or lower (between terminals T1 and T2)
(f = 100 kHz, with network circuit isolated)

Grounding capacity : 200 pF or lower(between terminals T1/T2 and chassis)

CMRR (between terminals T1/T2 and chassis) : 60 dB or higher, at 60 Hz, 10 kHz
40 dB or higher, at 100 kHz, 1 MHz

■ Network (human simulated resistance)

- For medical electrical equipment : Basic measurement element: 1 kΩ
  Filter: 10 kΩ + 15 nF
- For IEC 60990 : Basic measurement element: 1.5 kΩ + 500 Ω
  Filter 1: 10 kΩ + 22 nF
  Filter 2: 10 kΩ + (20 kΩ+ 6.2 nF) // 9.1 nF
- For JIS : Basic measurement element: 1 kΩ
  Filter: 10 kΩ + 11.22 nF + 579 Ω
- For UL : Basic measurement element: 1.5 kΩ // 0.15 μF
- General-purpose 1: Basic measurement element : 1 kΩ
- General-purpose 2: Basic measurement element : 2 kΩ

■ Functions

110% voltage application function : Equipped with a voltage output terminal (T3) that applies 110% power supply voltage between the functionally insulated signal input/output section (or Type F applied part) and ground.
Output ON/OFF selection
Output impedance: 22.5 ±1 kΩ
•Applied when positive phase (to input power supply voltage)
•Applied when negative phase (to input power supply voltage)
Automatic switching function (automatic measurement function)

Wiring check function : Polarity check/VA check

Automatic measurement function : Setting of measuring time.
Setting of delay (wait) time for changing setting conditions.
The power supply polarity and equipment status are automatically switched during measurement.

Application line selection function : Use of T2 and internal contact/Use of T1 and T2

Ground fault prevention function : Pre-check of current value between connection terminals to prevent a ground fault. Only effective for leakage current measurement between enclosure and line.

Setting of single-fault condition : •Setting of malfunction mode for power line for sample equipment.
1. Disconnection of one wire in power line (neutral side)
2. Disconnection of protective earth conductor
•Application of 110% voltage for simulated connection of malfunctioning equipment.
Positive phase/negative phase
•Selection of application line for leakage current measurement between enclosure and line.

Power line for sample equipment (switching power supply polarity) : Positive/negative phase
(Automatic switching possible when using automatic measurement function)

Setting of measuring time : Setting range: 1 sec. to 5 min., in 1-sec. increments
Effective only in automatic measurement

Measurement delay (setting) function : Setting range: 1 sec. to 30 min., in 1-sec. increments
•Wait time from the completion of measurement to power supply disconnection
•Wait time from switching power supply polarity to the start of measurement
•Wait time for operations other than switching polarity

Maximum value hold function : Effective in all measurement modes

Allowable value judgement function : Allowable value: Sets the upper-limit current value
Judgement: PASS measurement value ≤ upper-limit value
FAIL measurement value > upper-limit value
Processing: Indication, buzzer, judgement output from EXT I/O

Mode selection function : •Current measurement function
Unit of current measurement: Auto/ mA, fixed
•Voltage measurement function
Isolates the internal network for using the product as a voltmeter between terminals T1 and T2.
Maximum measurement voltage: 25 V

Beep sound setting : •Allowable value judgement
•Key input
•T3 (110% voltage application terminal) output
•Line voltage output from T2

Save/load function : 30 panels for saving the following setting data (measurement mode, network, equipment name, control number, grounding class, applied part, measurement range, filter, target current, allowable value setting, malfunction condition setting, power supply polarity switching, automatic measurement items, automatic measuring time, measurement delay time)

Data save function : Saved content: Sample equipment information (equipment name, control number), measurement data, date
Memory capacity: Data on up to 100 units

Clock function : Auto calendar, automatic leap-year adjustment, 24-hour clock
Clock accuracy: Deviation of about 4 minutes a month

Data backup function : SRAM (test condition data), RTC
Backup battery life: 4 years (reference value at 25°C)

Backlight automatic OFF function : Constant ON/Auto OFF
1 min. to 30 min., in 1-min. increments

Self-test function : MEM (internal RAM)/KEY (6 x 6 matrix touch panel)/ LCD (front LCD panel)/LED /Buzzer

Language setting : Japanese or English

System reset : Clears all data including measurement conditions and measurement data.
Clears all saved measurement data.
Clears all saved condition setting data including panels.

SG032(3) 様式4

計測装置社外校正記録書

管理番号 Control Number	F-56	管理部門 Division	リペアサービス Repair Service
計測装置名称 Product	LEAK CURRENT HITESTER S/N 051238345		
依頼先供給者名 Supplier	日本電計株式会社 Denkei		
校正実施日/期間 Date of Calibration	2018年11月5日 11/05/2018		
校正証明書の文書番号 ※受取った校正証明書の全ての文書番号を転記	・校正証明書：発行番号 UI-4518429 ・試験成績書：HIK-0021-03 / 170217R01 ・トレーサビリティ体系図：UTM-006-1-017-20 / UTM-006-1-119-18		
校正結果の確認	①校正担当者は校正結果の校正項目、公称値、測定値をレビューのうえ、許容範囲(合格範囲)内であることを確認し、校正結果にレ点チェックにより記録する。 (レ点チェックは、赤、青、緑などの色つきのペンを使用すること。)		
	②校正担当者は①の確認の結果、問題がなければ下記にチェックを記載する。 ☑ 校正項目、公称値、測定値をレビューし、許容範囲(合格範囲)内であることを確認しました。		
合否判定 Result	pass (合格) / 不合格 fail		
次回校正実施期限*1 Due Date	2019年11月 11/2019		

*1 次回校正実施期限は、前回校正実施年月に校正周期を加えた年月の月末までとする。

【作成】校正担当者 署名: K. Murai 11/8/2018

【レビュー】計測装置管理責任者 署名: Yuki Shimizu 11/8/2018

【承認】QO 署名: E. Ota 11/08/2018

1/1

Date of Issue 11/15/2018
発行日：2018年11月5日
Control Number
発行番号：UI-4518429

校正証明書

Calibration Certification

顧客名：ジョンソン・エンド・ジョンソン株式会社 御中
Customer Johnson and Johnson k.k.

事業所名：
Plant

部門名：
Division

製品名：リークカレントハイテスタ
Product Leak Current Hi Tester

型番：3156
Product Code

製造者名：日置電機
Manufactured Hioki

製造番号：051238345
Manufacturing Number

管理番号：F-56
Control Number

校正日：2018年11月5日
Date of Calibration 11/05/2018

上記の製品は、当社の管理規定にもとづき校正されています。
使用した基準器は国際度量衡委員会（CIPM）/国際度量衡局（BIPM）に加盟する、国立研究開発法人産業技術総合研究所（AIST）等の国家、国際標準にトレーサブルである事を証明します。

ISO／IEC17025（RCL00030）認定校正機関
（直流電圧・電流／交流電圧・電流／直流抵抗）
ISO9001（JQA-QMA15393）、ISO14001（JQA-EM7241）認証取得
ユウアイ電子株式会社
埼玉県川越市かし野台2-22-
TEL:049-243-8611 FAX:049-242-19
E-mail:calroom@yuai.co.jp

試験成績書

(1/1)

顧客名 ジョンソン・エンド・ジョンソン株式会社 御中
Customer Johnson and Johnson K.K.

校正日 2018年11月5日
Date of Calibration 11/05/2018
温度 23 ℃ 湿度 47 %
Temperature Humidity

製品名 リークカレントハイテスタ
Product Leak Current Hi Tester
型番 3156
Product Code
製造者名 日置電機
Manufacturer Hioki
製造番号 051238345
Manufacturing Number
管理番号 F-56
Control Number

校正者 金子正志
Tester
承認者
Approved
判定 合格 pass
Result
埼玉県川越市かし野台2-22-20
ユウアイ電子株式会社

上記の製品は、当社の管理規定にもとづき校正されています。使用した基準器は国際度量衡委員会(CIPM)/国際度量衡局(BIPM)に加盟する、国立研究開発法人産業技術総合研究所(AIST)等の国家、国際標準にトレーサブルです。

試験項目 Test Contents

直流電流測定 DC Current

レンジ Range	分解能 resolution	試験点 Test Point	確度 Spec	下限値 Lower	測定値 Measured	上限値 Upper	結果 Result
50 μA	0.01	10 μA	1 % fs	9.50 μA	9.96 μA	10.50 μA	合 格 pass
500 μA	0.1	100 μA	1 % fs	95.0 μA	99.9 μA	105.0 μA	合 格 pass
5 mA	0.001	1 mA	0.2 + 3	0.995 mA	0.998 mA	1.005 mA	合 格 pass
25 mA	0.01	10 mA	0.2 + 3	9.95 mA	9.99 mA	10.05 mA	合 格 pass

確度 ±(% rdg+dgt)
Spec

交流電流測定 AC Current f=50Hz

レンジ	分解能	試験点	確度	下限値	測定値	上限値	結果
50 μA	0.01	10 μA	2 % fs	9.00 μA	10.01 μA	11.00 μA	合 格
500 μA	0.1	100 μA	2.0 + 6	97.4 μA	100.1 μA	102.6 μA	合 格
5 mA	0.001	1 mA	2.0 + 6	0.974 mA	0.998 mA	1.026 mA	合 格
25 mA	0.01	10 mA	2.0 + 6	9.74 mA	9.98 mA	10.26 mA	合 格

確度 ±(% rdg+dgt)

ネットワーク 患者測定モードT-1 T-2間で測定。

data end

使用基準器 Reference Equipment

No	基準器名 Name of Equipment	製造番号 Manufacturing Number	管理番号 Control Number	基準器の有効期限 Due Date
1	デジタルマルチメータ DMM 34410A	MY53003789	U-1-017	19年10月
2	マルチプロダクトキャリブレータ 5500A Multi Product Calibrator	7455002	U-1-119	19年08月

5.0 PHYSICAL REQUIREMENTS

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

PHYSICAL REQUIREMENTS

Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

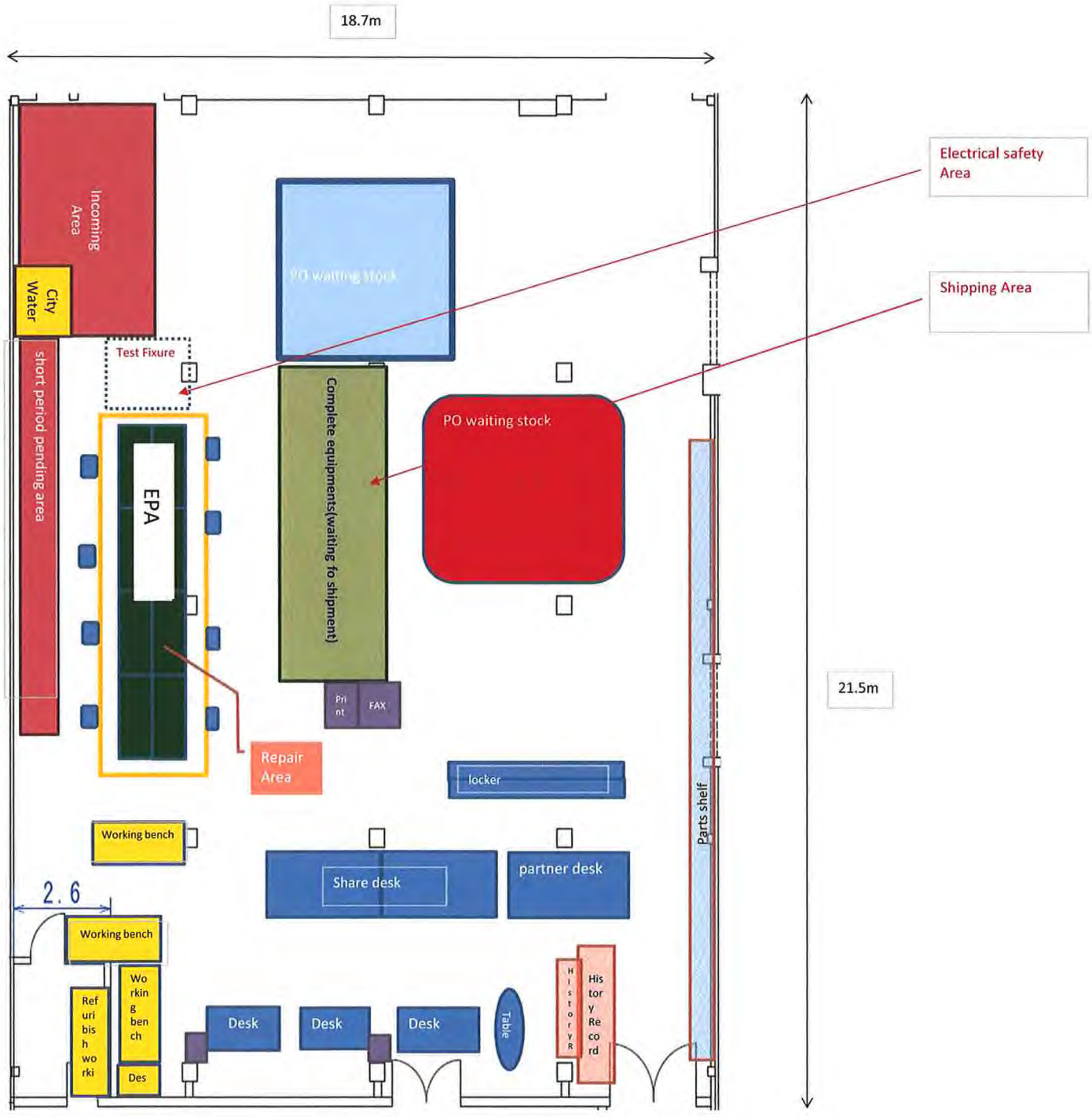
Re: 1000

Refer to Attachment for the support documentation that the J&J K.K. Medical Products Service and Repair Depot, Sukagawa, Japan has the necessary physical requirements to provide adequate space for the service and repair of the 1000.

The service center meets the electrical power requirements and has separate work spaces for product receiving/shipping, decontamination, service area, and electrical safety.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer


18.7m
Incoming Area
City Water
short period pending area
Test Fixure
PO waiting Mock
Complete equipments(waiting fo shipment)
PO waiting stock
EPA
Pri nt
FAX
Repair Area
locker
Working bench
Share desk
partner desk
2.6
Working bench
Wo rkin g ben ch
Ref uri bis h wo rki
Des
Desk
Desk
Desk
Table
His tor y Re co rd
Parts shelf
21.5m
Electrical safety Area
Shipping Area

6.0 OPERATING AGREEMENT

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

OPERATING AGREEMENT

Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

Re: 1000

EES and Johnson & Johnson Medical KK, Japan have entered into an operating agreement. The Operating Agreement is located in International Contract database and can be located under e-ICD # 1340355. The most recent version of that agreement is also attached to factbook.

Additionally, Johnson and Johnson K.K. Medical Products, has entered into a quality agreement with Ethicon Endo-Surgery, LLC. The most recent version of that agreement is in Adaptive under #100592785.

E-Sig in EpiCenter

_____

Jason Stivers
Service Engineer, EES – Service Staff Engineer

SERVICE OPERATING AGREEMENT

THIS SERVICE OPERATING AGREEMENT ("Agreement"), effective as of the (February 7, 2019), between **ETHICON ENDO-SURGERY, Inc.**, ("**EES**") an Ohio corporation, having offices at 4545 Creek Road, Cincinnati, Ohio 45242 and **JOHNSON AND JOHNSON K.K. Medical Company** with offices at 5-2 Nishi-kanda 3 chome Chiyoda-ku, Tokyo 101-0065, Japan.

RECITALS

WHEREAS, EES is engaged in the manufacturing, distribution, and sale of medical device products and employs the necessary qualified personnel and/or has agreements with service providers, including without limitation, SERVICE CENTER, to provide the services described hereto; and

WHEREAS, SERVICE CENTER has the capability and expertise to perform the Services described herein; and has been engaged to provide for the service and repair of affiliate units including but not limited to the purchase of spare parts and technical services;

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements, provisions and covenants contained herein, and for other good and valuable consideration, the receipt and legal sufficiency whereof are hereby acknowledged, the parties hereto further agree as follows:

ARTICLE I
DEFINITIONS

Section 1.1 Definitions

(a) Affiliate. "**Affiliate**" of a party shall mean any entity or person that directly or indirectly controls, is controlled by or is under common control with such party. For purposes of this definition, "control" shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise.

(b) Agreement. "**Agreement**" shall mean this agreement, including the appendices, exhibits and attachments hereto, and any Modifications issued hereunder.

(c) Management Services. "**Services**" shall mean (i) all services, tasks, functions and other responsibilities and activities associated to the service and repair of the EES products to be performed by SERVICE CENTER in accordance, including without limitation, the provision of providing spare parts, technician training, service bulletins; and (ii) all Implied Services. Services are described in more detail in Attachment 2, attached hereto and incorporated herein.

(d) Technician In Training. "**Technician In Training**" shall mean an employee of SERVICE CENTER with at least 2 years of formal electro-mechanical training or equivalent experience.

(e) Term. "**Term**" shall mean the period of time during which this Agreement is in effect in accordance herewith.

ARTICLE II
TERM

Section 2.1 Term.

(a) This Agreement shall be effective for an initial period of twelve (12) months from and after the Effective Date. At the end of this period, the Agreement shall automatically renew for additional successive twelve (12) month Terms, unless one party shall give the other party thirty (30) days' notice of its intention not to renew the Agreement at the end of its then-current term.

(b) This is the entire Agreement. Previous agreements before the agreement hereto are superseded. This agreement can only be modified in writing, in an amendment signed by both parties

Section 2.2 Termination

(a) Upon termination of business by either party, for one product or all business, the responsibility for the transfer of assets will be as follows:

a. SERVICE CENTER will transfer all tooling, equipment and materials owned by EES or its independent contractor to the location determined by EES or its independent contractor.

b. SERVICE CENTER will provide all original documentation, or copies including device master records, device history records, drawings, material inspection documentation, process and inspection instruction sheets for all EES products to EES.

ARTICLE III
RETENTION OF SERVICE CENTER

Section 3.1 Performance of Services

(a) EES hereby engages and retains SERVICE CENTER to perform the Services described in Article IV hereof and SERVICE CENTER hereby accepts and agrees to provide such Services to EES upon the terms and conditions set forth herein.

(b) SERVICE CENTER shall, in its sole discretion, determine the corporate facilities to be used in rendering the Services and the personnel who will render such Services.

(c) Nothing herein shall be deemed to restrict SERVICE CENTER or its directors, officers or employees from engaging in any business, or from contracting with other parties, including, without limitation, other subsidiaries of SERVICE CENTER, to provide such services contracted through this Agreement. Nothing herein shall be deemed to restrict EES or its directors, officers or employees from engaging in any business, or from contracting with other parties, to obtain services such as those contracted through this Agreement.

a. SERVICE CENTER and EES hereby agree that all Services for which EES engages SERVICE CENTER hereunder including but not limited to the service and repair of EES capital device units, will be done in accordance with the procedures and processes requirements as established in: Product Qualification at Service Centers per EES procedure WE001534, "Establishment and Certification of Service Depot, Field Service and Parts Depot Centers."

Section 3.2 Disclaimer, Limited Liability

(a) Neither party makes any express or implied representations, warranties or guarantees relating to the subject matter of this Agreement.

(b) EES will use reasonable efforts to make the Services available with substantially the same degree of care as it employees in making the same or similar services available for its own operations; provided, however, that EES shall not be liable to SERVICE CENTERS or any other person for any loss, damage or expense which may result there from or from any change in the manner in which EES renders the Services, so long as EES deems such change necessary or desirable in the conduct of its own operations.

ARTICLE IV
SERVICES

SERVICE CENTER shall, at the request of EES, provide Services in the following areas as required by EES, or such other services as the parties may agree from time to time.

Section 4.1 Good Manufacturing Practices

(a) SERVICE CENTER agrees to comply with Good Manufacturing Practices (GMP) for service and repair of all EES products as defined by the FDA Code of Federal Regulations, 21 CFR – Part 820, the applicable ISO 9000 and /or 13485, Quality Systems standards, and EES requirements.

(b) These requirements include but are not limited to:

a. Maintaining a certified quality system is preferred. When the SERVICE CENTER does not maintain a certified quality system, the establishment process will ensure the FDA Code of Federal Regulations, 21 CFR – Part 820 is adhered to.

b. Maintain viable quality assurance functions separate from and not reporting to manufacturing.

c. Conduct ISO 9000, 13485, or similar training as required by the service center's Quality Management System of all personnel on a regular basis and at least once every two years.

d. Conduct complaint training at least once every year.

e. Comply with the listed procedures and process requirements as well as with spare parts serial number traceability.

(c) Maintain and comply with the Documentation Retention Policy. Each of SERVICE CENTER and EES will maintain all records for which it is responsible that are required to support compliance to FDA Code of Federal Regulations, 21, CFR – Part 820 in compliance with Worldwide Records and Information Management; WWRIM Standard RIMS-12.

(d) Provide, within five business days, any information and/or records requested by EES.

Section 4.2 Product and Service Quality

(a) In compliance to WE001534, SERVICE CENTER shall maintain at least one technician who received certified training by EES for each product line. Said technician(s) will be given a training certificate upon completion of the EES-provided training and will then be qualified to train other technicians at SERVICE CENTER on the service and repair of EES capital device products at EES. All associates working on EES products will be trained by EES or its designated independent contractor trained associate. EES will provide all technical service documentation required to service the EES products.

(b) SERVICE CENTER will perform the activities of service and repair on EES products only if (i) the individual performing such services have a minimum of 2 years formal electro-mechanical training or equivalent experience, as determined by the center; and/or (ii) the individual performing such services is considered to be a Technician In Training and SERVICE CENTER employs an individual with a minimum of 2 years formal electro-mechanical training or equivalent experience, as determined by the center, which overviews the work performed by such Technician In Training.

(c) SERVICE CENTER shall not commence servicing any device until the requirements of WE001534 have been met and documented, also per WE001534, in writing from EES.

(d) Replacement/spare parts are only those listed in the service manual or service bulletins. All spare parts shall be purchased through EES. Serial numbers of spare parts used to repair a device shall be recorded in the service record.

(e) SERVICE CENTER will use the medical device sector's complaint and service data bases to capture service records. SERVICE CENTER that have no access to these databases will provide EES with weekly service reports containing the following information

a. Product Code
b. Serial Number
c. Problem reported by the customer
d. Service performed
e. Date equipment was received at the Service Center
f. Date of service
g. Person who performed the Service
h. Was the customer problem verified?
i. Which part/parts caused the customer's reported problem
j. Which parts were related to the reported issue
k. Which parts were unrelated
l. Description(s), part number(s), and quantity of parts used.

(f) All documentation related to the service and repair of EES products must be in English.

(g) SERVICE CENTER shall comply with and/or execute all EES provisions and/or modification instructions regarding the equipment when carrying out service and repair work according to Service Manuals and Service Bulletins. SERVICE CENTER likewise shall check and record the function of equipment as per current equipment specifications once it has been repaired.

(h) EES shall inform SERVICE CENTER of all hardware and software changes of equipment and their effect on the functionality of the equipment. EES shall also make the relevant technical modification documentation available to SERVICE CENTER. This shall be accomplished per the EES service bulletin process.

(i) SERVICE CENTERS will be notified of product/process/part changes through EES service bulletins issued by the equipment service team.

(j) Annual Business/Quality Reviews will be conducted between EES and SERVICE CENTER as described in Attachment 3, attached hereto and incorporated herein.

(k) SERVICE CENTER has the options (or a combination thereof) listed below for communicating complaint and service information. This information will be communicated in accordance with Johnson & Johnson global medical device reporting mandates. SERVICE CENTER shall work closely with its Johnson & Johnson complaint management organizations to ensure reportable linkages between the service records and EES product issue records.

a. SERVICE CENTER may use a Johnson & Johnson complaint management system; or,
b. SERVICE CENTER may provide the information described in paragraph 4.2 (e) above using EES's service database/complaint system.

(l) EES shall respond to escalations that require technical support

Section 4.3 End of Life

(a) SERVICE CENTER will continue to service each device for seven (7) years after the end of manufacturing or a period determined by EES.

(b) End of product notification will be communicated to SERVICE CENTER via a service bulletin.

ARTICLE V
RECORD RETENTION

Section 5.1 Record Retention

(a) SERVICE CENTER shall be responsible for retention of documentation generated in the performance of the Services. SERVICE CENTER shall comply with the Documentation Retention Policy. All records required to support compliance to

FDA Code of Federal Regulations, 21, CFR – Part 820 will be stored for fifteen (15) years after the last of the Services has been discontinued.

(b) To the extent the Services under this Agreement involve the creation of records that demonstrate regulatory, legal and/or other compliance, the party creating such records and/or its subcontractors will comply with the provisions hereto, and will include such provisions in its contracts with any subcontractors it engages to perform the Services.

ARTICLE VI
COMPENSATION AND ASSET MANAGEMENT

Section 6.1 Compensation for Services

(a) Pricing for service and repair of Affiliate units shall be negotiated between EES and SERVICE CENTER.

(b) SERVICE CENTER will place purchase orders to EES or any of its independent contractors for any service and/or spare parts to be provided. Compensation for services rendered will be paid to the company to which the SERVICE CENTER has placed the purchase order with.

Section 6.2 Asset Management

(a) SERVICE CENTER, as the owner of the unique capital assets, has financial responsibility for maintaining them.

(b) SERVICE CENTER agrees to keep and maintain service life history for all EES assets used by the SERVICE CENTER in the service and repair of EES capital products. The service history will be maintained in a Johnson & Johnson service database.

(c) SERVICE CENTER agrees to maintain all assets required to service and repair EES products to ensure continuity of product service. SERVICE CENTER agrees to fund all maintenance expenses to refurbish EES related custom test fixtures/tooling.

ARTICLE VII
REGULATORY AND SAFETY

Section 7.1 Regulatory and Safety.

(a) SERVICE CENTER will provide access and support for the audit plan for EES/ Johnson & Johnson/ISO/FDA quality system audits. Written Corrective Action plans will be submitted to the EES Compliance organization per applicable audit procedures.

(b) With respect to all environmental, safety and industrial hygiene matters related to the SERVICE CENTER activities in supply of services to EES, SERVICE CENTER shall (a) comply with all applicable laws and regulations issued by national, state and local authorities, (b) Inform EES promptly of any significant adverse events (e.g. fires, explosions, accidental discharges), (c) Inform EES promptly of any allegations of findings of violations of applicable laws or regulations, (d) allow EES to inspect the SERVICE CENTER facilities, such inspection to be at reasonable times and upon reasonable notice, and (e) implement promptly and corrective action which may be reasonably requested by EES including (without limitation) adhering to reasonable and significant elements of the Environmental, Safety and Industrial Hygiene Program adhered to EES in its own operations.

(c) SERVICE CENTER agrees to notify EES immediately when contacted by a regulatory agency that has jurisdiction over EES products or business.

ARTICLE VIII
MISCELLANEOUS

Section 8.1 Indemnity. SERVICE CENTER assumes all liability for and agrees to defend, indemnify and hold EES, its employees, officers, directors, shareholders and agents harmless from

and against all demands, liability, damages, costs and expenses, including attorneys' and expert witness fees ("Loss"), incurred by EES arising from or in connection with the Services, other than any loss caused by the gross negligence or willful misconduct of EES.

Section 8.2 Notices. All notices and other communications hereunder shall be in writing and shall be delivered by hand or through electronic mail or mailed by registered or certified mail (return receipt requested) or transmitted by facsimile to the parties at the following addresses (or at such other addresses for a party as shall be specified by like notice) and shall be deemed given on the date on which such notice is received:

If to EES:
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242
ATTN: Service and Repair Manager

If to (SERVICE CENTER):
Johnson and Johnson K.K. Medical Company
1 Meotozaka Ohkanbara Sukagawa Fukushima 962-8501 Japan
ATTN: Technical Services Manager

Section 8.3 Independent Contractor. This Agreement shall not be construed to appoint either SERVICE CENTER or EES as agent of the other, and the parties shall at all times be considered as an independent entity in the performance of this Agreement. Neither party shall be responsible in any way for any obligations or liability incurred or assumed by the other party, except as expressly set forth in this Agreement.

Section 8.4 Force Majeure. Neither party shall be in default of this Agreement or liable to the other party for any delay or default in performance where occasioned by any cause of any kind or extent beyond its control, including but not limited to, armed conflict or economic dislocation resulting there from; embargoes; shortages of labor, raw materials, production facilities or transportation; labor difficulties; civil disorders of any kind; action of any civil or military authorities (including priorities and allocations); fires; floods; and accidents. The dates on which obligations of a party are to be fulfilled shall be extended for a period equal to the time lost by reason of any delay arising directly or indirectly from;

(a) Any of the foregoing causes, or

(b) Inability of that party, because of causes beyond its reasonable control, to obtain instruction or information from the other party in time to perform its obligations by such dates.

Section 8.5 Entire Agreement. This Agreement constitutes the entire understanding between the parties with respect to the subject matter hereof and all prior agreements or understandings shall be deemed merged herein. No representations, warranties and certifications, express or implied, shall exist as between the parties except as stated herein.

Section 8.6 Amendments. No amendments, waivers or modifications hereof shall be made or deemed to have been made unless in writing executed by the party to be bound hereby.

Section 8.7 Severability. If any provisions in this Agreement or the application of such provision to any person or circumstance shall be invalid, illegal or unenforceable, the remainder of this Agreement or the application of such provision to persons or circumstances other than those to which it is held invalid, illegal or unenforceable shall not be affected thereby.

Section 8.8 Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

Section 8.9 Successors and Assigns. This Agreement shall not be assignable, in whole or in part, directly or indirectly, by any part hereto without the prior written consent of the other party hereto, and any attempt to assign any rights or obligations arising under this agreement without such consent shall be void. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

Section 8.10 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Ohio without reference to the conflict of law doctrine of such state.

Section 8.11 No Third-Party Beneficiaries. This Agreement is solely for the benefit of the parties hereto and should not be deemed to confer upon third parties any remedy, claim, liability, reimbursement, claim of action or other right in excess of those existing without reference to this agreement.

Section 8.12 Confidentiality. The SERVICE CENTER shall treat as confidential all information, including customer data, which SERVICE CENTER acquires in the context of the co-operation

with EES and/or its affiliates and shall not make information accessible to third parties for the period of validity of the Agreement and after its expiration, with the exception of those employees of the SERVICE CENTER to whom information has to be revealed for the purpose of executing this Agreement. The SERVICE CENTER shall have such employees undertake in writing to maintain confidentiality.

IN WITNESS THEREOF, the undersigned have caused this Agreement to be duly executed and operable the Effective Date.

ETHICON ENDO-SURGERY, INC.

By: MARK COSIMI Digitally signed by MARK COSIMI DN: c=US, o=JNJ, ou=Subscribers, cn=MARK COSIMI, 0.9.2342.19200300.100.1.1=32153 Reason: I am approving this document. Date: 2019.09.13 11:15:20 -04'00'

Name: Mark Cosimi

Title: Director, Project Management

Date: _____

JOHNSON & JOHNSON K.K. Medical Company

By: KOHEI SEKI Digitally signed by KOHEI SEKI DN: c=US, o=JNJ, ou=Subscribers, cn=KOHEI SEKI, 0.9.2342.19200300.100.1.1=152816107 Reason: I attest to the accuracy and integrity of this document. Date: 2019.09.13 07:45:20 +09'00' Adobe Reader version: 11.0.10

Name: Kohei Seki

Title: Repair Services Manager

Date: _____

Attachment 1

Key Contacts

The primary contacts are:

(SERVICE CENTER):
Kohei Seki, Repair Services Manager
Kenta Tomikoshi, Quality Assurance Manager

Ethicon Endo Surgery, Inc.:
Eric Smith, Sr Manager, Service Center
Shannon Gillespie, Service Center Manager
Milton Garrett, Director, Customer Quality
Robert Peters, Team Lead, Customer Quality

Attachment 2

Description of Services

Article I. DEFINITIONS

The terms used in this Attachment 2 shall have the meaning as set forth in Article 1 of the Agreement.

Article II. PRODUCT DESCRIPTION

- 1000 – MegaPower 1000 A Generator
- 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S - MEGADYNE MEGA SOFT Reusable Patient Return Electrodes
- GEN04 – Generator GEN04
- GEN11 – Generator GEN11
- RF60 – Generator RF-60

Article III. SCOPE

This agreement covers all aspects of the service and repair process including decontamination, product, evaluations, troubleshooting, repair, spare parts, testing, quality assurance, packaging, daily reporting, and database administration.

Article IV. SERVICE REQUIREMENTS

SERVICE CENTER is responsible for:

- Generating, maintaining and controlling internal process work instructions for servicing EES designated repairable products.
    - EES Service Manuals and Service Bulletins will address the following areas: Service and Repair, testing, upgrades, and product certification and decontamination (when applicable).
- Return and packaging of replaced devices/parts to the EES Service Center along with the corresponding Service Report (when applicable).
- Complete copy of the service report for the complaint handling system
- Product specific letters of service to customers
- Storage and inventory of EES capital devices and spare parts

Article V. DATABASE ADMINISTRATION

The main interface to EES complaint and service databases will be using Unity and OneMD database software. It is the joint responsibility of both EES and SERVICE CENTER to create, and maintain, compliant/service documentation. SERVICE CENTER technicians will complete the necessary documentation for service and repair. When necessary, the SERVICE CENTER will ensure timely return of documents to EES for entry into the EES database software. When

the SERVICE CENTER technicians can enter their documentation into a service software database, they will be responsible for entering their own entries in the database.

Article VI. PRODUCT UPGRADES

Only approved product upgrades will be made to the product and the DHR. EES service bulletins or ECO changes will define approved product upgrades. All product service upgrades will be documented through the service manual or service bulletins. The upgrades will be conducted at time of service.

Article VII. PARTS AND ACCESSORY INVENTORY

SERVICE CENTER will store and provide inventory control for the parts and accessories designated by EES. These parts and accessories are owned by SERVICE CENTER. Non-conforming parts and accessories will be segregated from the inventory and must be dispositioned.

Article VIII. SERVICE PROCESS INSTRUCTIONS

Servicing is conducted using the current revision of the service manual and released service bulletins. The applicable service manual may be used as a reference guide for troubleshooting and repair. Service Manuals and Service Bulletins will be supplied by EES to change or aid the service and repair process. SERVICE CENTER is responsible for providing relevant and valid process documents. EES is responsible to conduct training on the repair process for each product serviced by the EES. SERVICE CENTER is responsible for being trained and performing re-certification training annually.

Article IX. TROUBLESHOOTING AND REPAIR

Planned maintenance, troubleshooting, repair, and testing will be performed utilizing approved test fixtures and calibrated equipment. Fixtures will be documented and have current preventive maintenance/calibration schedules completed.
Planned maintenance, troubleshooting, repair, and testing will be conducted by trained technicians only and the results of their activities, findings, service and repair will be recorded and reviewed in accordance with the Service and Repair Procedure. Calibrated equipment used in the service and repair process will be documented in the service record containing the equipment calibration number and calibration due date.

Article X. PARTS PROCUREMENT AND INSPECTION

All spare parts will only be purchased from the EES Part Depot. The parts planning, procurement, inspection, and warehousing will be performed by SERVICE CENTER when received by the service center.

Article XI. EQUIPMENT

The equipment used for servicing and validation of product are detailed in the product specific Validation Master Plan. SERVICE CENTER will only use equipment that has been successfully validated for service and repair.

Article XII. SERVICE LEVEL

The goal is to service a customer's EES device to manufacturer's specification within five business days from receipt of the device. SERVICE CENTER can set the required service timeliness based on the customer needs within their country or region.

Attachment 3

Business/Quality Reviews

Business/Quality Reviews between EES and SERVICE CENTER will be held annually. The minutes will be reviewed by the service and quality organizations from both EES and SERVICE CENTER. The topics to be reviewed at a minimum will include:

1. Follow Ups from previous review
2. Service and Quality Agreements Update
3. Review of Service Metrics
4. Review of Specifications
5. Review of trending data by product
6. Service documentation review
7. Data entry into Service Database/Service reports
8. Project Review and Optimization
9. Loaner, Surplus Pools Review
10. Cycle Time for Complaints
11. Service Bulletins
12. Changes (Personnel)
13. Audits
14. Miscellaneous

7.0 START-UP ACTIVITIES

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

START-UP ACTIVITIES

Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

Re: 1000

In accordance with WE001534 Rev F, the following start-up activities have taken place to prepare the EES Service and Repair Depot, Cincinnati, Ohio to begin service and repair on the Megadyne Mega Power 1000 Electrosurgical Generator.

- Spare parts needed to perform repairs have been communicated to the service center and will be ordered by the center from the Ethicon parts depot upon factbook approval.
- Johnson & Johnson Medical KK has been added to the authorized supplier list. (EES CASL)
- Loaner pool processes have been established per business needs.
- The linkage to the Complaint Management/Service System has been established. The service center has been using the process for the routing of all service data to the Complaint Management/Service System and will include 1000 reporting as well.
- Equipment required to perform repairs and testing has been purchased and properly installed.
- The service center has been made aware of the requirements for repair tracking and expediting through the repair center, and monthly reporting requirements.
- Products have been added to the monthly reporting process.
- Product-related service documentation has been delivered and implemented.
- Established access to the Megadyne SharePoint site has been completed.

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer

8.0 SUPPLIER APPROVAL

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Supplier Approval

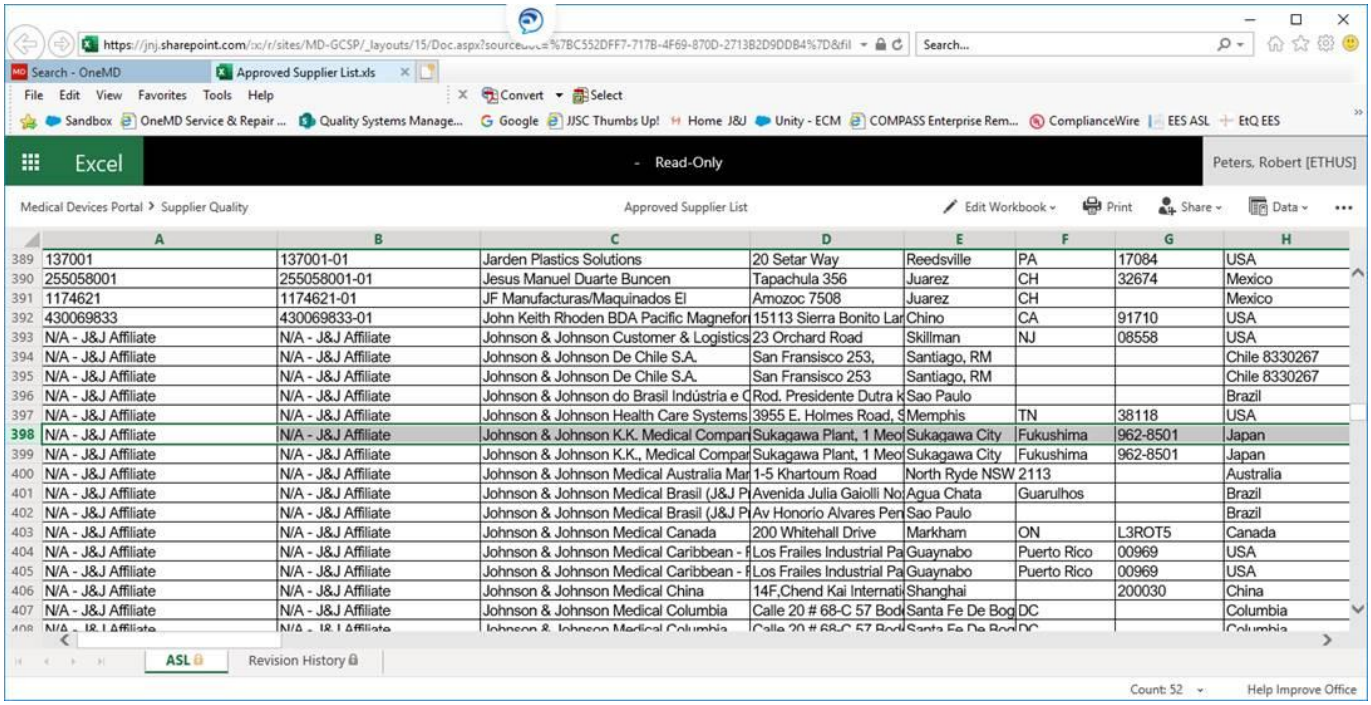
Date: October 29, 2019

From: Jason Stivers

Attention: Factbook # FB003289

Re: 1000

Reference DOC000657 in Epi Center for supporting documentation that established Johnson and Johnson K.K. Medical Products as an authorized supplier. The service center will be maintained on the approved supplier list according to WE0652, Monitoring/Communication with Service Centers and Parts Depots. A snapshot of the Corporate Approved Supplier List is below showing Johnson and Johnson K.K. Medical Products, Sukagawa, Japan as currently being approved as of October 29, 2019.



	A	B	C	D	E	F	G	H
389	137001	137001-01	Jarden Plastics Solutions	20 Setar Way	Reedsville	PA	17084	USA
390	255058001	255058001-01	Jesus Manuel Duarte Buncen	Tapachula 356	Juarez	CH	32674	Mexico
391	1174621	1174621-01	JF Manufacturas/Maquinados El	Amozoc 7508	Juarez	CH		Mexico
392	430069833	430069833-01	John Keith Rhoden BDA Pacific Magnefor	15113 Sierra Bonito Lar	Chino	CA	91710	USA
393	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Customer & Logistics	23 Orchard Road	Skillman	NJ	08558	USA
394	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson De Chile S.A.	San Fransisco 253,	Santiago, RM			Chile 8330267
395	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson De Chile S.A.	San Fransisco 253	Santiago, RM			Chile 8330267
396	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson do Brasil Indústria e C	Rod. Presidente Dutra k	Sao Paulo			Brazil
397	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Health Care Systems	3955 E. Holmes Road, S	Memphis	TN	38118	USA
398	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson K.K. Medical Compan	Sukagawa Plant, 1 Meo	Sukagawa City	Fukushima	962-8501	Japan
399	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson K.K., Medical Compar	Sukagawa Plant, 1 Meo	Sukagawa City	Fukushima	962-8501	Japan
400	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Medical Australia Mar	1-5 Khartoum Road	North Ryde NSW	2113		Australia
401	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Medical Brasil (J&J P	Avenida Julia Gaiolli No	Agua Chata	Guarulhos		Brazil
402	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Medical Brasil (J&J P	Av Honorio Alvares Pen	Sao Paulo			Brazil
403	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Medical Canada	200 Whitehall Drive	Markham	ON	L3ROT5	Canada
404	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Medical Caribbean - F	Los Frailes Industrial Pa	Guaynabo	Puerto Rico	00969	USA
405	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Medical Caribbean - F	Los Frailes Industrial Pa	Guaynabo	Puerto Rico	00969	USA
406	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Medical China	14F,Chend Kai Internati	Shanghai		200030	China
407	N/A - J&J Affiliate	N/A - J&J Affiliate	Johnson & Johnson Medical Columbia	Calle 20 # 68-C 57 Bod	Santa Fe De Bog	DC		Columbia

E-Sig in EpiCenter

Jason Stivers
Service Engineer, EES – Service Staff Engineer