

Electrosurgical Generators

A preventative maintenance publication
written for the hospital's Director of Clinical
and Biomedical Engineering

Guide to Performance and Safety Testing

TEKTRANSM

Turnkey OEM/Private Label Design & Production Services

Disclaimer:

Tektran, Inc. has no affiliation with the agencies or companies referenced within this booklet, nor do they endorse its contents. This booklet was written to assist the BMET and CCE or those responsible for Performance and Safety Testing of electrosurgery generators. We highly recommend you use this booklet as a general guide only and seek specific advice from the manufacturer of any particular electrosurgery model generator prior to performing any of the tests covered herein.

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INTRODUCTION

The Current GMPs (Good Manufacturing Practices) as required by the F.D.A. as of June 1997 follow the full twenty parts of ISO 9001 with a few exceptions. ISO 9001 is the internationally recognized standard manufacturers follow when developing a Quality System Plan for production.

Manufacturers are required under the F.D.A. Rules & Regulations (C) GMP Part 21 CFR 820 to train, test, and monitor the performance of any factory personnel placed in charge of inspection, measurement, testings, or service and to keep records of such tests as well as provide reliable equipment (periodically calibrated) to perform those activities during the production phase. Paragraphs in "The Final Rule" dated October 7th, 1996 that relate to personnel training, testing, and service are as follows:

Subpart B - Quality System Requirement

¶ 820.25 Personnel

Subpart G - Production & Process Control

¶ 820.72 Inspection, Measuring, and Test Equipment

Subpart H - Servicing

¶ 820.200 Servicing

J.A.C.H.O. also referred to as the "Joint Commission", accredits hospitals and requires during their routine audits that the healthcare organization seeking accreditation have a preventative maintenance program in place as well as record-keeping practices to insure the reliable operation of hospital equipment. They refer to the testing required as "Performance and Safety Testing" under their respective standard [EC.2.13]. A copy of this standard is reprinted in the Appendix section of this booklet. This does not include or suggest the repair and replacement of internal parts by the hospital biomedical technician without proper certification or training to perform such repair. This is the reason that many manufacturers affix a seal to their unit cover and void the warranty should the seal be tampered with.

As a manufacturer of RF electrosurgical generators, we must be concerned about both complying with the F.D.A. regulations as well as assist the healthcare provider who is our ultimate customer in performing the pre-op or periodic testing they must perform to insure that equipment is working up to standards. We feel that there has been up to now some confusion about the J.A.C.H.O. standard above and the role of the biomedical technician. In part, due to the conflict that exist between, A.A.M.I. 's standard HF-18 (¶ 4.1.3) and the FDA/GMP federal regulations above that all manufacturer's of medical devices must adhere to as a matter of law.

It is our position that to provide schematics or detailed service manuals to the hospital or any end-user would in fact invite those who may not have proper certification to alter the internal workings of our generators, regardless, whether or not they are CBET or even CCE certificated. This is why we provide this booklet, instead, with each generator sold, in addition to the Operating Manual. It is intended to assist the BMET to perform only the "Performance and Safety Tests" which are as a matter of standard practice performed by hospital personnel.

In the case of electrosurgical generators, this is easy, since there are two benchmark companies that have for years provided special testers for use by hospital biomedical technicians, not only for electrosurgical generators, but for other modern electro-diagnostic and electro-therapeutic equipment employed by healthcare provider today. Those test instruments are featured in this booklet along with contact information of the suppliers. The measurements these testers provide have become a norm in the profession and, therefore, satisfy the JACHO standard [EC.2.13] in addition to the record keeping and other practices required under that standard.

IMPORTANT:

We suggest that if the results of these tests indicate a failure or defect in the operation of the generator, the generator be returned immediately for corrective action by the manufacturer or those service organizations that are authorized to perform such repairs. **DO NOT Attempt to Make Internal Adjustment or Replace Internal Parts.**

1.1 Performance and Safety Measurements

These tests can be conducted without removing the sealed cover of the generator. The objective is to test the input and output characteristics of the generator against the standards given in the operating manual for each generator. Normal practice is to test for the following:

- AC Leakage
- Ground Continuity
- RF Leakage
- Power Output
- Open Circuit Peak-to-Peak Voltage
- Crest Factor
- Return Fault Test
- REM Test
- Neuro-Muscular Stimulation

1.2 Definition and Purpose

AC Leakage:

This is a measurement of the AC input line current leakage from chassis and patient-connected probes to earth ground respectively. For double-isolated ESUs this should not exceed 50uA (from chassis parts to earth ground), and 20uA (from ACTIVE and INACTIVE leads to earth ground when output is isolated). Purpose: To insure against low frequency electrical shock. *Refer to section 3.1.*

Ground Continuity:

This is a measurement of resistance from any exposed metal part on the chassis to earth ground. This resistance should not exceed 0.15 ohm. Purpose: To insure against the possibility of shock should live internal components come in contact with those metal parts on the chassis. *Refer to section 3.2*

RF Leakage:

This is a measurement of high frequency output current from either the ACTIVE or INACTIVE (Return Electrode) to earth ground. Leakage should not exceed 4.5 watts or 150 milliamps to earth ground when measured through a simulated load of 200 ohms (non-inductive impedance). Purpose: To insure against alternative current paths that could cause unwanted burns or injury to the operator, staff, or patient. The test is performed differently for isolated and ground-referenced generators. *Refer to section 4.1.*

Power Output:

This is a measurement of rms (root-mean-square) power in watts or *Actual Power* across a non-inductive resistance. The power should be at least within +/-15% or whatever tolerance the generator manufacturer has stated in its accompanying container documents as standard. Depending upon the purpose of the generator, the response or delivered power in watts across the Load (non-inductive resistance) is either flat or peaks at some desirable impedance level. Some minimally invasive electrodes call for matched impedance levels as low as 10 ohms and some as high as 1500 ohms. Typically, generators intended for general purpose applications or invasive surgery have monopolar outputs rated at 300 ohms and remain flat from 100 ohms to 1000 ohms, depending upon the output filter. This response curve can be extended further out with feedback. Bipolar output for general forceps usually peaks at about 125-150 ohms and then drops off sharply as a higher impedance is reflected back to the generator. Purpose: The size of the electrode (its contact density to the tissue) and the conditions within the surgical site (type of tissue, wet or dry field) can require various levels or delivered power. The physician sometimes needs this information to determine depth of cut and the amount of tissue shrinkage to expect. However, deliberate motion through the tissue as well as the skill of the surgeon can have even greater importance in the results. This information is often printed on the top cover of the ESU or in the operating manual. *Refer to 4.2 and section 5.3 for blank load response forms.*

Open Circuit (Peak-to-Peak Voltage):

This is a measurement of peak-to-peak AC voltage potential with an "unloaded" output circuit in each current mode. Purpose: There is really a two fold reason for this test. One is to determine if the insulation afforded by the combination accessories or other instruments (probes and electrodes) is rated to provide adequate insulation for the operator. The other reason is to determine if the generator can withstand open-circuit operation for some period of time without damage to its internal circuitry. This is usually more critical in the Coagulation mode where peak-to-peak waveform potentials are in the kilovolt range. For example, the earlier spark gap generators could produce Coag mode potentials as high as 13 kV (kilovolts). However, most modern ESUs today employ solid state circuits to deliver damped waveforms with outputs of 5 kV to 7.5 kV. *Refer to section 4.3*

Crest Factor:

It is measured by taking the open circuit peak-to-peak voltage displayed on an oscilloscope, dividing this by 1/2 to arrive at Peak Voltage and then divide that potential by the loaded rms voltage [which is $(1/2 \times PP) \times .707$]. Typically, the load used to measure this potential is the rated load (i.e. 300 ohms) for that mode. $CF = \text{Peak Volts} \div \text{rms Volts}$ It is desirable to have a high crest factor when Coagulating tissue and a low crest factor when Cutting tissue. Purpose: This is a measure of how well an ESU output current mode can Coagulate without cutting. *Refer to section 4.4*

Return Fault Test:

Critical to monopolar operation only. This is a test to determine if the generator will shut off and alarm in the event of a cable fault in the INACTIVE PATIENT RETURN lead - from the generator to a single-cell dispersive return plate. A.A.M.I. standard requires a trip point at no greater than 200 ohms of introduced impedance. Purpose: To insure the integrity of the patient return circuit.

REM Test:

Critical to monopolar operation only. REM patient return systems employ a dual-cell dispersive plate which by its very nature introduces an impedance (or capacitive gap) between the two-lead patient return cable. The trip point standard, again, is 200 ohms. Purpose: To insure integrity in the REM circuit's ability to trip into the fault state with no more than the maximum impedance allowed.

Neuro-Muscular Stimulation:

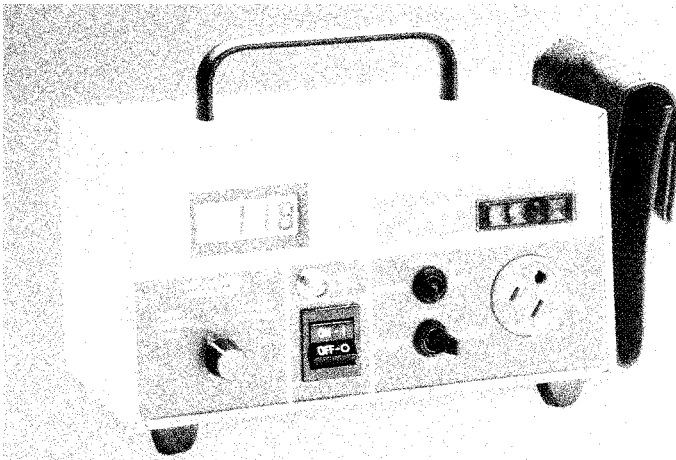
This is an undesirable conditioned reflex said to be caused by rectified or low-frequency components that may be present in the ESU output current modes. Unfortunately, there is no sure way to test for these undesirable electrical components other than to solicit a human volunteer. *Refer to the test set-up in section 4.7* Manufacturers are required to block Direct Current by employing high-voltage blocking capacitors. The proper value of these capacitors in pF (picofarads), as well as their use in the return circuit, can reduce or eliminate noticeable presence of these undesirable electrical currents to the patient. Purpose: To insure minimum patient discomfort and prevent more serious results such as patient reaction during delicate procedures and worse - defibrillation.

As a disclaimer, we caution that the purpose of this booklet is to provide the hospital BMET with a general overview of the various protocol Performance and Safety measurements that have become a norm with most accredited healthcare facilities for inspection of ESU generators. However, standards can change at any time by organizations such as JACHO, ANSI, IEC, UL, ISO, AAMI, and the U.S. FDA, or your ministry of health or others that set the standards for your facility. Therefore, it is up to Clinical or Biomedical Engineering Director of each facility to keep abreast of any changes. Furthermore, any references made herein to third party suppliers are not endorsements, but are only offered as a courtesy. Any use of third party tradenames or marks are the wholly owned property of those respective third party suppliers.

The Performance and Safety Tests covered in this booklet can be conducted by employing two specific purpose measurement devices and a wide bandwidth (+50 MHz) oscilloscope to inspect waveforms. The first type of instrument covered here deals with safety issues concerning **AC INPUT** circuits such as low frequency line chassis leakage and grounding integrity. The second type of instrument covered deals with both performance and safety issues concerning **OUTPUT** circuits (those that come in contact with the patient), regardless of line operating current employed. The first type of Electrical Safety Analyzers, as they are commonly referred to, must be selected for the **INPUT** operating current and frequency employed (115/230 VAC - 50/60 Hz). The Electrical Safety Analyzers featured here employ U.S. plug type outlets on their respective panels. However, a power cord with a U.S. plug and a molded IEC female plug can be used to connect to the back panel of the ESUs which have an A.C. line inlet or IEC receptacle. All the instruments covered here can be used as stand-alone devices and some are designed for use with a computer and employ an RS-232 interface connector.

Two suppliers that have gained a reputation as leaders in the field of performance and safety test instruments for healthcare providers are Bio-Tek Instruments, Inc. and Dyna-tech Nevada, Inc. Their instruments are not only extensively employed by Clinical and Biomedical Technicians in healthcare facilities, but the tests these instruments perform have become the norm for testing based upon ANSI/AAMI protocols. Contact information is provided at the end of this section. We have placed a photo here of one each Electrical Safety Analyzer and ESU output test instrument. Models and prices may vary, so we suggest you contact each company.

2.1 Input Measurements



Courtesy of Bio-Tek Instruments, Inc.

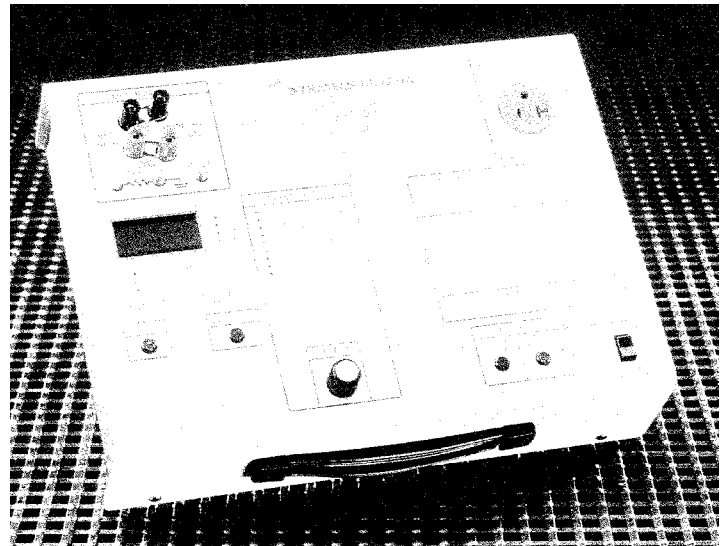
Figure 2.1 -1

The DynaTech Nevada Model 234A is listed as a "Manual Safety Analyzer" with remote RS-232 computer interface capability. It can be ordered in 115 or 230 VAC input configuration. It features some optional modules that permit it to perform additional safety tests.

The Bio-Tek Model 170B is an example of a relatively inexpensive tester for measuring both ground resistance and chassis leakage. It has a 100-250 VAC input feature. This is a manual instrument with no computer interface.

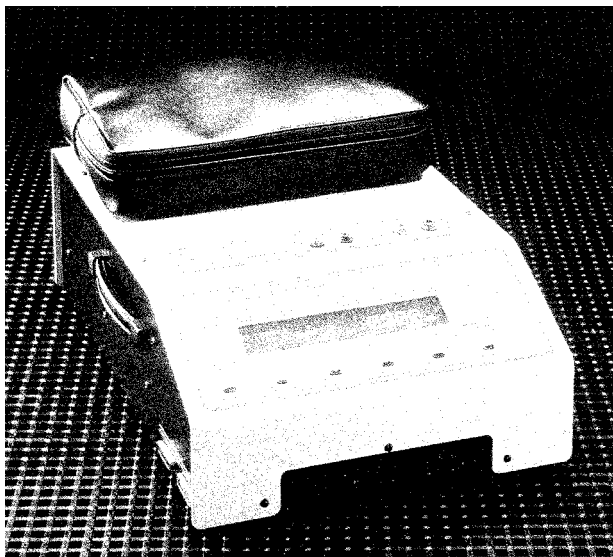
Figure 2.1-2

Courtesy of Dynatech Nevada, Inc.



2.2 Output Measurements

Both of the instruments featured below offer user selectable test loads and can be used to complete the sample reporting form offered in section 5 of this manual as well as the blank load response forms.



Courtesy of Dynatech Nevada, Inc.

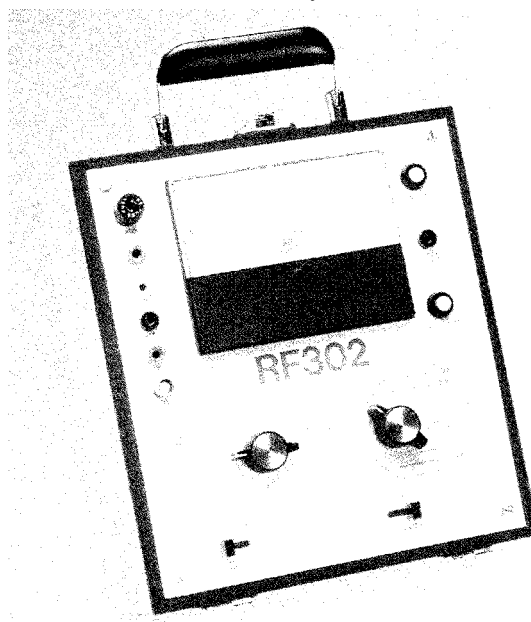
Figure 2.2-1

The Bio-Tek Model RF302 Electrosurgical Analyzer can also be used to perform all of the protocol tests covered in this booklet. Although, it offers only manual operation, it does have a distinguishing feature. Some special purpose generators offer higher frequency output. This tester employs a RF thermocouple which is not limited in frequency response or accuracy of power measurement for these higher frequency ESUs.

The Dynatech Nevada Model 454A Electrosurgical Analyzer can be used to take all the necessary performance and safety output measurements that we have listed in section 4 of this booklet. Three modes of operation are listed as manual, user programmable, and remote with an RS-232 interface.

Figure 2.2-2

Courtesy of BioTek Instruments, Inc.



2.3 Contact Information

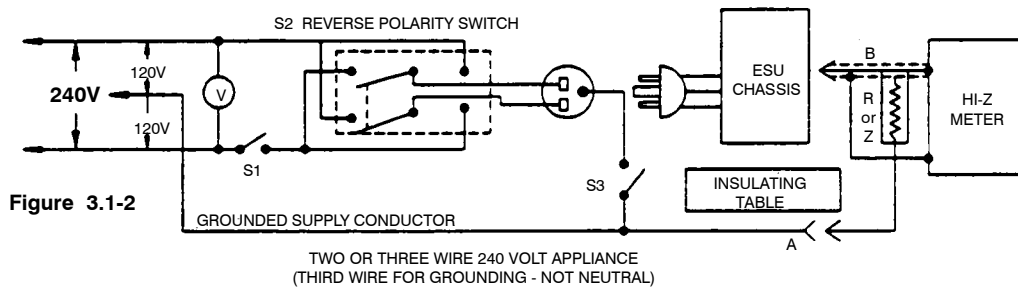
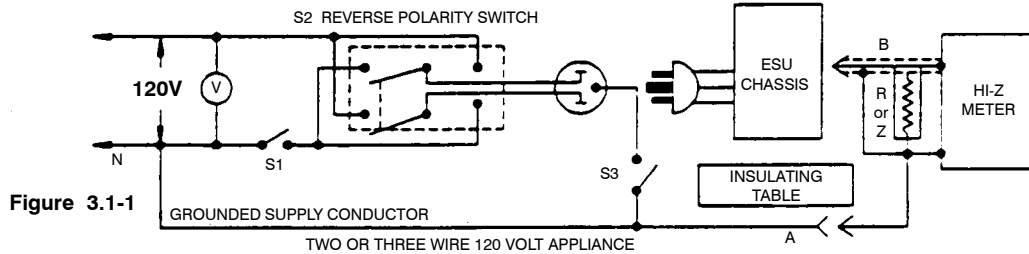
Both of the companies offering the instruments featured here have been acquired by the same parent company - Lionheart Technologies Company. The Bio-Tek Instruments division has a website and Dynatech(DNI) has an e-mail address: (The Bio-Tek website has links to additional testing information).

BioTek Instruments, Inc.
Highland Park, Box 998
Winooski, VT 05404
TEL: 802-655-4740
FAX: 802-655-7941
www.biotek.com

Dynatech Nevada, Inc. (Now DNI Nevada)
2000 Arrowhead Drive
Carson City, Nevada 89706 USA
TEL: 702- 883-3400
FAX: 702- 883-9541
e-mail: sales@DNINevada.com

3.1 AC Leakage

With the source current connected and the unit under test turned ON, this test measurement is conducted from all exposed metal parts on the chassis-to-earth ground as well as from accessories like foot switches to earth ground. The leakage is measured from patient connected leads (ACTIVE and INACTIVE) to earth ground.



Viewing the front panel indications of the Bio-Tek Model 170B Analyzer, you will note the reverse polarity switch and the switch that closes and opens the ground-pin connection on the plug. The BNC receptacle is used for the test lead which is to be applied to both the exposed metal parts of the chassis frame as well as the output ports or patient connected leads. In the case of an electrosurgical generator, this is the ACTIVE and INACTIVE electrodes. A power outlet strip is available with international plug outlets that will plug directly into the front of this model analyzer to take advantage of the wall plug check feature. Otherwise, you may employ any IEC molded power cord assembly that will mate with the rear panel receptacle on the electrosurgical unit. This model Analyzer has additional features such as an AC input voltage display reading, and ground continuity resistance reading as well as a display reading for current leakage.

Maximum Leakage in Microamps

Table 3.1

PATIENT CONNECTION				ENCLOSURE OR CHASSIS			
Isolated		Ordinary		Grounded		Double Insulated	
AC RMS	DC	AC RMS	DC	AC RMS	DC	AC RMS	DC
10*	14	50	70	100	140	50	70
* Measured at the ports - without cables. With cables no more than 20ua. This table was taken from IEC 601 standards for patient connected equipment.. The term Ordinary refers to ground referenced vs. isolated output. These standards may vary.							

3.2 Ground Continuity Measurements

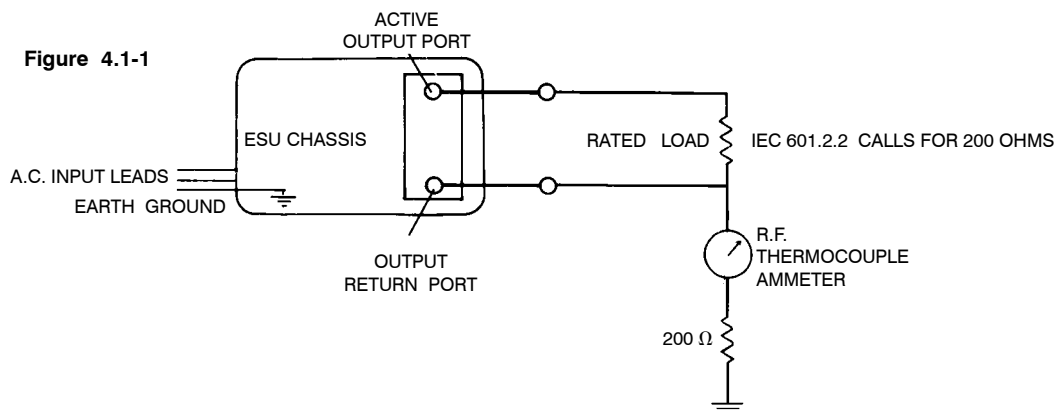
This measures the quality of the ground path from exposed metal parts of chassis-to-earth ground that might otherwise be impeded by painted, anodized, or separated chassis surfaces. For example, manufacturers will often employ a number of grounding straps if required. The maximum recommended resistance is 0.15 ohm from earth ground to exposed metal parts. Note: When taking ground continuity readings, remember to subtract the lead resistance of the test cables.

4.1 RF Leakage

As covered in *section 1* of this pamphlet, this is a measurement of high-frequency output current from either side of the output (ACTIVE or INACTIVE) to earth ground through a non-inductive impedance of 200 ohms which simulates body impedance of the patient, operator, or operating staff. The purpose of this test is to insure that any current that might find its way to earth ground through an alternative path is low enough as not to cause patient, operator, or staff injury. IEC 601.2.2 is the international standard for high frequency electromedical equipment. In order to pass this standard, RF leakage should not be 4.5 watts across a 200-ohm non-inductive resistor when measured to earth ground or pass more than 150mA of leakage current. *Note: In all cases, when we refer to resistance or ohms, we are referring to non-inductive test resistors such as Carbon Stick, Ayrton-Perry, or Serpentine wound resistors. Also, the test setup calls for an insulated table 1 meter off the ground and the cables spread out in a parallel pattern.*

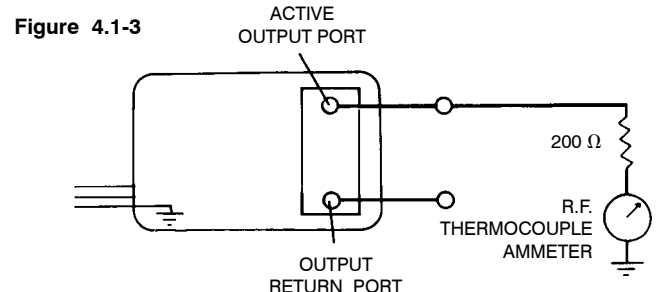
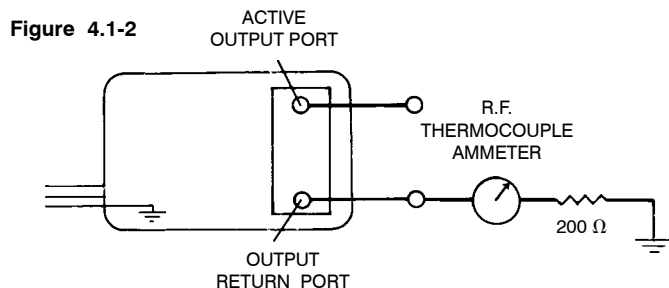
Measuring Leakage of ESUs with Ground Referenced Outputs:

Here, leakage is measured only when a simulated load is placed across the output or when the circuit is "closed" or "loaded". It would do no good to measure leakage when the output circuit is not loaded, for the simple reason that in a ground referenced ESU, the return port is referenced to earth ground, usually through a low-impedance bypass capacitor. IEC requires you use 200 ohms as a simulated load. Some standards require instead that you use the ESU's rated load, or the load used for the published maximum power output in each mode. Here is a diagram displaying the test circuit employed for this leakage current measurement:



Measuring Leakage of ESUs with Isolated Outputs:

Most modern day ESUs employ isolated outputs. In this case, leakage is measured with the output circuit "open" or in its "no-load" state. Again, IEC requires this test to be conducted with a 200-ohm resistor in the path to earth ground from each output port (ACTIVE and INACTIVE) separately as follows:



All of the leakage tests above can be performed with either of the ESU Analyzers featured on page 4 of this booklet. The Bio-Tek Model RF302 employs a thermocouple meter while the Dynatech Nevada Model 454A employs active simulated load elements and digital readout.

4.2 Power Output

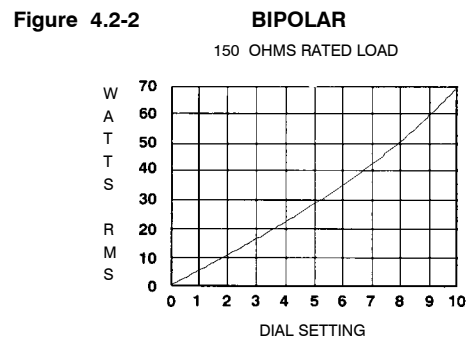
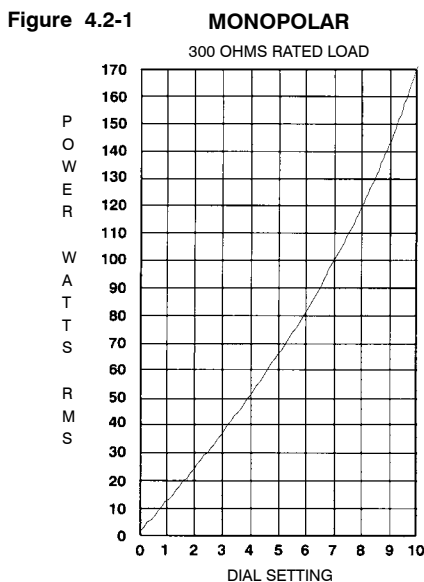
All makers of ESU generators publish their maximum power output for each mode in rms (root-mean-square) watts or "actual" power ($P = I^2R$). This is usually at some rated impedance (i.e. 300 ohms). Again all output power measurements are with non-inductive resistors such as Carbon Stick, Aytron-Perry, or Serpentine wound resistors. Some testers employ active elements to simulate a shunt load and caution should be used when employing this type of load. For example, as output exceeds the typical frequency, as it does with some special purpose ESUs, the accuracy of reading drops off in (dB) or decibels. A drop of (-3dB) is half power! Unless the manufacturer of the tester publishes a response curve to indicate the point of drop off, it would be advisable to use such testers for only those hospital grade units that typically employ operating frequencies of between 500KHz to 1.0 MHz. Any reading over 1.0 MHz may be questionable. Both of the ESU Analyzers or testers featured on page 4 of this booklet offer a range of shunt loads for measuring the load response in watts. In section 5.3 of this booklet, a blank recording form is offered to list the reading at various loads for each output mode. Blend-mode readings should simply be a percentage of the PURE Cut mode as published. Follow the instructions recommended by the manufacturer of the ESU Analyzer used to perform the test.

Digital Readout vs. Dial Indicators:

There is a misconception by many BMETS that when an ESU employs digital readout the reading is actual power output. This is not true. All ESUs that employ digital readouts are "digital estimates" or "digital approximations" of the actual power, usually trimmed out on a separate display circuit not connected in any way to the output, set at the factory using the rated load as a benchmark for setting the A/D sweep. If the output were connected to the output display, it would be so erratic the display would be unreadable - even with reduced sampling rates. A physician needs to know what power level the ESU is set at before proceeding with the incision, not during. During the incision, the physician's attention is focused on the surgical site!

Dial Linearity & Tolerances:

Linearity can be defined as the percent of accuracy based on the published or rated load when the dial or reader display is set to an indicated level on the front panel. When employing a knob, it is important that the response to settings between 0-100 percent reflect the actual power within acceptable limits. With rotary knob control, this can only be accomplished when the dial response curve is linear. Typically, due to the tolerance of most RF type capacitors and other filter components, manufacturers offer (+/-) output tolerances. IEC will accept (+/- 20%).



Ideal vs. Actual:

Seldom is a dial response curve a perfect linear or straight line from zero to the maximum power setting. These dial response curves are typical.

Load Reponse Curves:

Typically, with a standard hospital grade ESU, the ideal load curve for monopolar mode output is a flat line response from about 100 ohms to 1000 ohms. In reality, even with filters, these monopolar response curves are relatively flat between 100 ohms and 700 ohms and then slowly drop lower. Unless the physician is working with soft cartilage or fatty tissue (i.e. found in orthopedic procedures), most of the actual range encountered in general surgery is 100-500 ohms. In the bipolar mode, the load curve or power output is designed to peak at about 125-150 ohms and drop off rapidly with higher reflected impedances (as the tissue dehydrates).

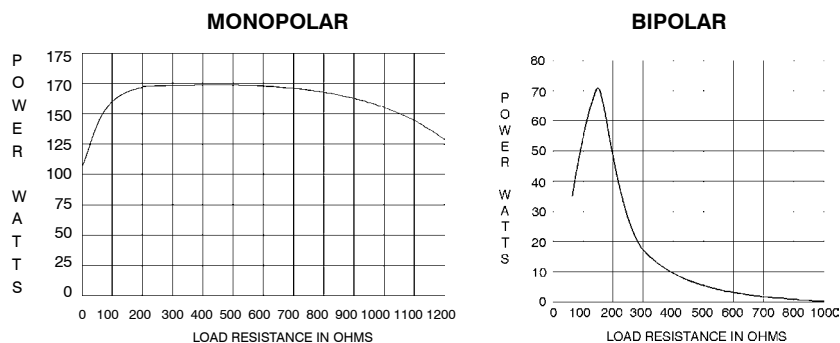


Figure 4.2-3

Figure 4.2-4

Taking Measurements:

Both ESU Analyzers featured on page 4 of this pamphlet have internal stepped loads. The Bio-Tek Model RF302 has internal test loads from 50-500 ohms. The Dynatech-Nevada has internal test loads from 50-1550 ohms, and offers optional add-on test load modules for special purpose generators at 25 ohms (i.e. for thermal ablation) and at 2000 ohms (i.e. for orthopedic surgery).

Recording Measurements:

In section 5, we have included a template or copy master for recording each test session. It has provisions for recording all INPUT and OUTPUT measurements covered in this pamphlet, and includes blank monopolar and bipolar power response vs. load impedance graphs which can be completed after recording the stepped measurements. It is important that the healthcare facility establish a protocol for periodic testing. This subject is covered in more detail in section 5.1

4.3 Open Circuit - Peak to Peak Voltage

Overview Regarding Open-Circuit Tests:

Not all makers of ESU-related devices such as switch pens, probes, insulated electrodes, etc. publish their maximum applied voltage breakdown levels, and for good reason. If the device is to be sold as a combination accessory, that is fine, but with standardization of output port connectors, it is difficult for the maker of either the ESU or the switch pen maker, for example, to know what the source or breakdown potential is.

Standard Regarding ESU Corded Devices:

The A.A.M.I. standard HF-18 requires that makers of such accessories or attached devices pass a test standard for dielectric breakdown and acceptable leakage. This involves testing insulated cords using a deep jar filled with saline and wrapping the device (i.e. switch pen) with saline-soaped cloth or conductive metal foil and then applying 1.5 times the ESU's RF output with a high-frequency step-up transformer. A scope is then placed across the output and the deflection is noted. However, this test is restricted for practical reasons to 1.0 MHz. Even silicone cords and P.T.F.E. insulation begin to break down at higher frequencies and it is difficult to get published specs from raw material suppliers regarding breakdown at these higher frequencies.

Coag Mode Amplitudes:

Breakdown is a function of source impedance, voltage, and frequency. Normally, if open-circuit voltage is going to be a problem, it will happen in the COAG mode where peak-to-peak waveforms are highest. Typically, the "ring frequency" or damped waveforms or modulated packets in the COAG mode is about 450-500 kHz. Modern solid state ESUs put out about 5 kV - 7.5 kV in their COAG modes.

Pre-Compliance ESUs:

To further compound the problem, some pre-compliance (pre-May 1976 date) generators are still being sold that produce outputs with frequencies of 2.8MHz or greater. Some earlier spark gap ESUs can produce waveforms with open circuit potentials as high as 13 kV. It is doubtful that any attachable device would withstand 19.5 kV or (1.5 x 13 kV).

Open Circuit Potentials & Distributed Capacitance:

In addition to the potential of insulation breaking down the BMET should be aware and brief the physician on matters regarding distributed capacitance as well. For example, the longer the insulated electrode when passed through a cannula or metal sheathed endoscopy device, the greater the chance for undesirable current paths or leakage to earth ground - perhaps through the physician, operating staff, or the patient. This distributed capacitance lowers the impedance path as can be seen by the following formula ($X_c = 1 \div 2\pi fC$). This has become an important consideration during, for example, laparoscopy where this condition is more likely present. This was a very real problem (i.e. in general orthopedic surgery or laparoscopy and arthroscopy) until the introduction of AEM* (Active Electrode Monitors). There are a number of papers available regarding this poorly understood safety issue. A paper quickly available on the web is a study document titled, "Port site electrosurgical (diathermy) burns during surgical laparoscopy" refer to (<http://www.alpha.n2kbrainwave.com>). Ground Referenced Units with very high open circuit potentials can be a real problem in this regard. The physician needs to balance his or her need for Crest Factor against this potential hazard. Refer to our booklet titled, "Principles of Electrosurgery", for more details.

Reliable Operation in Open-Circuit Mode:

Another purpose for the open circuit tests is to check for stable and reliable operation in open circuit mode. If the ESU is properly regulated, and voltage levels within the ESU are clamped to protect against component breakdown, then the unit should be able to operate in open-circuit mode or unloaded for at least reasonable or even an extended period of time. This is more an issue for the manufacturer than the BMET and addresses the quality of the ESU. However, the BMET should check the published open circuit figures against his tests. For example, if the supply regulator shorts out and regulation is absent, the output could shoot up to levels that could either damage the power oscillator elements or cause breakdowns to occur outside the ESU with the attached devices.

Conclusions:

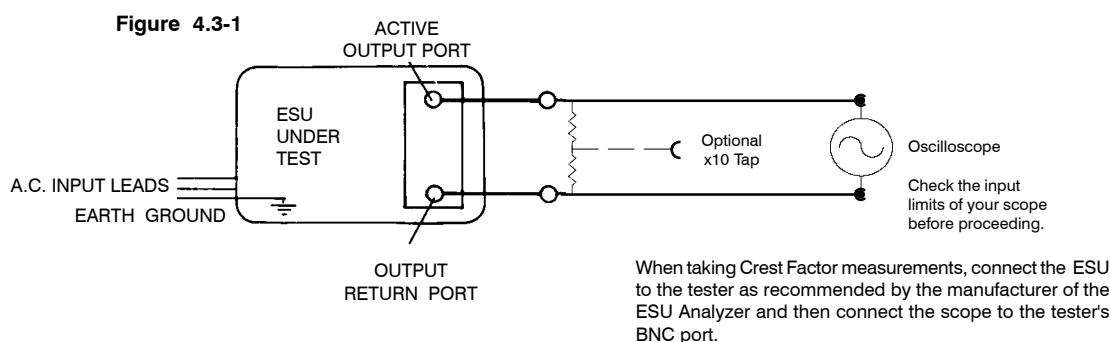
It does little good to just take and record open circuit potentials without engaging in a total spectrum approach to loss prevention when it comes to issues dealing with dielectric breakdown. This involves communication between BMET, operating room nurses, pre-op services (trained to check ESU related devices for deterioration after sterilization), physicians, and purchasing authorities who establish material qualifications.

Recommended Test Equipment:

Both ESU Analyzers featured on page 4 of this pamphlet include an isolated BNC connector port for attaching an oscilloscope to view waveforms and measure peak-to-peak amplitudes. To further protect your scope, we advise using an isolation transformer to power your scope. Also, x100 probes should be employed and the voltage scale on your scope should be first set to the highest voltage setting. Remember in the COAG mode especially, you will be reading potentials in the kV range. If you do not have probe sets or voltage settings capable of this high voltage, a simple voltage divider can be constructed with two high voltage (or 2 watt) carbon composition resistors (9.1M and 910K) values to provide a one tenth reading which you can multiply by x10. The 10 Meg load will clamp the output, but only slightly.

Open Circuit - Test Setup:

The diagram below displays the open circuit (peak-to-peak) test measurement setup. The scope is set to its highest voltage per division setting, and by using at least a x1000 RF probe, the reading can be taken directly off the output. A less expensive (x100) probe can be used if the high-impedance, non-inductive carbon resistor divider network below is employed. . A higher wattage carbon resistor (i.e. 2 watt types) should handle the kV potentials. Care should be exercised when taking this reading. Unfortunately, both of the ESU Analyzers featured in this booklet do not have calibrated outputs. **Caution!** When performing this test, potentials can be as high as 13 kV at the output ports of spark gap units and 7.5 kV in modern solid state units, especially in the COAG modes.



4.4 Crest Factor

Crest Factor, with respect to electrosurgery, is defined as a generator's output capability to COAG without cutting or penetrating the tissue. In other words, when COAG current is employed, unless it is used to dessicate the tissue by inserting the electrode into the tissue first, the objective is to seal the capillaries on the surface of the wound without causing necrosis deeper than necessary to stop the bleeding. $CF = (\text{Peak} \div \text{rms Voltage})$ Some ESUs now offer both "soft" COAG and "hard" COAG outputs. The first has a high Crest Factor and the later has a low Crest Factor output. In the previous section above, we mentioned that the two ESU Analyzers did not have calibrated outputs. However, each is capable of providing relative output measurements, meaning they are capable of taking portional output measurements of both the Peak to Peak voltage and rms voltage in the "loaded" state. This means that you can use either of these testers to measure CF at the ESU's rated load in each mode. Peak to Peak readings off the scope which is connected to the isolated BNC connector on either of the testers is used to arrive at "Peak" which is $(1/2 \times PP)$. The rms voltage can be read directly off the meter, or since rms is the DC equivalent, you can take the RF current reading through the test load and use the formula $(\text{rms voltage} = IR)$. Refer to the instruction note in the above diagram for proper test set-up procedure.

4.5 Return Fault Test

The diagrams presented in this booklet so far have shown only one lead for the patient return or INACTIVE electrode. In reality, all ESUs employ two leads to check against fault or changes in impedance. Both testers featured in this pamphlet are capable of measuring the maximum acceptable impedance before the ESU shuts off and warns the operator of an interrupt or unacceptable impedance which may be introduced into these biwire leads that complete the Patient Return Cable Fault. This test is used for those generators that employ only single cell dispersive plates. ESUs that use only single cell dispersive plates do not monitor contact density or quality of dispersive contact between the patient and the return plate, only cable interrupt. The recognized standard for allowable interrupt impedance is 200 ohms. The purpose is not only to detect a break in the line, but also to detect a poor connection which could set up a situation whereby return current can take an undesirable and alternative path to earth ground, or in the case of isolated ESU cause the unit not to deliver full output. A poor connection can also cause a "flame-out" when RF jumps an air gap or passes through a corroded connector whereby a galvanic effect is present.

4.6 REM Test

The term "REM" is defined as Return Electrode Monitor. If an ESU offers this feature, it not only has the ability to detect cable interrupts or induced impedance in the biwire patient return circuit, but can also monitor the quality of contact dispersion between the patient's body and the dispersive plate. If the return plate begins to peel away from the patient's body which might set up a high density contact point that could, in turn, cause a burn, then the ESU will shut off and warn the operator and staff of such a fault or potentially unsafe condition. The circuit displayed below represents the typical output portion of the patient return circuit. Both ESU Analyzers featured in this pamphlet have the ability to perform both fault and REM based upon the accepted standards for such tests. Refer to the manufacturer's instructions for test methods.

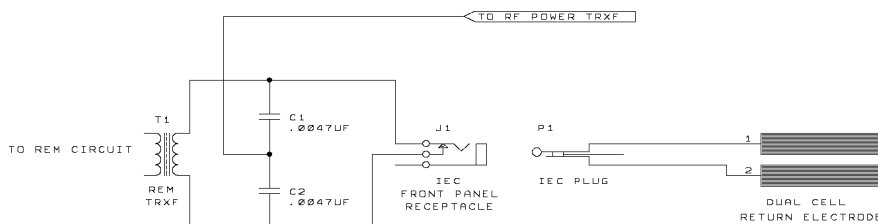


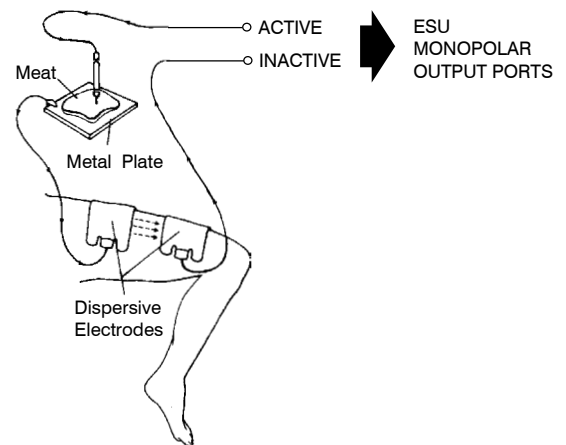
Figure 4.6-1

IEC 601.2.2 requires the capacitors with the proper X_c impedance be used to block DC and low frequency components that would otherwise cause neuro-muscular stimulation. See the C1 and C2 cap values above. A subject covered in the following section.

4.7 Neuro-Muscular Stimulation

This condition is said to occur when either rectified or low frequency current finds its way to the output circuit through the ACTIVE electrode, then back through the patient's body via the INACTIVE or return electrode. As indicated below, it can be greatly reduced by using the proper X_c impedance (capacitor values) in the output circuit. When the correct type of high-frequency capacitor is used, it is a rare occurrence to ever find a defective capacitor in an ESU's output circuit. However, it is possible that a defect could occur if caused by a transient (i.e. from a defibrillator discharge) or from other such operating equipment. The Bio-Tek Model RF302 ESU Analyzer includes a low-frequency filter that can trap and quantify low-frequency components and offer a "red line" acceptable limit based upon ESU standards. Another way is to solicit a human volunteer and perform a clinical test using the setup displayed in the adjacent illustration. The illustrated method is perhaps a better empirical test due to the low-impedance contact of each dispersive pad. This permits suspect currents to enter, pass through, and leave the body. A quicker or less cumbersome approach to a neuro-muscular stimulation test is to adhere a dispersive plate to your forearm and with an orange in that same hand, apply an activated electrode to the orange using a switch pen in the other hand. This will give you a pretty reliable indication if there is going to be a noticeable presence of such low frequency current. If so, contact your nearest authorized service center.

Figure 4.7-1



It is advisable when performing either of the empirical clinical tests mentioned here to bring the power up slowly until the subject either notices the presence of neuro-muscular stimulation or until you reach full power. Any high density contact point that comes in contact with the human body will cause injury. If you're holding an orange in your hand, for the quick test mentioned, make sure you have a firm hold of it. However, when employing the method illustrated above, if the dispersive plates are applied as illustrated here, contact with the body should not cause burns. Keep hands and other conductive items away from the metal plate, active electrode, and dispersive electrodes. Remove watches, rings, or any jewelry.

5.1 Software vs. Hand Written Forms*Overview:*

All accredited healthcare facilities are required to have a documented protocol in place for the periodic testing of medical devices as well as date, record, and store those findings in an orderly manner. This is referred to as either "Asset Management" or "Preventative Maintenance" depending upon your level of responsibility within the healthcare facility. Assuming that an accepted norm already exists for *Performance and Safety Testing* of a device, as the sheer volume of special purpose devices increases, the task of not only inspection and recording results increases, but developing a method to file or store this data and retrieve it can get time consuming. The norm for protocol inspection is dictated by the testing features offered by the leading makers of ESU Analyzers, who in addition, offer *PM* software programs as well as more sophisticated RS-232 computer interface modules for recording measurements. *Refer to section 2.1 thru 2.3 of this pamphlet.* For the larger healthcare facility some form of computer software can be the only way out. This section of our pamphlet deals a little with both approaches and at least provides enough insight and information so you can follow up with those that can assist you further.

PM Software Programs:

Bio-Tek offers what they refer to as their Profile* Equipment Management Software, and DNI Dynatech Nevada offers their program referred to as Sentinel* Equipment Management System. Bio-Tek has a website for followup information (www.biotech.com). There are also companies that do not sell testers, but offer Asset Management software programs such as Kinetic Biomedical Services, Inc. TEL: 814-864-4046 Website: (<http://www.kineticbiomedical.com/medman.htm>) Their system is referred to as MEDMan*. We advise you contact these vendors directly for more information.

AAMI has an excellent publication available on their website that is titled, "Computerized Maintenance Management Systems for Clinical Engineering: AAMI Management Information Report" Refer to the appendix in this pamphlet for AAMI website address along with other related group sites.

Handwritten Forms:

A small clinic may use an outside service or may have a BMET on staff and paper files, if properly set up, can suffice. Refer to the following section.

5.2 Blank Periodic Recording Form (including graphs for load-response measurements)

Refer to the following page which includes a blank copy master or forms template for recording ESU *Performance and Safety* test measurements. You have our permission to copy this form and use it to assist you in periodically inspecting our generators, recording and storing the results. *However, this is a copyright protected page as part of this booklet and publication of it or any part of this booklet for profit is strictly prohibited without the express written permission of Tektran, Inc.*

For Clinical Evaluation of Tissue Resistivity:

See the AAMI publication HF-18, Annex B and Annex E for reference to a paper published in the Journal of Clinical Engineering 1981 Vol. 6, No. 3, p 208-211 Refer to Appendix E in this booklet for information on ordering standards publications.

Performance and Safety Tests Protocol For Electrosurgical Generators

Preface:

This document includes data fields for recording test results which are recognized as the critical Performance and Safety Test measurements for RF Electrosurgical Generators. This template was prepared to provide the Biomet with a universal form based upon the features that may be offered on a standard hospital grade generator. It should be obvious when the make and model of the ESU under test is recorded here why some data is not recorded. For example, if the unit under test does not have bipolar output or REM, those place fields will remain blank. This document is not intended to cover all test standard organizations like A.A.M.I. or I.E.C. may recommend (i.e. 601.2.2) which are more appropriately conducted by the manufacturer.

FACILITY AND PERSONNEL INFORMATION

Date of Test Session:	Date of Previous Test Session:	Name of Healthcare Facility:
Service Contractor (if any) : [include license or qualifications]		Name of Person Performing Test: [include level of certification - i.e. CBET,CCE or other]

ESU UNDER TEST CRITERIA

Make:
Model:
Serial No:

WARRANTY & PM CONTRACT INFORMATION

Date of Purchase:	SUPPLY SOURCE: [Distributor or Mfr. Rep]	
Under Mfr. Warranty:	<input type="checkbox"/> Yes <input type="checkbox"/> NO	Under Service or PM Warranty: <input type="checkbox"/> Yes <input type="checkbox"/> NO
If Yes, date of expiration:		If Yes, date of expiration:

TEST EQUIPMENT CRITERIA

Test Instrument: Electrical Safety Analyzer	Make:	Model:	SN:	Date Last Calibrated:
Test Instrument: Electrosurgery Analyzer	Make:	Model:	SN:	Date Last Calibrated:
Test Instrument: Oscilloscope	Make:	Model:	SN:	Date Last Calibrated:
Test Instrument: (VOM or other)	Make:	Model:	SN:	Date Last Calibrated:

PRELIMINARY REVIEW OF TEST PROCEDURE

- ☐ Pre-Op Test or ☐ Periodic Protocol Test
- ☐ Visual Inspection of ESU
- ☐ Operating & Performance/Safety Test Manuals in Place
- ☐ Visual Inspection of Combination Accessories (i.e. Power cord, foot switch)
- ☐ Cable & Lead Deterioration Inspection (probes, patient leads or connected items)

- ☐ Chassis Low Freq. Leakage
- ☐ Low Freq. Patient Lead Leakage
- ☐ Ground Wire Resistance
- ☐ RF Leakage
- ☐ Open Circuit Voltage - P/P
- ☐ Crest Factor Test
- ☐ Patient Return Fault Test
- ☐ REM. Test
- ☐ Neuro-Muscular Stimulation Test

Damage Report: (if any)

PART I - Line Current Leakage & Earth Grounding Safety Measurements:

Consult sections (2.1),(3.1),(3.3) in the "Guide To Performance and Safety Testing" pamphlet and standards referenced therein for maximum allowable limits.

ELECTRICAL SAFETY TESTS (report worse case for each category)

Low Frequency AC Leakage in microamps

Chassis-to-Earth Ground	►	ua
Foot Switch to Earth Ground	►	ua
Patient Connect Leads to Earth Ground	►	ua

Ground Continuity or Resistance Tests

Chassis Points to Earth Ground	►	ohms
Foot Switch Case to Earth Ground	►	ohms

PREVENTATIVE MAINTENANCE RECORD

Page 2 of 2

Performance and Safety Testing Protocol For Electrosurgical Generators Continued - See page (2) for the Supplemental Dial & Load Response Test

PART II - RF Leakage & Output Performance:

Consult sections (2.2), (4.1) through (4.4), and (4.7) in the "Guide To Performance and Safety Testing" pamphlet and standards referenced.

☐ ISOLATED OUTPUTS or ☐ GROUND REFERENCED OUTPUTS

RF Leakage Measurements at Maximum Power Output in Each Mode

Consult Guide: For *ESU with Ground Referenced Outputs*, conduct test with circuit closed as outlined in section 4.1-1. For *ESU with Isolated Output*, conduct test with circuit open as outlined in sections (4.1-2) and (4.1-3) Table must be insulated (no ESD mats!) and one meter off ground. **NMST** - (Neuro-Muscular Stimulation Test) Peak-to-Peak Voltage readings taken Open Circuit, except with calculating Crest Factor.

MONOPOLAR OPERATING MODE - CUT OUTPUT					PASSED NMST	RF LEAKAGE in mA - Max. 150mA	
Current Mode	Watts -rms	@ Rated Load - Ω	*P To P- KV	Crest Factor		Active	Inactive
PURE CUT					<input type="checkbox"/> Yes <input type="checkbox"/> No	▶ mA	▶ mA
BLEND 1					<input type="checkbox"/> Yes <input type="checkbox"/> No	▶ mA	▶ mA
BLEND 2					<input type="checkbox"/> Yes <input type="checkbox"/> No	▶ mA	▶ mA
BLEND 3					<input type="checkbox"/> Yes <input type="checkbox"/> No	▶ mA	▶ mA

Blend Readings Optional - Duty Cycle % of PURE

MONOPOLAR OPERATING MODE - COAG OUTPUT					PASSED NMST	RF LEAKAGE in mA - Max. 150mA	
Current Mode	Watts -rms	@ Rated Load - Ω	*P To P- KV	Crest Factor		Active	Inactive
PIN POINT					<input type="checkbox"/> Yes <input type="checkbox"/> No	▶ mA	▶ mA
CONE SPRAY					<input type="checkbox"/> Yes <input type="checkbox"/> No	▶ mA	▶ mA

BIPOLAR OPERATING MODE					PASSED NMST	RF LEAKAGE in mA - Max. 150mA	
Current Mode	Watts -rms	@ Rated Load - Ω	*P To P- KV	Crest Factor		Active	Inactive
COAG MODE					<input type="checkbox"/> Yes <input type="checkbox"/> No	▶ mA	▶ mA
CUT MODE					<input type="checkbox"/> Yes <input type="checkbox"/> No	▶ mA	▶ mA

*OPEN

PART III - Patient Return Electrode Circuit Tests:

Consult sections (2.2), (4.2), (4.3), and (4.4) in the "Guide To Performance and Safety Testing" pamphlet

Note: The ESU Analyzers featured on page 4 in the Guide pamphlet will inject up to 1000 ohms into the patient return circuit to test for cable break or impedance between pad cells for REM Tests. Some ESU makers call for interjected capacitor values for REM tests based upon the monitor's clock frequency. Some ESU makers use different clock frequencies - if so the manufacturer should state so in their manual and recommend the correct capacitor to test. The ESU Analyzer may not have the correct value capacitor internally for different clock frequencies. If data is not available, use your oscilloscope to check the monitor's frequency and use the formula below to solve for (C) so 1000 ohms of impedance is injected into the patient return circuit for test.

☐ Patient Cable Fault Only or ☐ ESU Features REM (Return Electrode Monitor)

Maximum Allowable (Z) impedance is 1000 ohms

Did the ESU pass the patient circuit fault test? ☐ No ☐ Yes If Yes, at what impedance did the unit alarm _____ ohms.

ESU REM (Dual Cell) Circuit Test Criteria ▶

Monitor Frequency?	KHz	Let $X_c = 1000$ ohms $f =$ clock frequency of monitor $C = 1 \div 2\pi f X_c$ (picofarads = 10^{-12})
Cap Value Used?	pf	

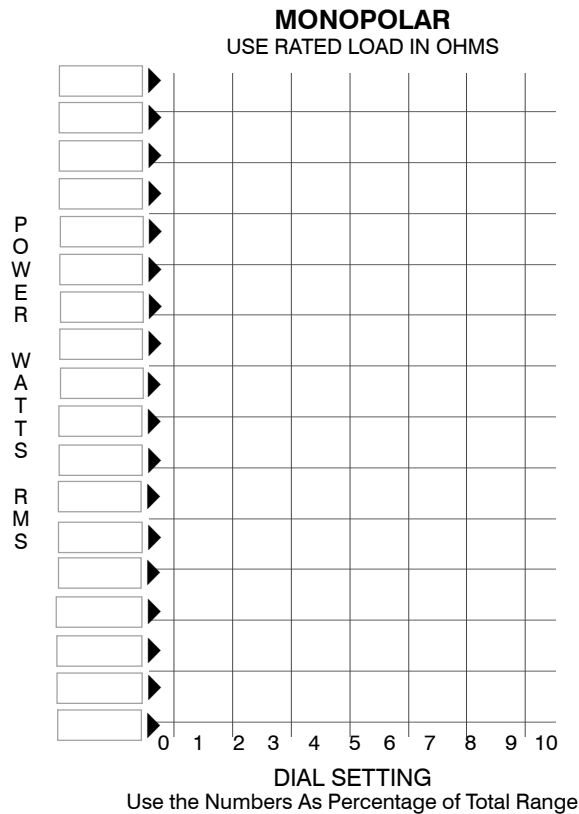
Non-Conformity Report - if any:

Signature Verification:

Signature of Person Performing Tests:	Date:	Department Approval Signature:	Date:
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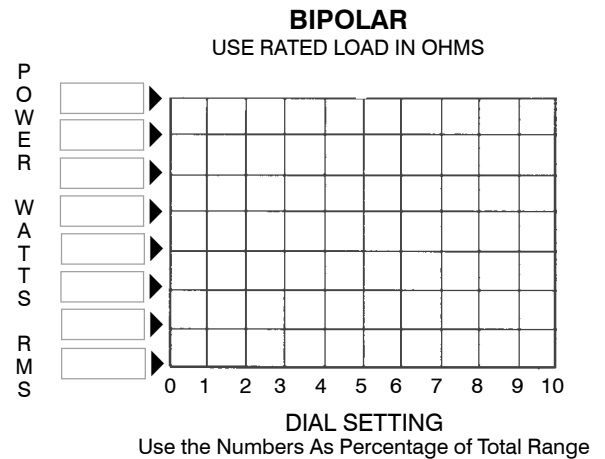
The vertical power gradations are left blank so you can enter the functional power range of the ESU under test.

Part A - Dial Linearity Tests

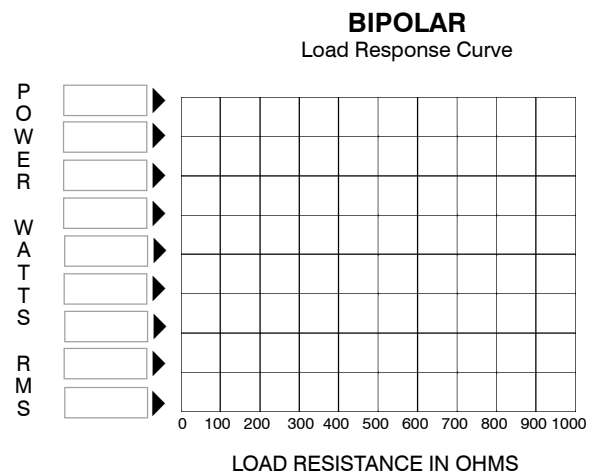
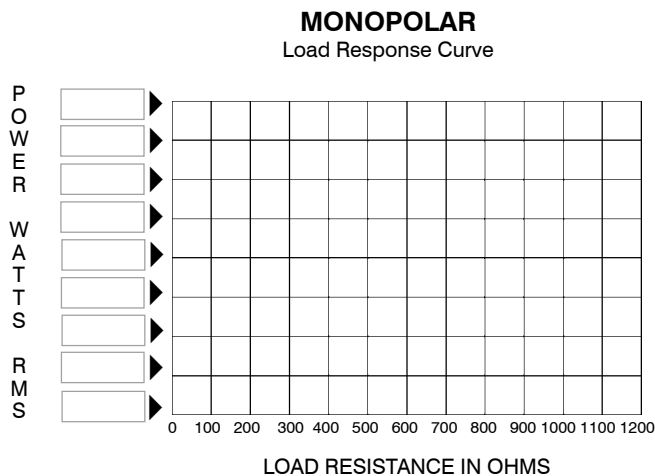


ESU Under Test Criteria

Healthcare Facility:
ESU Make:
ESU Model No:
ESU Serial No:
Operating & Current Mode: (if data on separate sheets)



Part B - Load Response Tests



Manufacturers usually provide a representative load response curve for their ESU and it is based upon a published tolerance (i.e. +/-15%). RF thermocouple ammeter reading calibrated or not is only capable of accuracy within (2%). I.C. r.m.s. converters chips based on heaters in high bandwidth "True RMS Voltmeters" are also only capable of accuracy within (2%). The only way two test sites could achieve less delta variance is if the meters are calibrated to relative readings. Test lead length and distributive capacitance of those leads also play a role in these reading, as well as capacitive coupling at termination points. If you use external resistors, they must be non-inductive types (i.e. Aytron Perry wound, Serpentine wound, or Carton Stick types). Refer to the appendix in the back of this Guide for vendors of thermocouple meters and non-inductive resistors.

Signature Verification:

Note: Use one page for each current mode output or separate pages.

Signature of Person Performing Tests:	Date:	Department Approval Signature:	Date:
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APPENDIX

A. U.S. Food & Drug Administration

Food & Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20850
TEL: 800-638-2041
WEB: <http://www.fda.gov/cdrh/>
WEB: <http://aosweb.psc.dhhs.gov/forms/fdaforms.htm>

Section 510 of the Federal Food, Drug and Cosmetic Act
21 CFR Parts 808, 812, and 820
Medical Devices; Current Good Manufacturing Practice (CGMP); Final Rule
Part 803
User Facility and Manufacturing Reporting

B. J.C.A.H.O. Standard

Joint Commission on Accreditation of Healthcare Organizations
One Renaissance Blvd.
Oakbrook Terrace, IL. 60181
TEL: 630-792-5000
FAX: 630-792-5005
WEB: <http://www.jacho.org>

Management of the Environment of Care

Standard

EC . 2 . 13 Medical equipment is maintained, tested and inspected.

Intent of EC.2.13

The organization maintains documentation of

- a current, accurate, and separate inventory of all equipment in the medical equipment management program, regardless of ownership;
- performance and safety testing of all equipment in the management program prior to initial use and at least annually thereafter;

Note: *An equipment time frame longer than 12 months may be justified based on previous experience and safety committee approval. The specification of an annual testing interval is not intended to be a single standard of testing needs. It is expected that organizations will apply professional judgement in establishing intervals so that risks and hazards are adequately managed.*

- preventive maintenance and inspection of medical equipment according to a schedule based on current organizational experience and ongoing monitoring and evaluation;
- annual chemical testing and monthly biological testing of water used in chronic renal dialysis; and
- performance testing of all sterilizers used.

Examples of Evidence of Performance for EC.2.13

- Staff interviews
- Building tour
- Review of medical equipment inventory
- Schedules and test performance reports for medical equipment included in the program
- Schedules and evidence of preventive maintenance for medical equipment included in the program

Courtesy of JCAHO Standards Department

C. A.A.M.I. Standard

A.A.M.I. - Association for the Advancement of Medical Instrumentation
3330 Washington Blvd. Suite 400
Arlington, VA. 22201-4598
TEL: 703-525-4890
FAX: 703-276-0793
WEB: <http://www.aami.org>
Popular Serial Publication:
Biomedical Instrumentation & Technology Journal

Publications:
HF-18 Standard For Electrosurgical Devices

Check the A.A.M.I. website below for other information and publications for the BMET and CCE.

D. List of recognized medical and electrosurgical device related standards

<p>E.C.R.I. - Health Devices Journals 5200 Butler Pike Pymouth Meeting PA 19462 TEL: 610-825-6000 FAX: 610-834-1275 WEB: http://www.ecri.org <i>An independent comparison testing and reporting group.</i></p>	<p>Publications: Hand Switched Electrosurgical Active Electrode Pencils Vol. 15 No. 6 1986 ISSN: 0046-7022 Electrosurgical Units Vol. 16 Nos. 9-10 1987 ISSN: 0046-7022 Safety Issues Regarding Earlier Spark Gap ESUs Vol. 24 No. 1993 ISSN: 0046-7022</p>
<p>ISO International Standards Organization Central Secretariat Offices: 1, rue de Varembe' Case postale 56 CH-1211 Geneve 20 SWITZERLAND TEL: 011-41-22-749-0111 FAX: 011-41-22-733-3430 WEB: http://www.iso.ch <i>General Assembly of Subsidiary National Bodies</i></p>	<p>Publications: ISO 9001 Quality System ICS 03.120.10 <i>Model for Assurance in Design, Development, Production, Installation, and Servicing</i> ISO 13485 Quality System ICS03.120.10; 11.020 <i>Medical Devices - Particular Requirements for the Application of ISO 9001</i></p>
<p>IEC - International Electrotechnical Commission U.S. National Committee of the IEC: ANSI - American National Standards Institute 11, West 42nd Street, 13th Floor New York, NY 10036 TEL: 212-642-4900 FAX: 212-398-0023 WEB: http://www.ansi.org <i>International Standards and Conformity Assessment Body</i></p>	<p>Publications: IEC 601 - Safety of Medical Electrical Equipment Part 1: General Requirements IEC 601.2.2 - Medical Electrical Equipment Part 2: Particular requirements for the safety of high frequency surgical equipment IEC 601-1-2 Collateral Standards: EMC EN55011</p>
<p>U.L. Underwriter Laboratories 333 Pfingsten Rd. Northbrook, IL 60062 TEL: 847-272-8800 FAX: 847-509-6219 WEB: http://www.ul.com <i>A Testing and Certification Agency</i></p>	<p>Publications: U.L. - U.L. 544 Medical and Dental Equipment ISBN 1-55989-469-5 U.L. - U.L. 2601-1 Medical Electrical Equipment Part 1: General Requirements for Safety ISBN 1-55989-660-4</p>
<p>C.S.A. Canadian Standards Association Central Office 178 Rexdale Boulevard Etobicoke (Toronto), Ontario M9W 1R3 CANADA TEL: 800-463-6727 WEB: http://www.csa.ca/ <i>A Required Testing and Certification Agency</i></p>	<p>Publications: C.S.A. Electro-Medical Equipment C22.2 No. 125 C.S.A. Electromedical Equipment Environmental Products C22.2 No. 125M</p>
<p>N.F.P.A. National Fire Protection Agency 1 Batterymarch Park Quincy, MA 02269-9101 USA TEL: 617-770-3000 FAX: 617-770-0700 WEB: http://www.nfpa.org</p>	<p>Publications: NFPA-99 Electrical Safety in Healthcare Facility Replaces NFPA-76B-T titled, "Electricity in Patient Care Facilities" and NFPA-76C titled, "High Frequency Electricity in Health Care Facilities"</p>
<p>F.C.C. Federal Communications Commission 1919 M. Street N.W. Washington D.C. 20554 TEL: 202-418-0200 WEB: http://www.fcc.gov</p>	<p>Publications: Rules & Regulations Vol II Part 18 Industrial, Scientific, and Medical Equipment 10/82</p>

E. Order fulfillment service for standards documents

Global Engineering Documents
15 Inverness Way East
Englewood, CO 80112
TEL: 800-854-7179
FAX: 303-397-2740
WEB: <http://www.global.ihs.com>

Global Info Centre/IHS Hong Kong Ltd.
Unit 1, 11F, Multifield Plaza, 3-7A Prat Avenue
Tsim Sha Tsui, Kowloon, Hong Kong CHINA
TEL: 852-2368-5733
FAX: 852-2368-5269

*Contractor for AAMI, ANSI, UL, CSA, BSI, VDE, NFPA,
as well as ASTM, NCCLS, AFNOR, and others*

F. Healthcare facilities & equipment related professional associations

ASHE American Society of Healthcare Engineering
One North Franklin
Chicago, IL 60606
TEL: 312-422-3800
FAX: 312-422-4571
WEB: <http://www.ashe.org>
A facilities related engineering group

American College of Clinical Engineering
5200 Butler Pike
Plymouth Meeting, PA 19462
TEL: 610-825-6067
WEB: <http://info.lu.farmingdale.edu/~acce/index.html>
Profession Association of Clinical Engineers

SMET Society of Biomedical Equipment Technicians
AAMI Sponsored Membership Association
Refer to AAMI contact information on page 20

Leading Journals For CCEs and BMETs:

Biomedical Instrumentation & Technology
WEB: <http://www.aami.org/publications>

Journal of Clinical Engineering
WEB: <http://www.lrpublish.com/jce>

G. Organizations for CBET and CCE certification

ICC International Certification Commission
USCC U.S. Certification Commission
AAMI Sponsored Certification Programs
3330 Washington Boulevard, Suite 400
Arlington, VA 22201
TEL: 703- 525- 4890 Ext. 207
FAX: 703- 525- 1067

H. Website addresses for SBET Societies - state and international chapters

<http://www.aami.org/news/sbet797.html> (*SBET votes to improve services and seek closer ties with locals*)
<http://www.mei.com/resource/mabis/sbet/regional.html> (*lists of U.S. state and also international groups*)
<http://www.wf.net/~snowgen/best/bmetdir.html>
<http://www.flordia-biomed-society.org>
<http://www.vabiomed.org>
<http://www.ihca.net/beai/introduction-page.htm#What> (*Association in Ireland*)
<http://www.ncbiomed.org/biomedic.html> (*includes links to state associations and individual members*)

Hong Kong
Charles F. Creswell, CBET
c/o Nellcor Limited
Suite 1204C
Admiralty Centre, Tower 1
18 Harcourt Road, Hong Kong CHINA

I. Healthcare standard for Bar Coding and E.D.I.

Health Industry Business Communications Council
5110 North 40th Street, Suite 250
Phoenix, AZ 85018
TEL: 602-381-1091
FAX: 602-381-1093
WEB: <http://www.hibcc.org>

Healthcare EDI Coalition
1405 North Pierce - Suite 100
Little Rock, AR 72207
TEL: 501-661-9408
FAX: 501-661-0507
WEB: <http://www.hedic.org>

HIBC - Health Industry Bar Code Standard utilized the full ASCII version of Code 39, which was recently revised to code 128 (c) with start and stop characters and check digit. This symbology includes the four digit registration license number, the item number, package level, and check character. An example of this format can be found on the hibcc.org website. The check digit can also be used to link to lot code and expiration information. Embedded PDF (portable document files) are also covered in the following website <http://www.taltech.com>

HEDI - Healthcare EDI Coalition is responsible for establishing the standards for Electronic Data Interchange or what is referred to by Healthcare Distributors as Automated Central Point Ordering Process. This website also has links to other professional associations such as the Healthcare Materiel Purchasing Association and Healthcare Information Systems Association.

J. Vendor sources for alternative testing devices

Sources for RF Thermocouple Meters: *Note: RF Thermocouple meters must be calibrated with special degaussing coils, etc. Do not attempt to adjust them using the face-plate screw - this does not calibrate the meter! Consult the factory.*

Weschler Instruments
16900 Foltz Pkwy
Cleveland, OH 44136
TEL: 216-238-2550
FAX: 216-238-0660
WEB: <http://www.electricnet.com>

Simpson Electric Co.
853 Dundee Avenue
Elgin, IL 60120
TEL: 847-697-2260
FAX: 847-697-2272
WEB: <http://www.simpsonelectric.com>

Sources for Non-inductive Resistors:

Ohmite Manufacturing Co.
3601 Howard Street
Skokie, IL 60076
TEL: 847-675-2600
FAX: 847-675-1505
WEB: <http://www.ohmite.com>

Huntington Electric, Inc.
550 Condit St.
Huntington, IN 46750
TEL: 219-356-0756
FAX: 219-356-7891
WEB: <http://www.heiresistors.com/>

Vishay/Dale Electronics
P.O. Box 609
Columbus, NE 68602
TEL: 402-563-6300
FAX: 402-563-6418
WEB: <http://www.vishay.com>

Sources for testing with a high bandwidth True RMS Digital Voltmeter, and current probe:
(Use the formula $P=I^2R$ to convert the reading into watts)

Fluke 8920A - True RMS Digital Voltmeter (capable of 2% accuracy up to 20 MHz)

Pearson Current Probe - Model No. 2878 Volts per Amp Output = (0.1 volt) Molded with BNC receptacle

Coaxco Cable - Tek No. 012-0113-00 (50-ohm cable with BNC connectors either end)

Fluke Corporation
Corporate Headquarters
P.O. Box 9090
Everett, WA 98206
TEL: 800-443-5853
FAX: 206-356-5116
WEB: <http://www.fluke.com>

Pearson Electronics, Inc.
1860 Embarcadero Rd.
Palo Alto, CA 94303
TEL: 415-494-6444
FAX: 415-494-6716

Tektronix, Inc.
Mailing Station 76-100
P.O. Box 500
Beaverton, OR 97075
TEL: 800-TEK-WIDE
WEB: <http://www.tek.com>

APPENDIX

K. RFI, EMI, EMC - The Electromagnetic Environment

Definitions:

RFI

This is defined as radio frequency interference. With respect to RF electrosurgery, this usually refers to the concerns regarding the radio frequency emissions ESUs generate and the degree of blocking or shielding employed to prevent interference either back through the line or through air to other equipment as well as through the operator's or patient's body while connected to or near other equipment, either therapeutic or diagnostic.

EMI

This is defined as electromagnetic interference. This refers to harmonic or intermittent electromagnetic energy generated by ESU *Emissions* that could possibly affect other equipment or even other circuitry within the ESU. This is usually as a result of poor input power factor, cross-over distortion, or surges due to rapid charging of either caps or large die size power MosFets in power oscillators or power supplies. It can also be created by poor bypassing of high frequency circuits or even by improper placement of magnetic parts or sensitive inputs left open and not tied high or low in control logic, as well as internal flyback transients not clamped as they should be. This list goes on!

EMC

This is defined as electromagnetic compatibility. This refers to negative effects upon the ESU as a result of outside energy sources. *Immunity* tests are performed to measure the ESU's ability to survive these test to see if the ESU is immune to this inflicted energy either at the input or output ports. This may include ESD (Electrostatic Discharge), or EFT (Electrical Fast Transients) caused by the line disturbances or by other surrounding equipment. This includes pulsed energy from defibrillator discharge, as covered in IEC 601.2.2. (The particular standard for High Frequency Electromedical Equipment).

IEC 601-1-2 Collateral Standard: EMC

Until recently, manufacturers in the USA were only required to comply with the part 1 of IEC 601 or IEC 601-1-1. In September 1996, the FDA sent out a letter encouraging U.S. manufacturers to embrace part 2 as well, or standard IEC601-1-2. They recommend that new devices include these standards when preparing for conformity to design controls now required under the current GMP/QS regulations in conformity to Europe's requirements. The EU's (European Union's) MDDs (Medical Device Directives) address Electromagnetic Interference and Compatibility currently in their requirements for applying the CE Mark. The EC's standards for conformity are also referenced by EN55011, and parts of EN55014 when dealing with motors. EN55011 can be detailed for the most part as follows:

CISPR 11 (EN55011) Conducted and Radiated Emissions

IEC 801 - 2	Electro-static discharge 3kV contact/8kV air discharge
IEC 801 - 3	Radiated Immunity, 3V/m 26-1000 MHz AM modulation
IEC 801 - 4	Electrical Fast Transient 1kV power/0.5kV I/O
IEC 801 - 5	Surge 1kV differential/2kV common mode (AC Line)

Testing Methods:

These tests are usually conducted in three manners: (1) using a bench setup and a spectrum analyzer (good only for pre-compliance measurements); (2) the use of a *G-Strip Cell* (bench top chamber); or (3), employing a certified third party testing service with a *Anechoic Chamber* (usually located in a desolated area). The latter is usually required for at least the final *Emission* compliance test.

Certified Testing Services:

Most manufacturers will use some form of bench test to avoid costly retesting fees and will only submit to a certified third party tester when they know they're likely to pass the required tests. Third body notifying bodies such as U.L. will require that they perform these tests or that the manufacturer use a certified testing service. An excellent source of EMC/EMI information is the website: <http://www.emcnet.com>

Minimally Invasive Procedures Can Create New Challenges:

Thermal ablation techniques often require taking temperature reading at the treatment site, in close proximity to a bath of RF radiated energy. Thermocouples are so sensitive they can read off even by using leads made of dissimilar metals (due to the induced galvanic effect). New technologies are being developed to address these very real EMI problems. Refer to our booklet titled, "Principles of Electrosurgery" which includes discussion regarding this issue as well as discussion regarding building safety when loading circuits with computers and other modern equipment employing switching power supplies.

L. View of FDA/CGMP QS Regulations vs. ISO 9001

The FDA issued their Rules and Regulation for good manufacturing practices on October 7th, 1996 and set the enforcement date for June/1997. These federal regulations were the result of a joint effort between government and industry to establish rules that would conform to international standards required by other countries with respect to ISO 9001 and the particular Quality System standard for medical devices referred to as ISO 13485.

21 CFR Part 820 (C) GMP; "Final Rule"

Section

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- 820.1 Scope
- 820.2 Definitions
- 820.3 Quality system

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- 820.20 Management responsibility
- 820.22 Quality audit
- 820.25 Personnel

Subpart C - Design Controls

- 820.30 Design Controls

Subpart D - Document Controls

- 820.40 Document controls

Subpart E - Purchasing Controls

- 820.50 Purchasing controls

Subpart F - Identification and Traceability

- 820.60 Identification
- 820.65 Traceability

Subpart G - Production and Process Controls

- 820.70 Production and process controls
- 820.72 Inspection, measuring, and test equipment
- 820.75 Process validation

Subpart H - Acceptance Activities

- 820.80 Receiving, in-process, and finished goods
- 820.86 Acceptance status

Subpart I - Nonconforming product

- 820.90 Nonconforming product

Subpart J - Corrective and Preventive Action

- 820.100 Corrective and preventive action

Subpart K - Labeling and Packaging

- 820.120 Device labeling
- 820.130 Device packaging

Subpart L - Handling, Storage, Distribution, and Installation

- 820.140 Handling
- 820.150 Storage
- 820.160 Distribution
- 820.170 Installation

Subpart M - Records

- 820.180 General requirements
- 820.181 Device master record
- 820.184 Device history record
- 820.186 Quality system record
- 820.198 Complaint files

Subpart N - Servicing

- 820.200

Subpart O - Statistical Techniques

- 820.250 Statistical techniques

This is only a summary listing of the full twenty parts of ISO 9001 that manufacturers must conform to in order to be certified by a *Third Party Notifying Body* such as U.L. or other such approved organization with routine inspection resources. Manufacturers must comply with these standards to affix the CE mark on their products in addition to complying with the EU (European Union's)MDDs (Medical Device Directives), which now include IEC 60601-1-1 and IEC 601-1-2 standards dealing with safety and EMI/EMC environmental issues. These new standards include emission, and immunity tests covered in the previous section of this booklet. The FDA Quality Systems Regulations and ISO 9001 international standards are presented in column format here to display the similarity and conformity to each other.

ISO 9001 - Full Twenty Parts/Certification Requirements

Section

- 4.0 Quality System Requirements
- 4.1 Management Responsibility
- 4.2 Quality System
- 4.3 Contract Review
- 4.4 Design Control
- 4.5 Document Control
- 4.6 Purchasing
- 4.7 Purchaser - Supplied Product
- 4.8 Product Identification/Traceability
- 4.9 Process Control
- 4.10 Inspection/Testing
- 4.11 Inspection/Measuring/Test Equipment
- 4.12 Inspection/Test Status
- 4.13 Control of Nonconforming Product
- 4.14 Corrective Action
- 4.15 Handling/Storage/Packaging/Delivery
- 4.16 Quality Records
- 4.17 Internal Quality Audits
- 4.18 Training
- 4.19 Servicing
- 4.20 Statistical Techniques

ISO 13485 - Particular Quality System Standards For Medical Devices

This standard extends the requirements under each category above as it relates to medical equipment.

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