An Introduction to Electrosurgery

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Foreword

This booklet is written as a guideline for people involved in testing electrosurgical generators. All reasonable care has been taken to ensure that the information, reference figures and data are accurate and have been taken from the latest versions of various standards, guidance notes and recognised "best practises" to establish the recommended testing requirements. Rigel Medical, their agents and distributors, accept no responsibility for any error or omissions within this booklet or for any misinterpretations by the user. For clarification on any part of this booklet please contact Rigel Medical before operating any test instrument.

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Introduction

Electrosurgery generator units (ESUs) are a crucial piece of equipment in the majority of operative settings and are the most useful and common instruments used by surgeons today. Electrosurgery generators produce high frequency alternating (AC) electric current and differ from electrocautery units in that both cutting and coagulation effects can be achieved through one piece of equipment. Electrosurgery, also known as surgical diathermy, was first developed by William Bovie in 1926, and is a treatment method involving the production of electrically induced heat through the passage of high frequency AC currents through biological tissue. This technique allows the high frequency current to cut or coagulate the tissue, minimising blood loss and shortening operating times, see Figure 1. The technique is determined by the frequency and power of the ESU which causes burning and thermal damage to tissue cells [1, 2, 3].

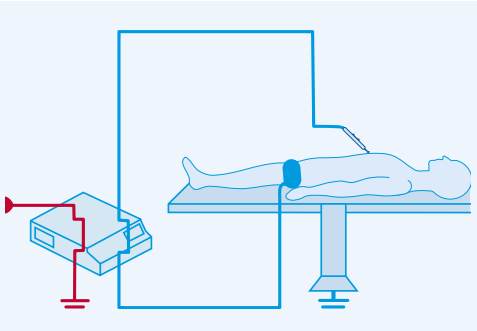


Figure 1 - Electrosurgical equipment

The principle of heat production via current passing into tissue can be adjusted to produce a variety of tissue effects such as coagulation, cutting, desiccation and fulguration. The crest factor (CF) is defined by the ability of an ESU to coagulate without cutting and centres on the idea of shrinking the top layer of tissue which seals and prevents blood loss from the capillaries without causing further thermal damage or tissue necrosis. The CF is measured by the peak voltage divided by the RMS voltage which ranges from 1.4 for a pure sine wave to around a value of 10 for coagulation. There are two electrosurgical delivery techniques; monopolar and bipolar. The monopolar circuit requires electrical current to flow through the human body, whilst in the bipolar system the current flows from one tine to the other through the tissue held between forceps [2, 4].

Electrosurgery was introduced in the 1920s and centred on rapid tissue heating. Temperatures over 45˚C can cause the normal cell function to be inhibited and between 45˚C and 60˚C coagulation occurs causing the cell protein to solidify. Increasing the temperature further to 100˚C produces desiccation and evaporation of the aqueous contents. Beyond 100˚C carbonization occurs and the solid contents of the cells are reduced to carbon [1, 5].

History

The concept of using heat as a form of therapy and treatment to stop bleeding has been used for centuries. This was initially known as thermal cautery where tissues were burnt by thermal heat, including steam or hot metal with the intention of destroying damaged or diseased tissue to prevent infections and reduce bleeding. The earliest example of this can be found in ancient Egyptian writing which described a process in which the tip of a probe was heated and applied to the tissue to produce coagulation, necrosis, or desiccation. In 3000 BC, battle wounds were treated with heated stones or swords producing hemostasis and the Ancient Greeks cauterised wounds to destroy abscesses and stop bleeding.

As technology evolved away from thermal cautery, a variety of devices which used electricity as a means to heat tissue and control bleeding were created. Electrocautery developed in the 19th century as a means of destroying tissue by using electrical currents to intensely heat an instrument; a clinical effect was realised when the heated tool was applied to the tissues. However, electrocautery encountered problems including not being able to cut tissue or coagulate large vessels efficiently.

Further advancement in electrical technology developed into modern-day electrosurgery beginning at the turn of the century when a French physicist, Alex d'Arsonval, demonstrated that radio-frequency currents could heat living tissue without muscle or nerve stimulation.

In the 1920s, electrophysicist William Bovie, with the help of neurosurgeon Harvey Cushing, used electricity as an energy source to facilitate the production of an ESU which offered a means to cut and coagulate human tissue efficiently using the same device, as well as minimise blood loss and reduce surgery times, see Figure 3. The development of the Bovie ESU allowed Cushing to perform more complex neurosurgical procedures that he had previously deemed inoperable before the development of electrosurgical technology, especially where vascular tumours were very problematic to operate on due to the risk of blood loss.

The original "Bovie" machine has served as the model for the majority of subsequently produced ESUs until the invention of the isolated generator in the 1970s. The principal advantage of isolated ESUs is that they can produce lower voltages and more consistent waveforms, while isolated circuits allow for safety improvements including impedance monitoring and reduced risk of skin burns [1, 3, 6, 7].

Figure 2 – William T Bovie

Figure 3 – The Bovie ESU

Electricity and Current

All matter is composed of atoms, which consist of negatively charged electrons, positively charged protons, and neutrons which have a neutral polarity. Atoms are neutrally charged when equal numbers of electrons and protons are present.

Electrons orbit atoms and with energy move out from one atom to another. The net charge of the atom changes due to this movement; atoms with more protons than electrons become positively charged, and atoms with more electrons become negatively charged. Two properties of electricity that can influence patient care during surgery are that electricity will always follow the pathway of least resistance; and that it will always seek to return to an electron reservoir like ground [1, 2, 8].

Electrical current is the movement of electrons due to a force which is driven by a difference in voltage. Electrical current is directly proportional to the voltage in relation to the electrical resistance in the circuit, as defined by the equation:

Current (I) = Voltage (V) ÷ Resistance (R)

Two types of current exist; direct (DC) and alternating current (AC). Direct current allows electrons to flow from the negative terminal through the circuit to the positive terminal in one direction (polarity) such as a simple battery. Alternating current, such as the current from an electrical wall outlet, constantly changes polarity. Frequency is used to define the number of times an AC changes polarity per second, measured in cycles per second or hertz (Hz). AC current is used to power most electrical devices within operating rooms [1, 2].

In electrosurgery, the patient is a fundamental part of the electrical circuit as the current must flow through the body, which acts as a conductor. Early studies into electricity with the body by d'Arsonval discovered that electricity can cause body temperature to increase. Current density is the current applied per unit area. Heat production is a function of the current density, resistance and time. The heat generated is inversely proportional to the surface area of the electrode which means the smaller the electrode, the more localised and intense the heat energy produced will be, and a higher current density results in a higher concentration of heat production [1, 2].

Electrosurgery

Electrosurgery is based on the transformation of an energy current into heat, with the resulting effect of cutting and coagulating tissue at the point of current application. Electrosurgery uses high voltage and high frequency AC current and the electrosurgical circuit is composed of an electrical generator or ESU, an active electrode, the patient and a return electrode. Current enters the body because it is included in the circuit and biological tissue provides impedance which results in heat production as the electrons try to overcome this resistance [1].

Standard mains operate at a frequency of 50 or 60 Hz throughout most of the world. However; at this relatively low frequency, current can be felt by the body with possible complications including acute pain, muscle spasms, cardiac arrests or heart arrhythmias that could result from excessive neuromuscular stimulation due to the current and even a high risk of electrocution, see Figure 4. Therefore for patient safety and because muscle and nerve stimulation cease above frequencies of 100 KHz, radio frequencies are utilised, where radio refers to the region of the electromagnetic spectrum where electromagnetic waves can be generated by AC currents, see Figure 4. The use of high frequencies is crucial as frequencies above 200 KHz do not affect susceptible tissue therefore eliminating the possibility of neuromuscular and cardiac interference with the patient during surgery. The ESU's generator is used to convert the mains electricity supply at a frequency of 50 or 60 Hz to high radio frequency waveforms and creates a voltage for the flow of current which allows the electrosurgical energy to pass safely through the patient [1-3, 6, 8].

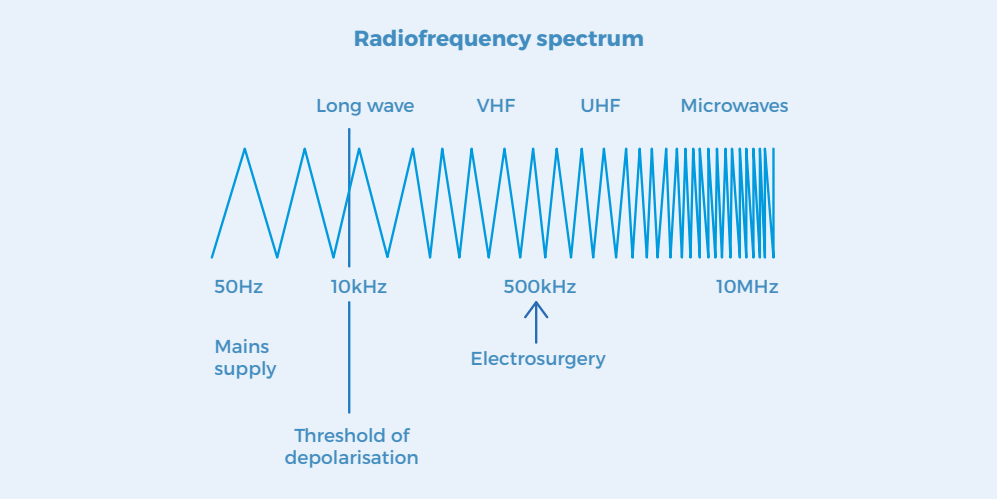


Figure 4 – AC current frequency

Techniques of Delivery

Monopolar

Monopolar electrosurgery is the most commonly used mode in surgery and is usually represented by the Bovie pencil (small single probe), which is an active electrode located at the surgical site. The electrical current flows from the active electrode through the patient's body, to the patient return electrode and back to the generator, see Figure 5. The return electrode which is located on the patient's body away from the surgical site, has a large surface area and low impedance used to disperse the electrical current back to the generator, which is necessary to complete the circuit and prevent alternate burn sites as the high frequency AC current leaves the patient's body. A high current density is produced at the tip of the probe which results in thermal heating and localised destruction. Monopolar techniques are used for cutting, fulguration and dessication. Cutting and fulguration require sparking and high voltages whereas desiccation needs a large current flow through the patient [1, 3, 5, 9, 10].

Bipolar

In bipolar electrosurgery the active and return electrodes are both located at the site of surgery, typically within the instrument tip which is usually forceps, see Figure 5. The current pathway is confined to the tissue grasped between the forcep tines with one tine connected to one pole of the generator (active electrode) and the other connected to the opposite (return electrode). Therefore no patient return electrode is required to complete the circuit and the patient's body does not make up part of the electrosurgical circuit as only the intervening tissue between the tines contains the high frequency electrical current. Due to the small amount of tissue held in the instrument much lower voltages are required and the thermal energy produced is evenly dispersed between the two electrodes, coagulating the tissue with minimal thermal damage to surrounding tissue. Bipolar techniques are used for dessication without sparking which avoids damage to adjacent tissue caused by the arc and spraying of high frequency current and are used in delicate highly conductive tissue [1, 5, 9, 10].

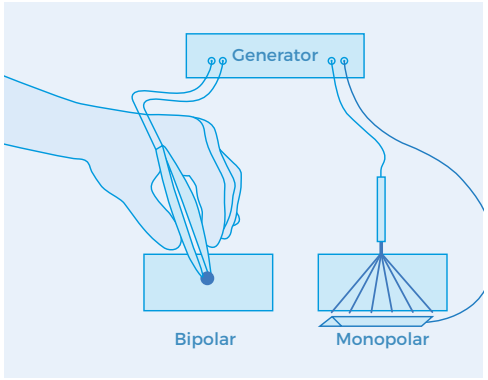


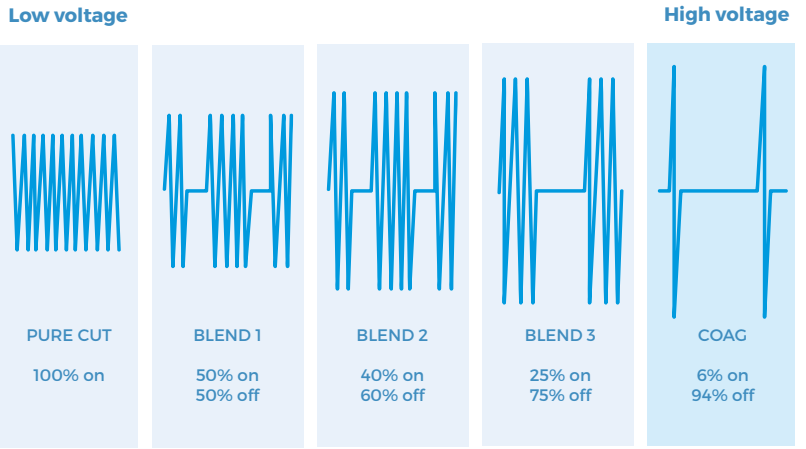
Figure 5 – Monopolar and Bipolar delivery techniques for electrosurgery

Electrosurgical Waveforms and their Tissue Effects

ESUs can be programmed to function in several modes with distinct tissue characteristics. The generator output can be varied in two ways: the voltage can be altered to drive more or less current through the tissues, or the waveform can be modified which influences the tissue effect. The tissue effect associated with the different electrosurgical current waveforms is dependent on the size and shape of the electrode and the output mode of the generator. There are three types of current waveforms: cutting, coagulation, and blended currents, see Figure 6 [1, 6, 9, 10].

Cutting Currents

Cutting currents use an uninterrupted sinusoidal waveform with high average power, high current density and a CF of 1.4, see Figure 6. The use of electric sparks allows for precise cutting and focused heat which minimises widespread thermal damage. The electrode should be held slightly away from the tissue to create a spark gap and discharge arc at specific locations which produces a sudden and localised heating effect over a short period of time which causes extreme heating and vaporisation of intracellular fluid that bursts cells. A fine, clean incision is created through the biological tissue with minimal coagulation (hemostasis) or extensive thermal damage and the continuous current does not allow for tissue cooling [1-3, 6, 9, 10].



Typical Example

	PURE CUT	BLEND 1	BLEND 2	BLEND 3	COAG
On (%)	100	50	40	25	6
Off (%)	0	50	60	75	94
CF (approx.)	1.4	3	5	7	10

Figure 6 – a) Pure cutting current b) Blend 1-3 c) Coagulation current

Coagulation Currents
Coagulation currents are characterised by high voltage intermittent bursts of dampened sine waves which drive the current through the tissue and relatively low current which reduces the duty cycle to 6%, Figure 6. Coagulation currents typically have a CF of around 10. Coagulation is electrical sparking over a wide area therefore less heat is produced resulting in evaporation and relatively slow dehydration which seals blood vessels while keeping cells intact. "The coagulation current is operated with the power setting between 30 to 50 W with voltage spikes as high as 9000 V at 50 W" [8]. In between bursts of current, the heat dissipates into the tissues reducing the cutting effect whilst enhancing the coagulation during the 94% off cycle.

Desiccation is a direct contact form of coagulation where 100% of the electrical energy is converted into heat within the tissue, not seen with other current waveforms. It uses low current density over a broad area which causes dehydration of cells without the need for an electrical spark.

Fulguration is a non-contact form of coagulation, producing a spark gap and electric discharge arc to mediate the tissue as the air between the probe and tissue ionises. A spray effect at various regions causes shallow tissue destruction [1-3, 6, 9, 10].

Blended Currents
A blended current is a modification of the duty cycle and operates at voltages between those of cutting and coagulation with a CF usually in the range of 3 to 10. Blended currents allow for tissue division whilst maintaining a variable degree of hemostasis which is defined by the off period. Although the total energy remains the same, the ratio of voltage and current is adjusted to increase hemostasis; by interrupting the current and increasing the voltage, to deliver a waveform in intermittent bursts. Three blends are shown in Figure 6. Modifications and reductions to the duty cycle through progressive blends produce less heat and as the interval between bursts progressively increases, greater coagulation is produced. However, as homeostasis increases, the cutting ability of the blended current decreases [1-3, 6, 9, 10].

The rate at which heat is produced is the dominant factor and only variable in determining whether a waveform vaporises or coagulates biological tissue. Surgeons have the option to combine the cut and coagulate currents to produce different tissue effects. Coagulation can be performed with the cutting current by using the electrode in direct contact with the tissue and this requires less voltage than the coagulation waveform. However power settings may need to be adjusted and electrode size varied to achieve the desired surgical effect [1].

Electrosurgical Units (ESUs)

Ground Referenced Generators
Originally, ESUs were ground referenced where the electrical current passed through the patient's body and returned to ground. The grounding is intended to occur via the patient return electrode which is usually situated on the thigh of the patient and away from the surgical site. However, electrical currents seek to travel down the pathway of least resistance and therefore current can travel through any conductive grounding object which is in contact with the patient as a method of ground return; such as ECG electrodes or tables and operating staff. This increases the possibility of of creating alternate site burns on the patient at alternative grounding sites where the high frequency current has exited the patient. Many manufacturers no longer rely on ground referenced ESUs due to the high risk of skin burns associated with alternative grounding [1, 8, 9].

Isolated Generators
Isolated generator systems were developed in the early 1970's to overcome the risk of alternative site burns due to grounded systems. The current still passes through the patient and must return through the patient return electrode which leads to the negative side of an isolation transformer located within the generator. The return electrode is not connected or referenced to ground and therefore alternate pathways are avoided. The transformer isolates the power with no voltage reference to ground so that the current does not return to ground or seek other grounded objects, therefore eliminating alternate skin burns. If the current does not find its way to the patient return electrode then the ESU will stop delivering energy current as there must be an alternative grounding path of less resistance than the return electrode [1, 8, 9].

Active Electrode
The active electrode delivers the high frequency AC current from the ESU to the surgical site. At the tip of the active electrode, electron flow and current density are high and spread across a relatively small area. The current density varies depending on the type, size and shape of the tip. There are a variety of tips available including bipolar forceps for desiccation, needle electrodes for precise cut and coagulation, blade electrodes for faster cut and coagulation and ball tips for broad coagulation. The monopolar active electrode is typically a small flat blade with the edges shaped to easily initiate discharge arcs. Needle tip electrodes require a lower power setting than blade or ball electrodes because the current is concentrated on a very small area at the tip of the electrode, see Figure 7. The active electrode should be used in an insulated holster which will prevent accidental burns to the patient and surgeon. To control the waveform, footswitches or switches on the active electrode handle allow the surgeon to alternate between cutting and coagulation currents [5, 8].

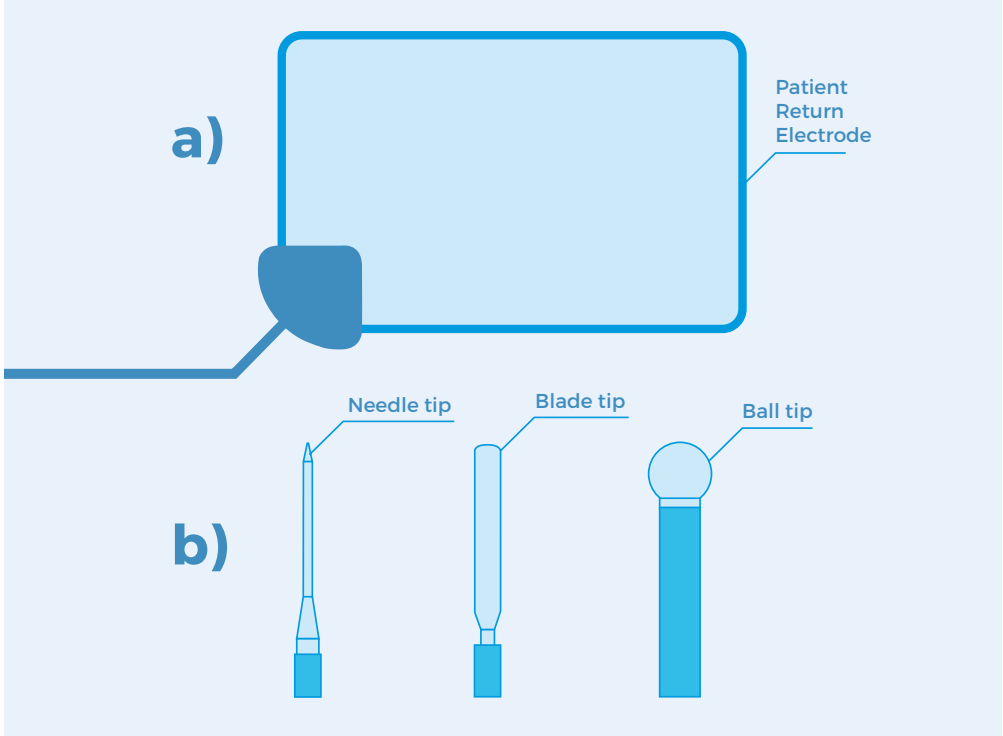


Figure 7 – a) Patient Return (Dispersive) and b) Active Electrodes

Patient Return Electrode

The primary function of the patient return electrode is to collect the high frequency current delivered to the patient during electrosurgery and remove it from the patient safely back to the ESU. The size of the return electrode should be proportional to the energy and the time that the ESU is used. The large electrode area and small contact impedance reduces the current density of the energy dispersing from the patient to levels where tissue heating is minimal thus preventing skin burns, see Figure 7 [1, 5, 8].

To combat failures in the return electrode and subsequent patient injury, contact quality monitoring (CQM) systems were developed in 1981 to monitor the quantity and quality of contact and impedance between the return electrode and the patient. The CQM system is a separate monitoring current which is sent to the patient return electrode and measures the patient impedance. If the contact is interrupted, or there is a failure, an alarm sounds and the ESU is deactivated to prevent further damage; the CQM system only allows the ESU generator to function between a preselected safe range and detects increases in impedance at the return electrode to prevent potential injury and skin burns at the return electrode [1, 3, 6-10].

ESU Hazards and Complications

An electric current needs a closed circuit for electricity to flow and therefore current has the potential to travel along alternative pathways of less resistance which can cause undesired effects. Improper electrosurgery can expose both the patient and staff to potential hazards such as electric shock and skin burns [6, 8, 9].

ESUs can cause burns at the intended surgical site, at alternate sites and at the return electrode. The patient return electrode is a common site of injury; which can be caused due to insufficient size to safely disperse current, or interrupted and significantly reduced contact with the patient, which can result in the current exiting the body and producing unintended burns. Current can divert through an alternative earthing point and cause accidental burning elsewhere on the body. To avoid this, the patient should not touch any metal object and is usually placed on an insulated mattress to isolate the patient [9, 10].

Surgical smoke is produced as the tissue is heated and vaporised and some of this smoke contains potentially harmful chemicals such as carcinogens and cellular debris. To minimise the associated health hazards, specially designed smoke evacuation systems are used and filtration masks worn during surgery [2, 8, 10].

ESUs are the most common source of ignition in operating room fires and explosions. Alcohol based skin preparation should be avoided because liquids can pool under surgical towels and be ignited by sparks from the active electrode. Electrosurgery sparks can also ignite flammable gases within body cavities [6, 10].

Testing Electrosurgical Generators

Electrosurgery is the principle of inducing heat by high frequency electrical current for coagulation, cutting, desiccation and fulguration of biological tissue developed by Bovie. The correct operation of electrosurgical generators is essential to ensure patient safety and manage the risks associated with the use of high and low frequency electrical current on the human body.

Manufacturers of electrosurgical generators must follow the strict design criteria of IEC 60601-2-2, which stipulates the specific requirements in order to provide a controlled approach to patient safety when using electrosurgical devices.

A thorough understanding of each energy modality, waveform and tissue effect is critical in reducing potential complications and hazards whilst the performance and safety of these electrosurgical devices must be regularly verified (every 3-6 months) for instance by using the Rigel Uni-Therm electrosurgical analyser, see Figure 8 [2, 9].

A typical test procedure to ensure the electrical safety and performance is assessed can consist of the following test steps:

1. Visual inspection
2. Low frequency electrical safety test (leakage currents up to 1kHz), see Rigel Medical's IEC 62353 guidance booklet
3. Verification of the contact quality monitoring (CQM) circuit (*see **Contact quality monitoring (CQM) verification** on page 17*).
4. Testing for high frequency leakage, (*see **High frequency leakage test** on page 18*).
5. Check output power at certain loads
6. in relation to the function and waveform selection, (*see **Power management** on page 20*).

> ⚠ **Note:** Be aware; when testing electrosurgical generators, it is crucial to understand the operation of the device under test (DUT). The output energy of electrosurgical generators can lead to burn injuries. Always ensure that the tests are conducted by a suitably trained individual and limit the amount of accessible conductive parts that become live with high frequency electrical current.
>
> To maximise safety, Rigel Medical has developed a number of accessories to automate the testing and reduce the need for manual interaction during testing and whilst the output of electrical surgical generators are active (*see **Automating safety** on page 21*).

The Uni-Therm electrosurgical analyser from Rigel Medical is the quickest and easiest way to test all leading electrosurgical generators, combining the test functions to verify the CQM, the high frequency leakage and the output power, all in a single test device. By providing built-in automation and data storage, the Rigel Uni-Therm can be utilised both in the field as well as at the end of demanding production lines or in test laboratories.

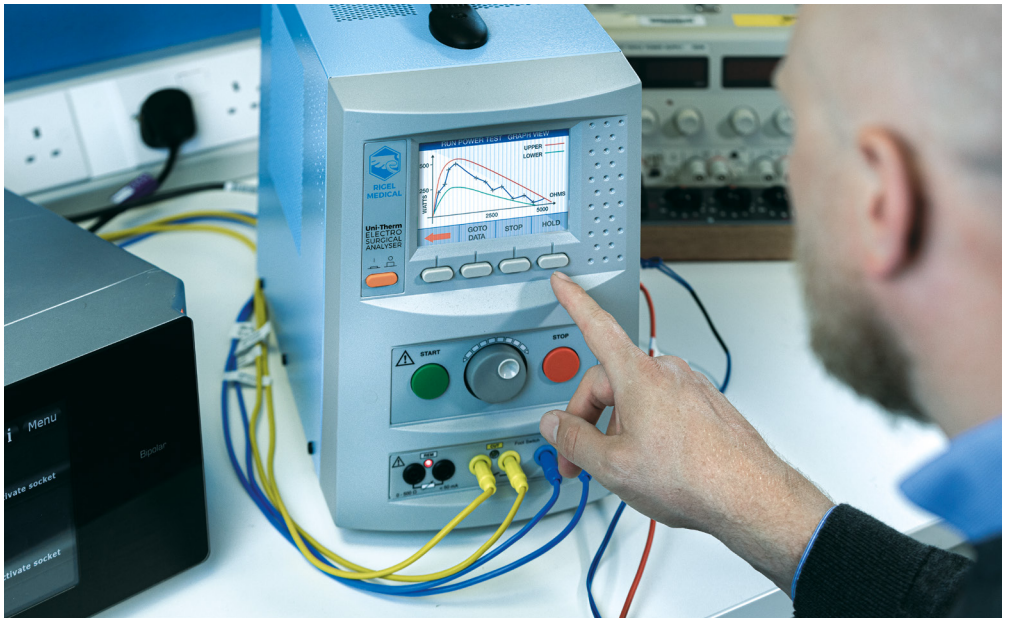


Figure 8 – Rigel Medical's Uni-Therm

Contact Quality Monitoring (CQM) Verification

To maximise the effectiveness of the surgical procedure and to reduce the risk of injury during electrosurgical procedures, the patient plate must cover an optimum amount of skin surface area (quantity) and be high in conductivity (quality) where the energy exits the patient. This is monitored by the electrosurgical device through impedance measurement (CQM) between the two (split) or more conductive pads within the patient return plate, see Figure 9. When extreme variations or very high/low impedance appears, the CQM will lead to an audible and/or visual alarm and can lead to deactivation of the output energy to prevent potential patient injury.

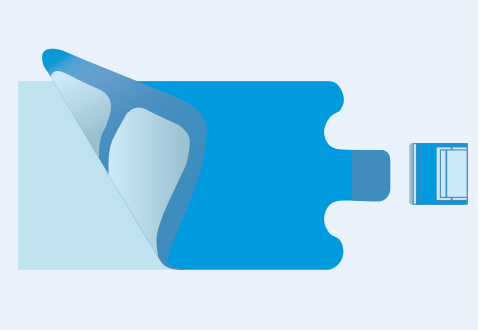


Figure 9 – Example of patient return plate

The Uni-Therm's accurate CQM function simulator allows automatic and manual increase or decrease of electrical resistance values in 1Ω resolution. This enables the testing of modern contact quality monitoring systems that are triggered by relative changes in resistance.

To carry out the CQM test using the Rigel Uni-Therm, connect a CQM test lead between the patient plate connector and the front panel of the Rigel Uni-Therm, see Figure 10.

Figure 10 – Connecting Rigel Uni-Therm to the CQM circuit

Unlike conventional analysers, the Rigel Uni-Therm utilises a motor driven potentiometer which can simulate resistance variations to within 1Ω resolution. This allows the user to trigger the CQM system by simulating fault conditions including very high or very low impedance values or a large variation in impedance, for example a change of 10%.

The variable resistance (0–475Ω) is connected to two black connectors on the CQM section at the front of the Uni-Therm, and also connects to the neutral plate connector on the ESU. Impedance can be controlled by utilising the rotary encoder on the front panel to increase or decrease the impedance, see Figure 11 and 12.

Figure 11 – Rotary encoder on the Rigel Uni-Therm

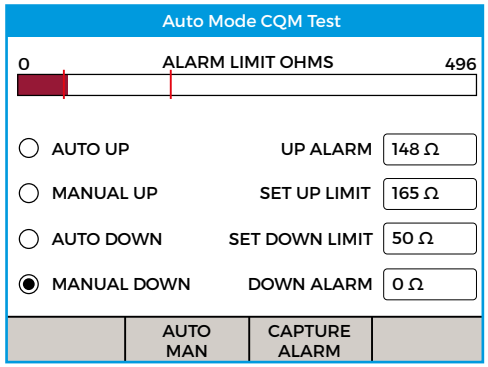


Figure 12 – CQM test screen on Rigel Uni-Therm

High Frequency Leakage Test

Design criteria of electrosurgical generators (IEC 60601-2-2), require the manufacture to limit the amount of capacitive leakage of the high frequency current. At frequencies exceeding 400kHz, the electrical current has a tendency to stray, leading to decrease in functionality and possible injury to the patient.

Capacitive coupling might occur between the test leads during the setup. This is the reason why IEC 60601-2-2 stipulates specific layout of test leads and test loads to ensure the capacitive coupling is limited and controlled in a laboratory environment, these tests are referred to as the long lead tests. A more practical approach is to ensure the test leads are as short as possible and do not cross over, to limit the influence of capacitive coupling.

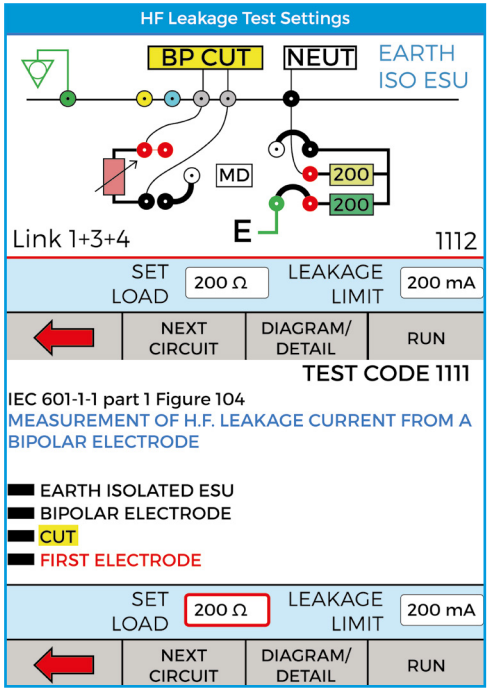


Figure 13 – Test screens for HF leakage on the Rigel Uni-Therm

Breakdown of insulation in the surgery leads as a result of high voltages (peak to peak up to 10kV) is also a consideration when testing the electrosurgical generator. This can be verified by including the surgical leads as part of the test setup. Beware that this might lead to exposure to conductive parts and possible injury.

The HF leakage test measures the HF leakage current in various test configurations and compares the result to a user set pass/fail value using the rotary encoder to navigate the screens.

Figure 14 – Connection panel on the Rigel Uni-Therm

The Uni-Therm simplifies the complex test configurations of high frequency leakage current measurement, as required by IEC 60601-2-2, by providing detailed instructional diagrams for each high frequency leakage test set-up on its colour display, see Figure 13.

Each high frequency leakage measurement can be automatically initiated through the cut and coag control on the Uni-Therm, improving safety and speed of testing, see Figure 14.

Power Management

The Uni-Therm provides a variety of options during the power measurement and has the ability to measure currents of up to 8 Ampere RMS. The unique internal load bank is designed to minimise the phase shift, which can lead to inaccurate measurements at high frequencies and is typical of traditional electrosurgical analysers, see Figure 15.

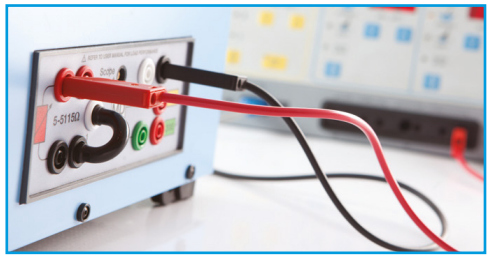


Figure 15 – Connecting the ESU power to the Rigel Uni-Therm

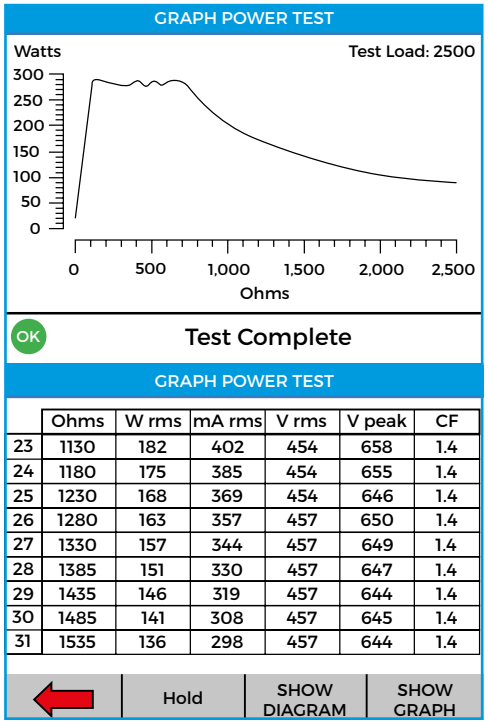
Current measurement in the Rigel Uni-Therm is done through the use of a custom designed current transformer, capable of accurately measuring high currents when calibrating electrosurgical generators with high current vessel sealing treatment functions.

The power management options include:

- **Continuous:** Measuring output power and current during a single load value
- **Graph:** Measuring the output power and current under a changing load condition
- **External load:** Measuring the output and current during short circuit testing or when using a specific external load resistor during development.

The large colour display provides a clear and detailed interpretation of output power whilst cut and coag foot paddle control automates the process; making this a fast, effective and safe test procedure.

Graphical representations of power distribution curves can be easily switched to numerical data at the touch of a button without the use of a PC, see Figure 15.



	Ohms	W rms	mA rms	V rms	V peak	CF
23	1130	182	402	454	658	1.4
24	1180	175	385	454	655	1.4
25	1230	168	369	454	646	1.4
26	1280	163	357	457	650	1.4
27	1330	157	344	457	649	1.4
28	1385	151	330	457	647	1.4
29	1435	146	319	457	644	1.4
30	1485	141	308	457	645	1.4
31	1535	136	298	457	644	1.4

Figure 16 – Power distribution in graph and numerical data

The Rigel Uni-Therm will control the device under test (DUT) by using the internal footswitch controller with a footswitch adapter leading from the footswitch connector on the ESU to the cut and coag sockets on the front of the Uni-Therm. There are three test options: continuous, graph or external load.

Automating Safety

The whole test procedure for testing the electrosurgical generator can be programmed into the Rigel Uni-Therm. The cloning feature makes sharing of test configurations between different Uni-Therms simple, so it is easier and faster to configure and update your test instrument.

Each test step can be set up with simple user instructions for DUT settings such as mono or bi-polar, energy settings and waveform selection.

The CUT and COAG footswitch controls on the Uni-Therm can be used to control the electrosurgical generator. This can reduce the over-all test time and increase user safety, see Figure 17.

Figure 17 – Connection panel for the cut and coag footswitch control on the Rigel Uni-Therm

A range of foot paddle switches are available for all leading brands of ESUs.

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Conclusion

The use of electrosurgical generators has led to more effective surgical treatments and improved patient safety through greater control and management of complications during surgery.

Never the less, the use of electrosurgical generators is not without risk and remains one of the more hazardous practises in operating theatres.

Regular performance and safety tests of these high frequency generators can lead to further improvement of patient safety by ensuring the safety features of each generator is in-tact, and that the performance accuracy is guaranteed.

When considering the purchase of electrosurgical analysers, ensure that you understand the manufacturer's requirements and the technical capability of your install base. For instance, when calibrating electrosurgical generators with high current vessel sealing technology, look for test equipment that can measure both short circuit currents as well as currents over 5A RMS.

The Rigel Uni-Therm is versatile and compact yet offers safer, faster and more accurate testing of electrosurgical generators enabling you to meet international and manufacturer specific test requirements simply and efficiently.

We hope you have found the information in this booklet useful and interesting, we welcome your feedback.

Please direct your feedback and questions to:
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Appendix A:

Table 1 - IEC 60601 Collateral Standards (© IEC Geneva, Switzerland)

IEC 60601-1
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-1-3
Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

EC 60601-1-6
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 60601-1-8
Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-9
Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design

IEC 60601-1-10
Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers

IEC 60601-1-11
Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-12
Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

Appendix B:

Table 2 - IEC 60601 Specific Standards (© IEC Geneva, Switzerland)

IEC 60601-2-1
Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

IEC 60601-2-2
Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

IEC 60601-2-3
Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment

IEC 60601-2-4
Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

IEC 60601-2-5
Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment

IEC 60601-2-6
Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment

IEC 60601-2-8
Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

IEC 60601-2-10
Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

IEC 60601-2-11
Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment

IEC 60601-2-16
Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

IEC 60601-2-17
Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy after loading equipment

IEC 60601-2-18
Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

IEC 60601-2-19
Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators

IEC 60601-2-20
Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

IEC 60601-2-21
Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

IEC 60601-2-22
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 60601-2-23
Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

IEC 60601-2-24
Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers

IEC 60601-2-25
Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

IEC 60601-2-26
Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

IEC 60601-2-27
Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

IEC 60601-2-28
Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

IEC 60601-2-29
Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

IEC 60601-2-31
Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

IEC 60601-2-33
Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

IEC 60601-2-34
Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

IEC 60601-2-36
Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extra corporeally induced lithotripsy

IEC 60601-2-37
Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

IEC 60601-2-39
Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment

IEC 60601-2-40
Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

IEC 60601-2-41
Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

IEC 60601-2-43
Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

IEC 60601-2-44
Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

IEC 60601-2-45
Medical electrical equipment - Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammomagraphic stereotactic devices

IEC 60601-2-46
Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

IEC 60601-2-47
Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

IEC 60601-2-50
Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

IEC 60601-2-52
Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

IEC 60601-2-54
Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

IEC 60601-2-57
Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

IEC 60601-2-62
Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

IEC 60601-2-63
Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

IEC 60601-2-64
Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

IEC 60601-2-65
Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

IEC 60601-2-66
Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

IEC 60601-2-68
Electrical medical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

IEC 60601-2-75
Medical electrical equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

IEC 60601-2-76
Medical electrical equipment - Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment

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