Shivani Sinha

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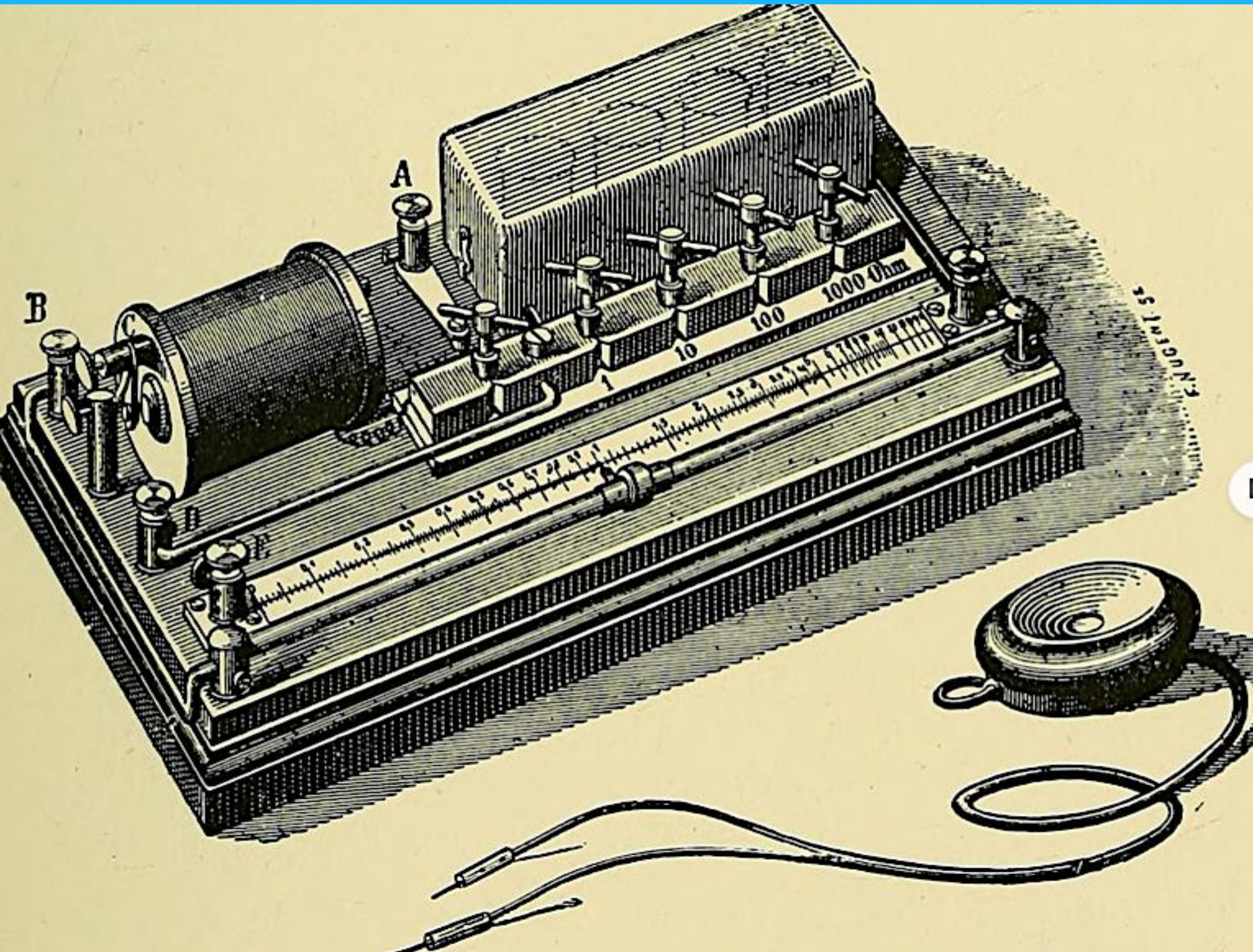
The conversion of Electrosurgical to Advanced bipolar power for Low-and-Middle-Income Countries



TU Delft

Design of a module for bipolar vessel sealing.
The conversion of Electrosurgical to Advanced bipolar power for Low- and Middle-income countries.

By
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In partial fulfilment of the requirements of the degree of

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Abstract

According to recent survey [1], about 6 billion people live in Low-and-Middle Income Countries (LMICs) who do not have proper access to safe surgical care. There are several reasons behind this, such as lack of funding to the healthcare department, below par maintenance of the available devices, poor infrastructure and most importantly high cost of the surgical equipment necessary in an operating room. A bipolar vessel sealing system is one of the many devices which is required for laparoscopic surgery and new innovations in the vessel sealing technologies have transformed the ways of electrosurgery as these devices perform surgery in a safe, reliable and efficient way with minimum operating time and reduced blood loss. Unfortunately, these units have been extensively designed and developed for High Income Countries but not so much for LMICs. The department of Medical Instruments & Bio Inspired Technology at TU Delft is currently working on a solution to produce a vessel sealing system which is safe and reliable to be used in LMICs.

Electrosurgery is a type of surgery where high frequency alternating current is used to obtain a desired tissue effect like cut, coagulate, desiccate and fulgurate by converting electrical energy into thermal energy. An Electrosurgical unit is a generator which provides energy for many such surgical procedures and is available in every hospital. The aim of this project is to provide an additional module which can be attached to the ESU and generate energy of a bipolar vessel sealing system. The module will have a simple circuit design for easy maintenance and will be made of easily available, replaceable and inexpensive components. This will provide a possible solution to use bipolar vessel sealing in low cost setting.

The list of requirements for the circuit of this module is collected from technical details in user manuals and experimental studies for both conventional ESUs and bipolar vessel sealing systems. It also determined the input and output characteristics of the module. The circuit design of the module is based on the block diagram of a common ESU and similar components have been used to establish a connection. The circuit was designed and simulated in a software and the outcomes were matched to the output of a bipolar vessel sealing system already in use (LigaSure vessel sealing system).

Further investigation and research are required to make this module functional for clinical applications as the module does not perform all the functions of a bipolar vessel sealing system, but it does fulfil the basic purpose for which such a system is used in electrosurgery.

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Abbreviations

ESU	Electrosurgical Unit
LMIC	Low-and-Middle Income Countries
AC	Alternating current
DC	Direct Current
RF	Radiofrequency
Hz	Hertz
kHz	Kilohertz
Op-amp	Operational Amplifier

1. Chapter I: Introduction

1.1 Introduction

Healthcare is one of the essential necessities every individual should have access to but unfortunately the distribution of this basic right is highly dependent on income. LMICs have poor surgical conditions and are more affected by deaths due to lack of proper infrastructure. If there is a possible way to improve these circumstances, the burden on global healthcare would be slightly alleviated. One such area of improvement should be in surgical equipment available in LMICs. Widespread of laparoscopic surgery has led to the introduction of novel technologies in the field of electrosurgery. Bipolar vessel sealing device is one of the many important parts needed for modern laparoscopy and these devices are powered by electrical generators of their own. The advancement in design of ESUs into bipolar vessel sealer in High Income Countries has helped reduce operating time and reduce pain and recovery time [2]. A number of clinical trials have been carried out to evaluate the safety, efficiency and reliability of the new instruments. These studies also try to derive a way to produce superior vessel sealers with higher precision and accuracy and lesser complications.

However, there are certain challenges that have hindered the wide use of laparoscopy in LMICs as they do not fulfil the requirements of LMICs. High costs of medical equipment are one of the major barriers preventing advancement of laparoscopy in LMICs. The bipolar vessel sealing device and electrosurgical generators are two different units and the problem with having two different units is much higher cost and bulkier equipment. Even though donating equipment is a common practice, training for the equipment and availability of the spare parts for the device is scarce[3]. Additionally, it is difficult to maintain the donated devices as they might not have instruction manuals with them, or the manuals are not available in the native language[3].
To summarize, in an article by Oosting et al. [4] some of the requirements that should be considered before designing an equipment for LMICs are mentioned such as:

- Affordable.
- User-friendly.
- Easy to maintain.
- Safe and reliable.

One possible solution to improve surgical conditions in LMICs is to provide access to low-cost, low and easy maintenance, robust and reliable medical equipment by designing and manufacturing them according to LMIC requirements with similar or close functionality to high-end devices.

Aim of the project

The aim of the project is to find a solution to use vessel sealing in a low-cost setting. This has been achieved by converting conventional electrosurgical power into advanced bipolar power by designing an add-on module that can be attached to an ESU and performs the conversion. To do so this project has been divided into two parts.

i. The first part consists of a background literature survey of all the available vessel sealing technologies and their design parameters. This helped to establish the most suitable energy source that will be incorporated into the add-on module to achieve vessel sealing. The energy source selected is advanced bipolar.

ii. The second part consists of the design and the simulation of the module on a software.

This add-on module will be used with an ESU, as the power supply, which is readily available in every hospital. The output of the add-on module will be the power of a bipolar vessel sealer. The design process is based on properties and technical details of already existing devices. The circuit design of this module is simple; therefore, it will be easy to maintain in case of malfunction. The components used are off-the shelf i.e. easily available, affordable and replaceable. The power output of the module will have three different intensities to choose from: low, medium and high. The output of this module is verified by comparing it to a bipolar vessel sealing system already in use (LigaSure vessel sealing system).

Overview of the thesis

After introduction in ***Chapter 1, Chapter 2*** is a background literature on what are the different energy sources used in vessel sealing systems available in market and why advanced bipolar energy was chosen for the design of this add-on module. ***Chapter 3*** which is the methods chapter where the approach to designing the circuit of the module is discussed. It clearly defines the research objective and the solution, and it elaborates on the procedure followed along with the simulation tool used. ***Chapter 4*** gives a brief description about three different ESUs and bipolar vessel sealing systems each and provides information on technical details of the devices. ***Chapter 5*** consists of general design considerations and the design requirements for this particular circuit i.e. the tasks the circuit should be able to accomplish. ***Chapter 6*** has the design of the circuit. It consists of the block diagram and the circuit diagram of the circuit. ***Chapter 7*** is the results section consisting of simulations of the circuit and the analysis. ***Chapter 8*** concludes the report and ***Chapter 9*** discusses the future work and research needed to use this product in clinical applications.

2. Chapter II: Review of Literature

In order to make an informed decision, before designing the circuit diagram of an add-on module which delivers the output of a vessel sealing system, it was important to thoroughly research the types of vessel sealing technologies available for use in clinical applications and what properties they exhibit. Therefore, a literature review was performed to study all types of vessel sealing technologies along with some of their design parameters.This literature review elaborates on different types of energy sources available to be used in vessel sealers based on their sealing quality, sealing time, thermal spread, feedback, power and activation temperature.

The choice of device for electrosurgerysurgery depends on many factors such as type of surgery, cost of device, surgeon's personal opinion and comfort and a few others. There is no one way to establish one superior device above all others. There are various different ways in which these sealing devices can be differentiated. Here the devices are categorized according to the methods in which one form of energy is converted into thermal energy to carry out the desired tissue effect. Thus, the question this literature review tries to answer is:- What are the different energy sources used in vessel sealing devices and what are the various design parameters in those devices? Six influential parameters have been discussed in this review: sealing quality, seal time, lateral thermal spread, feedback, power and maximum temperature at the tip. A brief description about the impact of these parameters in the design of a vessel sealer is also mentioned in the review.

The aim is to pick the most suitable source of energy and further investigate its features in a different design for vessel sealers.

Background

Before electrosurgery, the procedure of cutting and sealing blood vessels during surgery was performed manually by surgeons who had to be highly skilled with precision and accuracy. The invention of electrosurgical technology dates back to 1877 when P.Bozzinni described the construction of a device for electro-cauterization.[5] This unit used the same principle of cutting using a blade, but it used the conversion of electrical energy to thermal energy to seal the vessel. The thermal energy applied to the vessel evaporates the content of water present in the tissue, leaving the gooey solid to stick together and form a solid seal. The electrosurgical units used back then were not reliable enough to seal vessels larger than 3mm in diameter. In 1984, a team of neurosurgeons from Sweden presented a technique to reduce charring and burning produced by the introduction of electricity in the human tissue. They achieved this by monitoring the impedance of the tissue placed between the jaws of the device. Figure 1 shows the change in impedance of a tissue as a function of time when heat is applied to the tissue.[6] This monitoring was done with the help of pre-programmed computer algorithms.

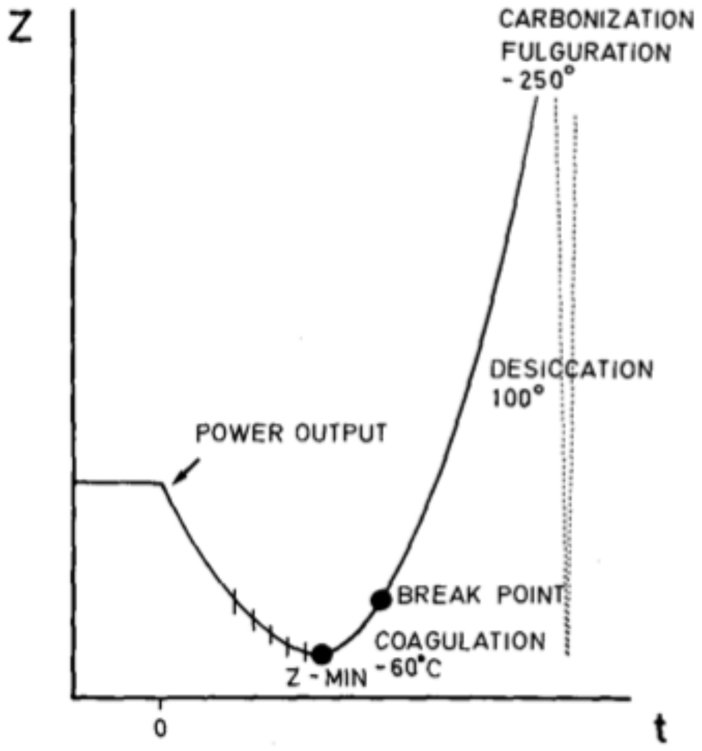


Figure 1: Impedance of a tissue as a function of time [6]

Since then, a number of modifications have been made, such as variations in jaw design, changes in the computer algorithm and even the use of a different energy source other than electrothermal, to improve the method of vessel cutting, sealing and coagulation.

The most commonly used electrosurgical devices in surgery are:

Monopolar

Monopolar devices use two electrodes namely active and passive. The active electrode is placed on the site of surgery and the passive electrode is placed somewhere on the patient away from the site of action. This means that the electricity passes through the patient's body in order to complete the electrical circuit. The use of continuous waveform results in flow of low energy and thus smoke production is less whereas the use of interrupted waveform results in flow of high electron energy causing high smoke production and increased temperatures, but it also causes better hemostasis. Unfortunately, high temperatures can cause burning and charring on the adjacent tissues which could be highly dangerous if it is a vital organ. The maximum temperature that reaches after activation remains lower than 100°C. Some of the tissue effects due to monopolar electrosurgery are fulguration, tissue vaporization and dissection. [5] [2]

Bipolar

Bipolar devices use two active electrodes so the current passes only through the tissue in contact with the device. This means that the electrical current does not have to pass through the patient's body in order to complete the electrical circuit. This results in low power requirements, absence of a remote electrode to be placed far away from the surgical site and capacitive coupling current which also causes injury. Except monopolar device, all the electrosurgical devices are bipolar as they use two active electrodes. This reduces the thermal spread as the voltage associated with the power is less. But the disadvantage of conventional bipolar device is it cannot perform the cutting action and the coagulation also takes longer leading to tissue charring and harm to adjacent blood vessel. [5] [2]

Advanced Bipolar

The difference between conventional bipolar and advanced bipolar is mainly the waveform of the electrical energy used. Conventional bipolar uses standard continuous current waveform whereas advanced bipolar employs highly pulsatile waveform to allow cooling of the tissue in contact with the electrodes to lower the probability of lateral thermal spread. This interrupted current delivery can have different waveforms depending on the modification of the degree of current interruption (duty cycle). [7] The device also has a feedback mechanism which monitors the target tissue's impedance and/or temperature.

Impedance of the tissue can be divided into two parts resistance (R) and reactance (Q). These values can be calculated by :

R=(Vm/Im)* cos(θ_v–θ_i) and Q=(Vm/Im)*sin(θ_v – θ_i) [8]

where Vm is voltage amplitude, Im is current amplitude, θ_v is phase angle of voltage signal and θ_i is phase angle of current signal. When thermal energy is generated, desiccation takes place in three stages. First, the impedance of the tissue decreases as the area of contact between the electrodes and tissue increases. Second, the impedance stabilizes as temperature increases constantly. Lastly, as the process comes to an end, the impedance of the tissue starts increasing indicating completion. [8]

Temperature controlled feedback works on the Arrhenius principle. The amount of thermal damage depends on the temperature which is a valuable feedback variable. To obtain constant temperature exposure, it is important to know the activation temperature and the amount of time the tissue is exposed to it. Arrhenius integral is used for this process.

$$\Omega(\tau) = \int_0^{\tau} A\, e^{-\left(\frac{E}{RT(t)}\right)} dt$$ [9]

where T(t) is the temperature that the tissue is exposed to, A and E are tissue specific, R is gas constant and τ is the time the tissue is exposed to the temperature.

Measurement of impedance and/or temperature helps to regulate the flow of current and voltage power to the tissue. The jaws are designed in a way to provide mechanical pressure on the tissue. In this way, advanced bipolar incorporates both mechanical pressure and electrical energy to effectively seal a vessel. [2] [10] [11]

Different advanced bipolar technologies have variations in their design and their feedback mechanisms. These parameters are discussed in the result section of the review. [12]

Figure 2 shows different types of bipolar vessel sealing systems.

(a)

(b)

(c)

Figure 2: (a) LigaSure (b) EnSeal (c) Plasma Kinetic   [2]

Reusable Bipolar Devices

Reusable devices have the same mechanism as that of advanced bipolar devices. See Figure 3. They too incorporate feedback mechanism for efficient power use and reliable sealing effect. The only difference is that the blade, which performs the cutting and sealing action, attached to the shaft is disposable. This means that a new blade can be used for different surgeries and the whole device does not have to be disposed of after single use. Since the blade of the device can be changed, specific jaw design can be chosen according to the requirements of the surgeon. [13]

Figure 3: MarSeal device [13]

Ultrasound

In ultrasonic devices, Figure 4, tissue seal and cut are performed without passing any electrical current through the patient’s body. They convert electrical energy first into mechanical energy and then to thermal heat. The electrical energy is sent to a piezoelectric transducer which begins to vibrate at a certain frequency converting electrical energy to mechanical energy. The active electrode is in contact with this transducer and vibrates with the same frequency. These vibrations create a heating effect (frictional heat) which is used for obtaining the desired tissue effect. The other electrode is stationary and provides a stable grip to hold the tissue. The cutting mechanism is achieved due to the mechanical friction between the oscillating jaw and the tissue. [2] [5] [14] [10] [11]

Figure 4: Harmonic ACE [2]

Hybrid

The innovation of this new hybrid device uses both ultrasonically generated frictional energy and electrical generated bipolar energy to perform the action of tissue dissection and coagulation. The cutting and dissection is done by using ultrasonic energy whereas sealing is performed by using advanced bipolar energy. [5] [10] [11] One example of the device is ThunderBeat. See Figure 5.

Figure 5: ThunderBeat [2]

Plasma Energy

This device uses a combination of cold helium plasma and RF energy to deliver the desired tissue effect. For example, J Plasma Helium device, See Figure 6.The plasma stream is created by passing inert helium gas through an electrically charged blade. This stream can be controlled by the surgeon by controlling the flow of helium gas and it can also be made pulsatile to allow cooling of the tissue between activation. The blade is retractable which is used for cutting and dissection. For sealing, the blade is retracted, and the plasma energy is used for ablation and coagulation. The focused beam also results in lower lateral thermal damage. [15] [16] [14] [17]

Figure 6 : J Plasma Helium device

Ferromagnetic Heat

The heating element is placed in the jaws which comes in contact with the tissue. A high frequency alternating current is delivered to this heating element which results in generation of magnetic field in the direction perpendicular to that of the electric current. The jaw is also coated with a ferromagnetic alloy which reacts to the magnetic field created due to the alternating current. This reaction causes the production of pure thermal energy due to magnetic hysteresis loss and Joule heating effect. Since the electric current is contained within the jaws, there is no electrical energy or magnetic effects on the tissue. This device is used for sealing purposes only. [18] [19] Figure 7 shows how a ferromagnetic device seals vessels.

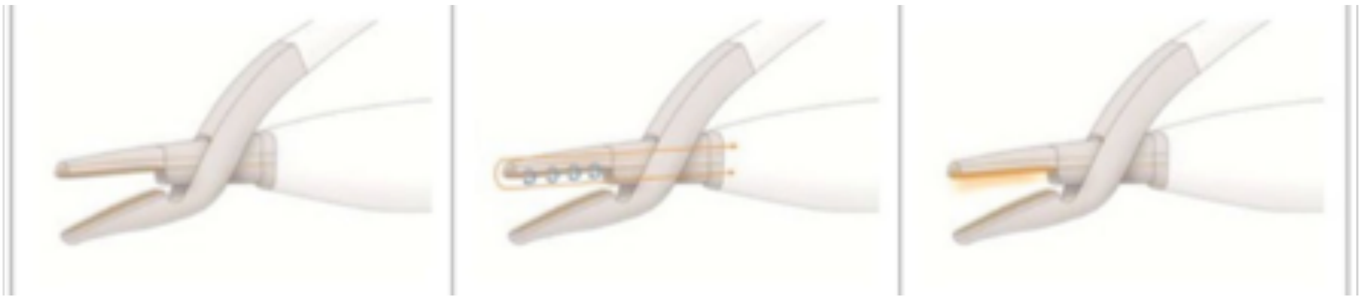


Figure 7: FM Sealer [18]

Infrared Energy/Laser

Infrared energy is focused on the target tissue in a laser. The heat produced due to this energy helps to perform the desired tissue action. Generally, dissection is carried out in contact mode where the optical fiber, emitting infrared light, is in direct contact with the tissue and coagulation is done in non-contact mode by keeping the fiber approximately 5mm away from the tissue. [20] [21] An example of infrared energy is a diode laser, See Figure 8.

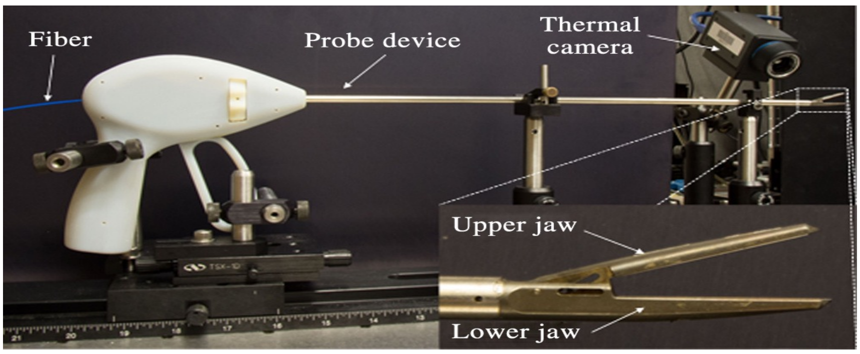


Figure 8: Diode Laser [20]

Primary variables evaluated of different bipolar vessel sealers:

Sealing quality

The sealing quality of any vessel sealer is determined by finding out the mean burst pressure of vessel after it has been sealed. This is calculated, in an experimental setup, with the help of device that applies pressure on the sealed vessel up to a point that it bursts. This is performed several times and a mean is calculated. The burst pressure may vary according to the type of vessel, size of vessel and specifically the device used to seal the vessel. All the devices need an FDA approval for sealing vessels up to certain diameters before they can be used for surgery. For example, advanced bipolar devices and ultrasonic devices have been approved to seal vessels that are 7mm in diameter or less. [22]

Sealing time

Sealing time is defined as the time taken by the device to create a seal, from activation to indication of the seal being created. Some devices have feedback mechanism that let the surgeon know that the sealing process is complete either by stopping the power supply or by giving audible signals to stop. Shortest seal time of a device does not mean that it is more efficient as it could be possible that it might have high seal failure rate. It is better to have increased operating time to ensure reliable seal. [22]

Thermal spread

Vessel sealers operate at a high temperature and there is a significant chance of tissue damage as these temperatures exceed 42°C. Prolonged exposure to these temperatures can cause permanent damage. This can also happen at a site which is farther away from the target site. This occurrence is termed as lateral thermal spread. This damage depends on many factors such as the type of target tissue, power settings of the device, contact or non-contact mode application, type of electric current waveform and the time for which the energy is applied to the target tissue. This damage can be studied with the help of temperature probes or thermal imaging. [22]

Feedback

Some vessel sealers have advanced feedback mechanism to make the process of vessel sealing efficient. They either monitor the impedance of the tissue held between the jaws or the temperature or both to regulate current flow and voltage. For, example LigaSure measures tissue impedance in real time. As the water vapor evaporates from the tissue, the impedance of the tissue changes. The change in impedance gives an indication for the completion of sealing process. Another example is EnSeal which uses Nano polar thermostats fixed in the jaws of the device. These sensors monitor the temperature of the tissue and changes current flow accordingly. [23]

Power

Every vessel sealer is paired up with a generator which has its own different power settings. Various levels and modes are included to perform cutting, coagulation, dissection and fulguration. The current output of these generators can be varied to deliver different waveforms. Every mode has a unique waveform which helps to achieve varying degrees of cutting with hemostasis. When comparing two devices, it is advised to keep the cutting and coagulation level of all generators at a constant level for accurate results. If the power levels and energy are kept constant, higher pressure results in more denatured tissue zone whereas under same pressure (compression) and heating time, high power produces larger denatured zone. [24] The best way to avoid any kind of injury is to keep the power level at lowest possible setting at which the desired tissue effect can be achieved and never go over the levels mentioned by the manufacturer.

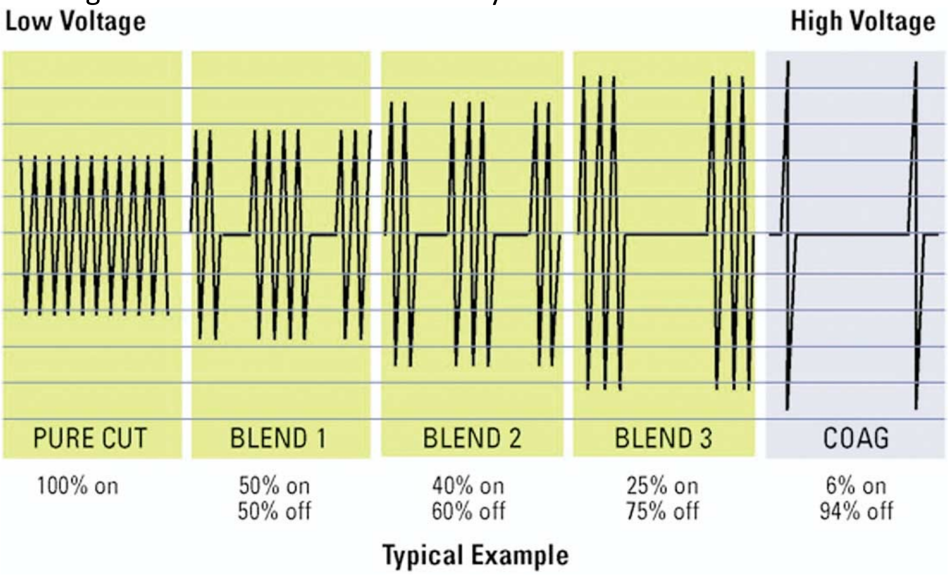


Figure 9: Relationship of instrument settings to voltage and current interruption. [7]

Figure 9 shows different waveforms in a generator. Continuous waveform for a pure cut at low voltage. Interrupted current for pulsatile waveform. Interruption in waveforms at higher voltages used to achieve cutting at different levels. Blend 1 has a 50% duty cycle whereas Blend 3 has only 25% duty cycle. In the coagulation mode, the temperature of the tissue rises slowly but not to a point of vaporization. As the current flow is less, less amount of heat is produced in coagulation mode.

Maximum temperature at the tip

Different energy source produces thermal output at different temperatures. This indicates that the maximum temperature at the tip of the device during activation varies with every device. Advanced bipolar devices maintain the temperature somewhere lower than 100°C whereas in ultrasonic devices the temperature can go as high as 200°C. [25]

Methods

The first search terms were established by looking for “bipolar vessel sealing” and “properties” in a wider aspect. This led to different types of energy conversion methods being used in devices, other than electrothermal, that are available in today’s market along with their description and features. In order to search for specific methods of these energy conversions and the parameters associated with a particular device, the terms “power, design, energy source, thermal spread, sealing quality, feedback and sealing time” were included in the search along with the names of the devices in the below mentioned manner.

Advanced bipolar energy/ electrothermal	Vessel seal*	Properties
Ultrasonic energy/ultrasound	Tissue coagulat*	Maximum temperature

Plasma energy/plasma stream	Electrosurgery	Power
Ferromagnetic heat/ferromagnetic energy	Tissue weld*	Sealing quality/burst pressure
Infrared energy/infrared pulse/laser		Thermal spread
Frictional heat/frictional energy		Feedback
Energy devices		Sealing time
		Design
		Current/voltage density

Table 1: Search terms

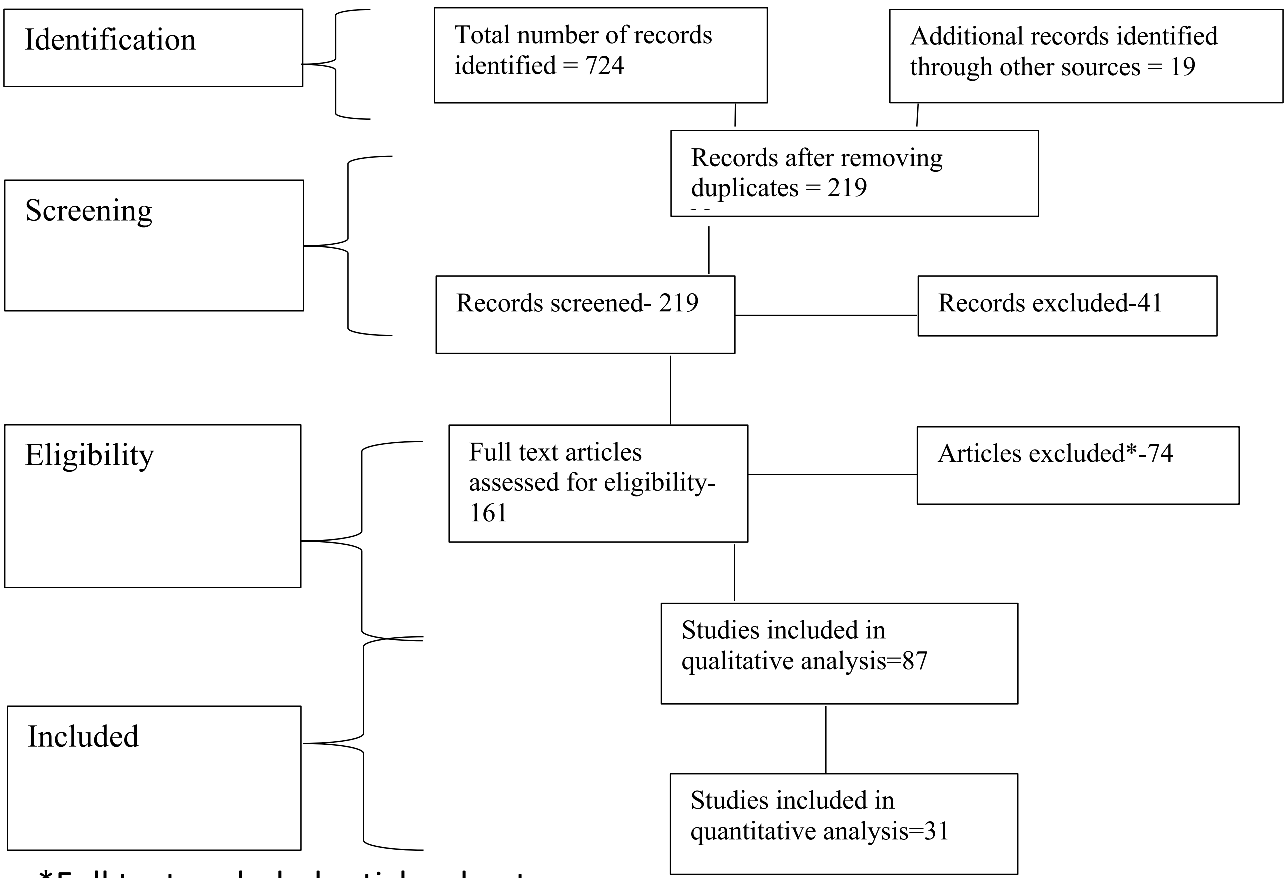
(“advanced bipolar” OR “electrothermal” OR “ultrasound” OR “frictional” OR “plasma” OR “ferromagnetic” OR “infrared” OR “energy devices”) AND (“ vessel seal*” OR “tissue coagulat*” OR “tissue dissect*” OR “tissue cut*” OR “electrosurgery”) AND (“power” OR “feedback” OR “sealing” OR “design” OR “thermal spread” OR “temperature”)
SCOPUS- 484 AND WEB OF KNOWLEDGE- 195

LigaSure	Vessel seal*	Properties
EnSeal	Tissue coagulat*	Maximum temperature
Caiman	Electrosurgery	Power
Plasma Kinetic Gyrus	Tissue weld*	Sealing quality/burst pressure
Harmonic ACE/Harmonic scalpel		Thermal spread
ThunderBeat		Feedback
J-Plasma Helium device		Sealing time
FM Sealers		Design
Diode Laser		Current/voltage density

Table 2: Modified search terms

(“LigaSure” OR “EnSeal” OR “Caiman” OR “Gyrus Plasma” OR “Harmonic scalpel” OR “ThunderBeat” OR “J-Plasma” OR “FM Sealers” OR “laser”) AND (“ vessel seal*” OR “tissue coagulat*” OR “tissue dissect*” OR “tissue cut*” OR “electrosurgery”) AND (“power” OR “feedback” OR “burst pressure” OR “design” OR “thermal spread” OR “temperature”)
SCOPUS- 116 AND WEB OF KNOWLEDGE- 163

PRISMA FLOW DIAGRAM



*Full text excluded articles due to

- If the devices are used only for monitoring purposes.
- If device can be used for one particular surgery.
- Checking blood loss and post-operative pain and complications.
- Used for cosmetic surgery.
- Interference of surgical unit with other devices in the body or in the operation room.
- Best operative technique to use the devices.
- Coagulation patterns by each device.
- Coating or device material to be used to avoid sticking. Chemical Analysis.
- Checking what happens to disposable devices if sterilized.
- Monopolar devices.

The table in the next section, Table 3, is the result comparing properties of various energy-based vessel sealing systems.

Energy Source	Properties						
	Device Examples	Sealing quality	Sealing time in seconds	Thermal Spread	Feedback	Power	Maximum temperature at the tip(activation temperature)
High Frequency alternating current **(advanced bipolar)**	MarSeal [13]	1545 (3-7mm)	7.71	-	Measures impedance of the target tissue during sealing process	Maximum permissible HF voltage of 3000Vp	-
	LigaSure [12] [13] [26] [27] [23] [28]	819.6 (2-3mm) 940 (4-5mm) 756.9 (6-7mm) Burst pressure greater than 3 times normal systolic blood pressure	2-4	~1.5mm	Measures impedance of the target tissue during sealing process	30-50 W	Less than 100°C
	EnSeal Surg RX [12] [27] [23] [29]	1025 (2-3mm) 927.9 (4-5mm) 720.5 (6-7mm)	4-8	~1mm	Maintain tissue temperature in real time	30-50 W	Less than 100°C
	Plasma Kinetic Gyrus [5] [25] [B] [C]	636.9 (2-3mm) 295 (4-5mm) 322.7 (6-7mm)	2-6	2-4mm	No feedback mechanism but allows the physician to choose how long energy is applied with the aid of audible tone change, indicating tissue desiccation.	90-200 W	Less than 100°C

Ultrasound	Harmonic ACE+7 [27] [23] [29] [D]	789.9 (2-3mm) 390.7 (4-5mm) 532.2 (6-7mm)	14-15	1-4mm	Uses adaptive tissue technology to regulate energy delivery according to tissue conditions	Frequency of 22,500-55,000 cycles per second	Higher than 200°C
Hybrid	ThunderBeat [27] [23] [A]	743±6 (5-7mm)	10.7 (cutting)	1-2mm	Intelligent Tissue Monitoring	-	Less than 200°C
Plasma energy	J Plasma Helium device [16] [17]	-	-	~4mm	-	-	Over 100°C
Ferromagnetism	FM Sealers [18] [19]	Mean of 1098	12.43±2	~1.5mm	-	30-40 W	Less than 100°C
Infrared energy	1470nm Diode Laser [20]	1038±474 (smaller than 5mm diameter)	Sealing with 3s of irradiation	~1.5mm	-	100W continuous wave	Around 60°C

Table 3: Properties for various bipolar vessel sealing devices

Results

All these devices have successfully been used for minimal invasive surgery except diode laser which is still in experimental phase. One of the major outcomes is the similarity in the bursting pressure of these devices for vessels less than 5mm in diameter. Infrared energy showed high failure rate when used to seal vessels with diameter more than 5 mm. [20] All the instruments, except infrared, have been approved to seal vessels up to 7 mm in diameter.

Instruments that use advanced bipolar energy have resulted in highest burst pressures and fastest sealing time (like LigaSure when used with Force triad generator). They also employ the use of mechanical pressure which provides even distribution of pressure on blood vessel for efficient seal. The mechanism of applying pressure for sealing can be achieved by two different modalities: contact and micro-discharge. Contact modality works on the principle of joule heating effect when inner walls of the vessel are in contact with each other and the heat is transferred from the tissue electrode interface to the inner vessel tissue. In this mode there is very little gap between the electrodes. In discharge modality, a micro-discharge is created in between the inner vessel walls and the heat moves from inside to the outside of the vessel. There is a bigger gap between the electrodes. The lateral thermal spread is expected to be lesser in the micro-discharge modality as the heat is delivered form the inside. [30] There is a little smoke production in such devices which can hinder the visibility for surgeons, but the amount of smoke depends on a lot of factors and is different almost every time and thus, this parameter has not been taken into consideration.

The feedback mechanism depends on measuring either tissue impedance or temperature. The value of the tissue impedance and temperature at various stages of sealing, starting from lowest temperature to the point a seal is created, has to be calculated very precisely and accurately before they can be used in the feedback algorithm. The average tissue impedance is a few tens of Ωs to hundreds of Ωs depending upon the tissue type. With the application of current, this value first decreases and then increases to indicate that the desired tissue effect has been achieved. Mechanical pressure and different power settings can also have varying effect in the impedance of the tissue. Figure 10 below is an experimental example of bipolar process which shows effect on tissue impedance of a porcine muscle tissue due to changes in power and pressure (compression). [24]

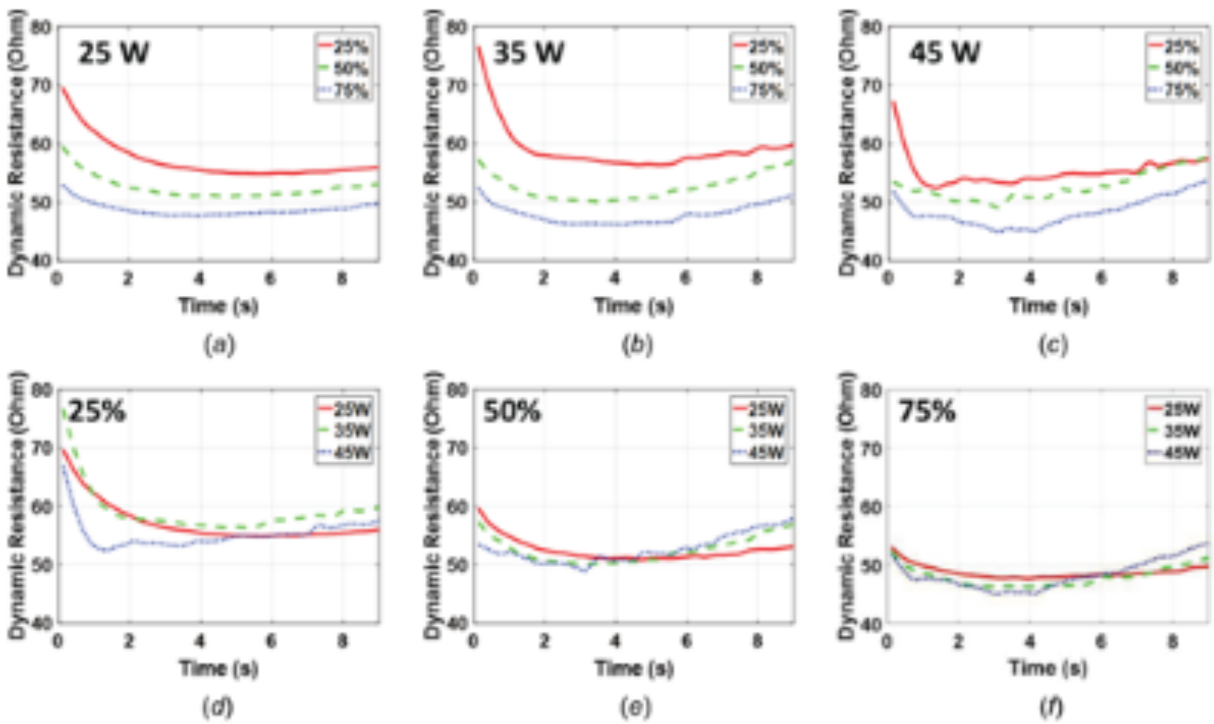


Figure 10: (*a*)–(*c*) Resistance plot with different compression levels under 25 W, 35 W, and 45 W power settings; (*d*)–(*f*) Resistance with different power settings under 25%, 50%, and 75% compression levels [24]

In (a)-(c) it can be seen that at increasing power levels, higher compression results in lower impedance. This implies high power and compression will cause higher desiccation rate. Whereas in (d)-(f) if the compression is kept constant, higher power results in faster heating.

In temperature-controlled feedback, the temperature of the tissue is monitored constantly to prevent tissue charring. At 45°C, denaturization of protein starts where the tissue loses its structural integrity. At 90°C, the water in the tissue starts to vaporize and after 250°C, tissue is reduced to carbon. [7]Advanced bipolar devices have activation temperatures below 100°C which also indicates lesser thermal damage. Advanced bipolar device (EnSeal Surg RX) noted thermal spread as little as 1mm.

Ultrasonic devices perform the function of cutting and sealing in a single process which makes it lighter in weight as compared to other devices. The Harmonic Ace+7 has 5 different power levels with MIN and MAX hand activation buttons. MAX has the highest power output at level 5 and provides fastest sealing for smaller vessels. MIN has adjustable power setting and it can be varied between 1 and 5. The default setting is 3 and this can be used to seal vessels up to 5 mm in diameter. It also has advanced hemostasis button which when enabled modulates the delivery of energy according to the data stored in the generator and is used to seal vessels up to 7mm in diameter. This mode works in 3 stages. The first stage is pre-heating stage where high power setting is used to establish the necessary temperature of the tissue. The second stage is vessel sealing phase where variations in power settings is used to get optimal compression, temperature and activation time for vessel sealing. The last stage is transection stage where the system determines the best way to complete the seal without compromising the structural integrity of the seal. [D]

For feedback, ultrasonic devices use adaptive tissue technology, see Figure 11. This advanced algorithm monitors the condition of tissue between the jaws of the device to optimize tissue sealing according to tissue thickness and tissue type and gives an audible feedback for better thermal management. Even though they operate at higher temperatures, the narrow jaw design of the instrument and lesser transection time causes relatively lesser charring and thermal damage. The intelligent energy delivery system and multifunctional blade provides the surgeon with flexibility as the number of devices needed in a surgery decrease.
Hybrid device, ThunderBeat, also has a SEAL & CUT mode which allows simultaneous safe coagulation and fast tissue transection. It employs intelligent tissue monitoring as a feedback mechanism system to manage the activation of ultrasonic vibrations for superior dissection.

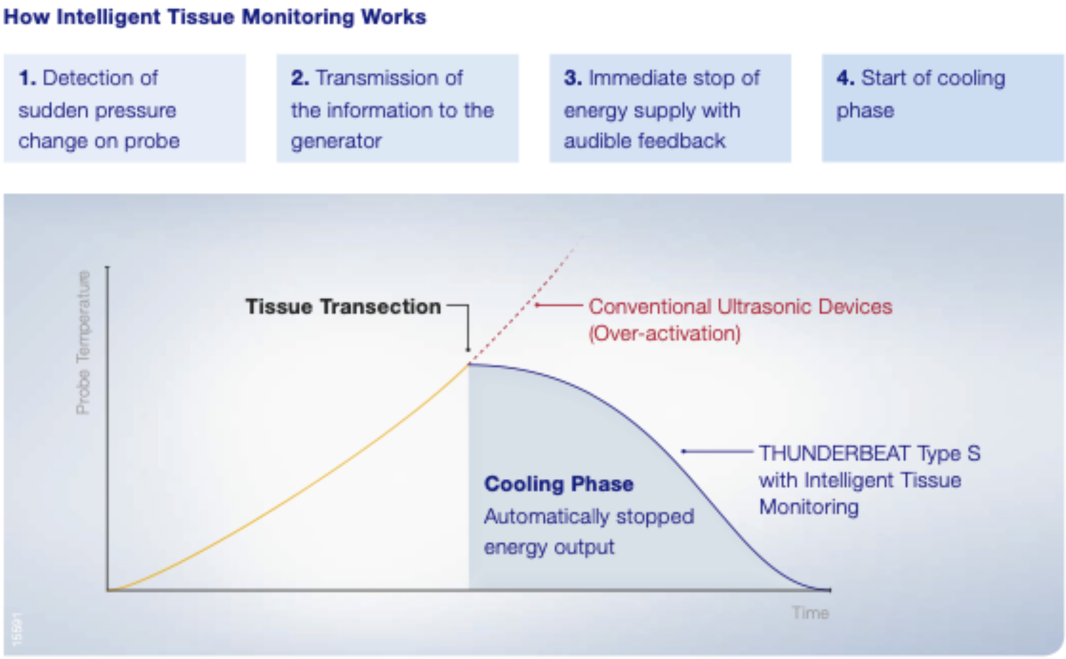


Figure 11: Intelligent tissue monitoring [A]

Both ultrasonic and hybrid devices reach an activation energy of over 200°C which is very high and if not handled properly, can lead to tissue charring.

Plasma devices are more often compared to laser and monopolar instruments. They have proven to be as effective as radiofrequency and ultrasound energy and they also have the advantage of being multifunctional as the process of cutting can be switched to fulguration by push of a button. Use of cold inert helium gas in pulses allows cooling of the tissue and comparatively lower activation temperatures. The generator used with plasma is a 3-in-1 energy source as it offers plasma energy along with monopolar and bipolar functions. It has two modes of cutting and three different blend modes. The power requirements are 100-240V with 50-60Hz frequency. Thermal damage highly depends upon the type of tissue and the activation time. Plasma device has relatively higher lateral thermal spread, 1-4mm, than other instruments.

Ferromagnetic devices are used for sealing and dividing and are as reliable, efficient and fast as other advanced bipolar and ultrasonic devices. This device has ergonomic advantage as the shape of the heating element can be designed according to the requirements of the surgeon or a particular surgery. It allows separate cutting and sealing which is preferred by some doctors. There is no effect of current or magnet anywhere near the patient's body hence there is no interaction between this device and other devices inside (ex. Pacemaker) or around the patient. It offers multiple power settings and activation modes. FMmax is the high-power seal and divide mode which is used for smaller vessels. FMmin has 2 levels, seal and divide mode and seal only mode. The generator used with the device intelligently monitors delivery of energy for optimal heating effect.

Laser devices have been used for quite some time in laparoscopic surgery. The use of diode laser is new, experimental and an improvement to the existing instruments. The prototype device can efficiently seal vessels up to 5mm in diameter in under 5 seconds. Thermal cameras showed the jaw temperature to be around 60°C which is very low as compared to other instruments. The different jaw designs used with the device also contributes to better seal with help of pressure mechanism. Infrared energy is also one of the quickest, completing sealing with only 3 seconds of irradiation. The disadvantage is that the jaw cooling takes a long time which can cause wait times in between application during surgery. There is also smoke production with use of infrared energy, but the exact amount has not been evaluated.

All these devices cause some amount of thermal injury when used because of the basic principle application of heat for sealing procedure. They also produce smoke that can hinder the visibility during surgery and can cause mistaken target application. Some of the other possible mechanical injuries are direct coupling, capacitive coupling and current injury due to defective insulation. Another disadvantage of all these instruments is that they are single use and have to disposed which makes them economically unfit. Even the reusable device has a very high one-time cost. [5]

Discussion

Vessel sealing devices differ in design and the type of energy they use to produce thermal energy. In this literature review, we compared various energy devices in bipolar vessel sealing. The primary outcome was to pick the most suitable energy source to be deployed in a bipolar vessel sealer. We found that no single device is superior to other in all aspect, but it can also be concluded that the technology of using advanced bipolar has an upper hand in certain areas.

These devices have highest mean burst pressure for both small and large vessels and the seal failure rate is also low. They have the fastest sealing time when used with the appropriate generator which results in lesser operating time. The use of pulsatile current waveform allows cooling of tissue in between activation which reduces thermal damage to the tissue. Different jaw designs, for example extended jaw in Caiman, provides more flexibility to the surgeon to move the device and hold blood vessels with a secure grip. A feedback system, impedance or temperature controlled, keeps in check the amount of energy delivered to the tissue according to the tissue conditions. EnSeal Surg RX uses Nano polar thermostats installed in the jaws of the device to calculate the dosage of energy delivery to the tissue according to tissue temperature. [23] LigaSure has an impedance-controlled feedback mechanism which alters the current waveforms as per the change in tissue impedance. [26] As thermal energy is produced from electrical energy, the activation temperature at the jaws remain below 100°C. This makes advanced bipolar one of the devices with minimal thermal spread.

Ultrasonic devices also have high burst pressure, but sealing is relatively slower. The multifunctionality and adaptive tissue technology for feedback makes it one of the most efficient devices for vessel sealing. However, they also have a very high activation temperature that can cause burns and damage to nearby tissue. Hybrid device has the same disadvantage. One of the bigger disadvantages of energy devices other than advanced bipolar and ultrasound is that they do not employ any feedback mechanism and thus the process of coagulation entirely depends on the surgeon's judgment. Ferromagnetic devices offer separate cutting and sealing that means a greater number of devices in the operating room which might not be a favorable option for some surgeons. Plasma devices also allow cooling of tissue between activation, but they still have a significant amount of lateral thermal damage to the tissue. Diode laser technology is still in experimental phase and not being used for larger vessels along with the drawbacks of higher cost because of expensive setup of the instrument and slow jaw cooling.

This literature review is limited by the fact that the values considered for comparing these instruments have been taken from clinical trials performed by surgeons and there might be a biasing factor present depending on the surgeon's preference.

Conclusion

Every energy-based device has its advantages and drawbacks and there is no one way to choose the best among these instruments. The choice of device depends on device parameters and the type of surgery. If a surgeon wishes to choose a device with multifunctionality and a systematic feedback response to make the surgery easy, advanced bipolar devices have been considered superior than all other devices. This does not necessarily mean that other devices are not safe, reliable and efficient, it just indicates that advanced bipolar devices have a few better specifications. To make an informed decision and to prevent complications, it is very important to understand the mechanism, functions, possible failures and injuries caused by every device.

3. Chapter III: Methods

From the literature review, it is concluded that advanced bipolar energy will be used to design the add-on module for ESU to achieve power conversion from conventional bipolar electrosurgery to vessel sealing.

Three conventional ESUs and three advanced bipolar sealing systems were studied and compared theoretically. The information on these devices have been collected from literature, previous thesis report and user manual guides. Each device was selected to study their output waveform. All the voltages are mentioned in volts, power in watts and frequency in kilohertz (kHz). The technical details of these devices are elaborated in Chapter IV, Overview of devices. The information obtained from this has been used as the foundation to define the design requirements and the input and output waveforms for the circuit.

Problem analysis

Conventional ESUs have been widely used as the only generator unit for electrosurgery and electrocautery but they have several differences than a bipolar vessel sealing unit. Primarily, these devices do not have a feedback mechanism to control the energy delivery to the tissues or any alarm system as to indicate completion of the specific surgical process. The absence of this feature can cause severe damage to the tissue if the energy output level is too high or can result in incomplete tissue effect due to low energy. The bipolar configuration has a lower power setting which means longer coagulation times and sometimes tissue sticking on the handheld device. There are chances of higher stray current in such devices which can result in further injuries to the patient.

The new vessel sealing systems have an adaptive generator which is a different technology from conventional ESUs. They have computer-controlled feedback mechanism that changes the delivery of the energy according to the tissue condition. The conventional device has a continuous and same output irrespective of the tissue type and impedance whereas the adaptive generator regulates power delivery as the impedance of the tissue increases. They use pulsatile wave that allows cooling of the tissue and the instrument in-between bursts of energy and the power intensity of these bursts depend upon the type of tissue at the target site. Additionally, they provide with optimal compression mechanism to the tissue in contact with the instrument to seal blood vessels and other tissues.

Research Question

The study of two different types of generators used in electrosurgery led to the aim of this project. To find a way to use bipolar vessel sealing in low cost setting by converting the conventional ESU power into advanced bipolar power by only using low-cost components.

General objective: How to convert power output from electrosurgical generators to energy used by bipolar vessel sealers?

Sub questions:

- What components will be required to design the circuit of the add-on module?
- Which mode, monopolar (cut) or bipolar, should be used as the input port for the add-on module?
- Can an impedance-dependent feedback mechanism be incorporated?

Solution

As a solution, to surpass the disadvantages of a conventional ESU and to compete with the cost of a vessel sealing system, there can be a new concept for a vessel sealing generator. This new concept will be an add-on module for the conventional ESU. The ESU is present in most operating rooms for many types of surgery. This add-on unit will use the output of the electrical generator of the ESU and transform it so that it is suitable for bipolar vessel sealing. Figure 1 shows schematic view of the solution. The module will be designed according to the requirements of Low-and-Middle income countries. It will also incorporate a feedback system that will sense tissue impedance and indicate the completion of seal. This design will include only the basic circuit of power conversion along with a feedback system and not all the power and safety considerations that goes into building a real sized generator which is used in the operating room.

The focus has been kept on achieving the capability of producing power output matching the level of a high-end bipolar vessel sealing system, with some kind of indicator or alarm circuit using simple electronic components. Adaptive feedback has not been incorporated as it would require programming a component to implement adaptive technology. And, it is easier for a technician to change a simple electronic component rather than reprogram when a component malfunctions.

Figure 1: Schematic view of the solution

Procedure

The output waveform of a general ESU which is about 160V, 350kHz of power supply is fed as the input to the add-on module. The output of the add-on module is based on a LigaSure vessel sealing system which has a frequency of about 480kHz with voltage ranging from 200-240V and power between 100-150W depending upon the intensity level selected. [31][E]

The signal from the ESU is an AC source which will be converted to a DC source with the help of a transformer and a full wave rectifier. This DC voltage will be used to power RF oscillator, signal modulator and trigger circuit in the add-on module to get the desired output feasible for bipolar vessel sealing. For feedback, a trigger circuit is used. The circuit has a potentiometer attached to it which, for simulation purposes, acts as the impedance of the target tissue. Once the process is complete and a target impedance value is reached, the trigger circuit gives an output which turns ON an LED and a buzzer to indicate completion and signal the user to turn off the power supply.

In order to keep the circuit design as uncomplicated as possible, the components used are simple electrical components that are easily available and replaceable. Therefore, for the time being, microcontrollers have not been implemented in the circuit for tissue feedback-controlled delivery of power. The circuit does not automatically cut off the power supply after completion of seal either. It has to be carried out manually by the user.

The circuit of the module is designed in the LTSpice software. LTSpice® is a high-performance SPICE simulation software, schematic capture and waveform viewer with enhancements and models for easing the simulation of analog circuits. [G]

The simulations are also recorded on the same software to verify the results of the circuit.

Detailed description and working of the module with a block and circuit diagram are discussed in Chapter VI, Design.

4. Chapter IV: Overview of current devices

Current electrosurgical generators

The relationship between an electrical generator and a patient can be depicted in a form of a simple circuit which includes a power source (Electrosurgical Unit), a body of resistance (patient) and wires connecting the two. See Figure 1. [32] As the current is delivered, it produces heat in the tissue.

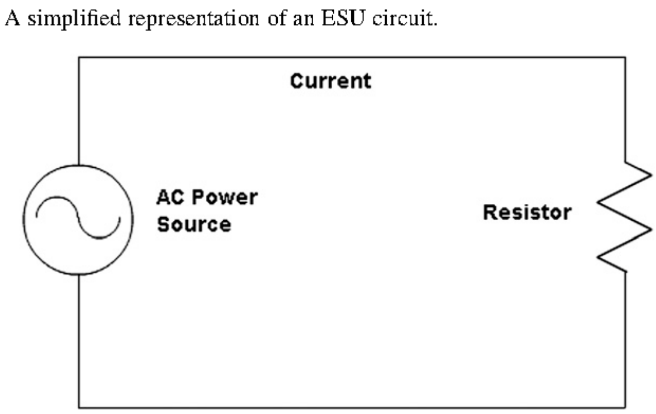


Figure 1: Representation of ESU circuit

The electrical energy from the generator is applied to the patient's body with help of electrodes, an active electrode and a return electrode. The amount of energy applied varies according to the power level intensity and the type of electrosurgical unit used. The power output by the generator is measured in terms of wattage and the energy output is defined as Joule energy. The input to the ESU is an AC source which has a frequency of 50-60 Hz. If the same level of frequency is applied to a tissue, it can cause muscle spasms and body movement during the surgery. It can also interfere with the conductivity of heart muscles causing heart attack and even death. In an article by O'Connor *et al*, it has been proven that higher frequencies in the range of a few tens or thousands of kHz can pass through a human body without causing pain or muscle spasms. [33]

Electrosurgical Units nowadays operate at frequencies under radio-frequency waves, ranging from 200kHz to 5MHz, in order to obtain optimal tissue effect. The input of 50 Hz AC wave is converted into a DC signal and then back to AC signal with a much higher frequency with the help of an oscillator. [32] They have different modes of operation to perform the functions of cut and coagulation and every function requires a different waveform depending upon the tissue effect to be achieved.

There are different types of electrosurgical generators available in the market. Conventional generators with monopolar and bipolar configurations, bipolar vessel sealing systems and units that combine both.

Conventional electrosurgical generators

All types of electrosurgery is, technically, bipolar as they require two types of electrodes, an active electrode to deliver energy and a return electrode to complete the circuit and return the current back to the ESU. Conventional devices have two modes of configuration: monopolar and bipolar. Monopolar electrosurgery requires an active electrode at the site of surgery and a return electrode which is placed on the patient somewhere far from the surgical site. This mode provides various settings on the ESU in terms of adjustment in the electrosurgical waveforms.

The pure cut mode, it is a sinusoidal waveform where a high current/low voltage output is delivered 100% of the activated time. It quickly increases the temperature of the tissue for a perfect incision and causes the least amount of charring or damage. The coagulation mode, it is also a sinusoidal waveform but current is delivered only 6% of the activated time. To compensate for the lack of activation time, it has a high voltage/low current output (2000-5000 Vpeak). [32]

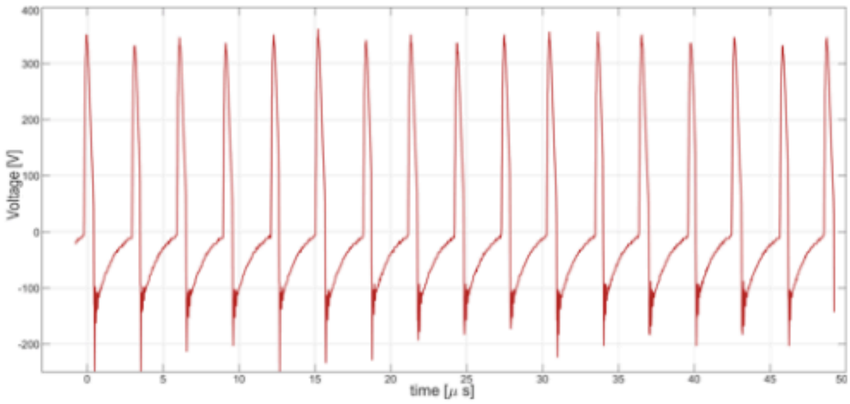
In Bipolar electrosurgery both the electrodes are at the surgical site and the current does not have to pass through the patient's body to complete the circuit. It has one mode of operation which is similar to the pure cut mode waveform with a high current/low voltage output and 100% activation time. [32] [7] Some ESUs also have a blend mode in which the activation time or the duty cycle can be varied between 30%-80%.

In a graduation thesis report by Felix Cranz (2018), [31], department of Mechanical Engineering, TU Delft, three electrosurgical units were experimented on in order to determine critical design requirements for an electrosurgical unit. The ESUs used were ERBE ICC 300 and ValleyLab Force FX which are considered to be high-end devices due to their popular use in high income countries and RDE Electrocut 100 which is regarded as low-end due to its low price and simple design. Table 1 shows some characteristics noted from all these devices are as follows.

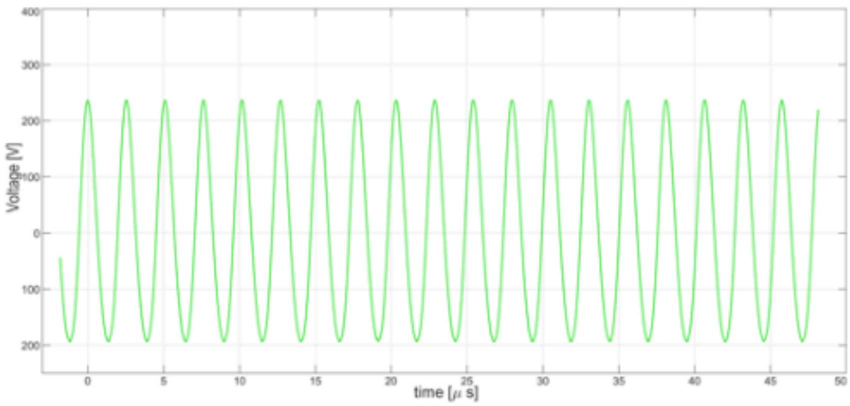
Electrosurgical Unit	**RDE Electrocut 100**	**Valleylab Force Fxc**	**ERBE ICC 300**
Picture			
Device Class	Low-end	High-end	High-end
Estimated Price	>€600*	>€15 000**	>€15 000**
Power Range Cut	0 − 70 W	0 − 120 W	0 − 120 W
Power Range Coagulation	0 − 110 W	0 − 300 W	0 − 300 W
Mass	2.7 kg	8.2 kg	10.2 kg
Dimensions	10x25x18 cm	12.5x36x46 cm	15x41x37 cm
Bipolar	✓	✓	✓
Monopolar	✓	✓	✓
Ports	1	2	2
Operating Temperature	5 − 35°C	10 − 40°C	10 − 40°C
Operating Humidity	20 − 80 %	30 − 75 %	30 − 75 %
REM plate	single	split	single/split

Table 1: Characteristics of conventional ESUs. [31]

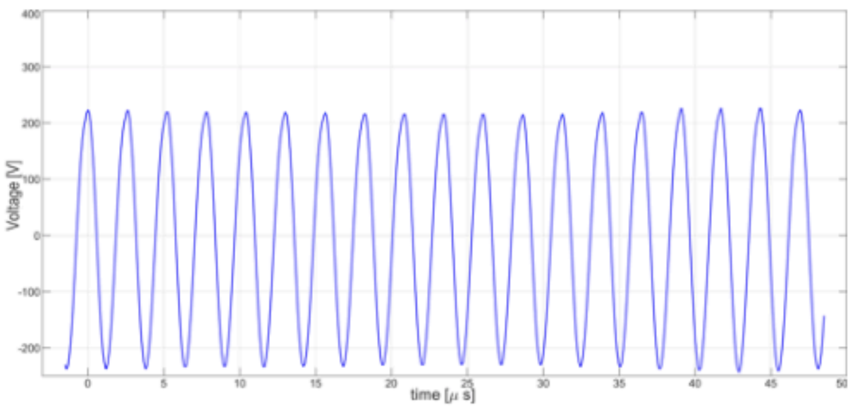
The output of cut mode waveforms at power of 110W and a load of 200ohms were observed for monopolar surgery. As mentioned before that bipolar mode has the same output waveform as that of the cut mode, it is safe to assume that these waveforms can be considered as the output for bipolar mode as well. The figure below, Figure 2, shows output waveforms of cut mode of RDE, Valleylab and ERBE units.



(a) *RDE Electrocut 100* cut mode waveform f = 318 kHz



(b) *Valleylab Force FXc* cut mode waveform f = 391 kHz



(c) *ERBE ICC 300* cut mode waveform f = 379 kHz

Figure 2: Output waveforms of cut mode for three different ESUs. [31]

Both high end devices, ERBE and ValleyLab, show a perfect sinusoidal waveform whereas RDE at high power with a load has a less smooth sinusoid. This variation in waveform can also be one of the reasons why RDE is a low-end device. Another observation is all the three devices have an output frequency in the range of 300-400 kHz which is well within the optimum frequency range for electrosurgery (200kHz-3.3MHz). [7]

Advanced bipolar vessel sealing systems

Conventional ESUs have been updated in technology with the integration of computer-controlled feedback algorithms into electrosurgical generators and are being used to create vessel seals for vessels up to 7mm in diameter. This algorithm allows the electrosurgical units to adjust the energy delivered by varying the output voltage and current according to the tissue impedance or temperature or both. The ESUs deliver this modified energy in combination with optimal pressure, on the tissue in contact with the instrument, to ensure a proper seal with minimum thermal damage.

The output of the ESUs are either continuous or highly pulsatile (to allow cooling of the tissue and the instrument in between pulses). The devices either gives out an alarm tone to indicate completion of the sealing process or stops the power supply automatically once the process is complete. Some of the most commonly used bipolar vessel sealing systems are:

LigaSure Vessel Sealing Generator[E]

The LigaSure generator is capable for providing power for both vessel sealing and bipolar surgery. It has an output waveform of 472 ± 5 kHz sinusoid with 100% duty cycle for bipolar and 472 ± 5 kHz pulsed sinusoid for sealing. The maximum power output is 95W and 150W and the maximum voltage is 335 Vpp and 575 Vpp for bipolar and seal respectively.

Figure 3 shows the relationship between the output power and the tissue impedance during seal cycle.

Figure 4 shows the relationship between the output voltage and the intensity setting during seal cycle.

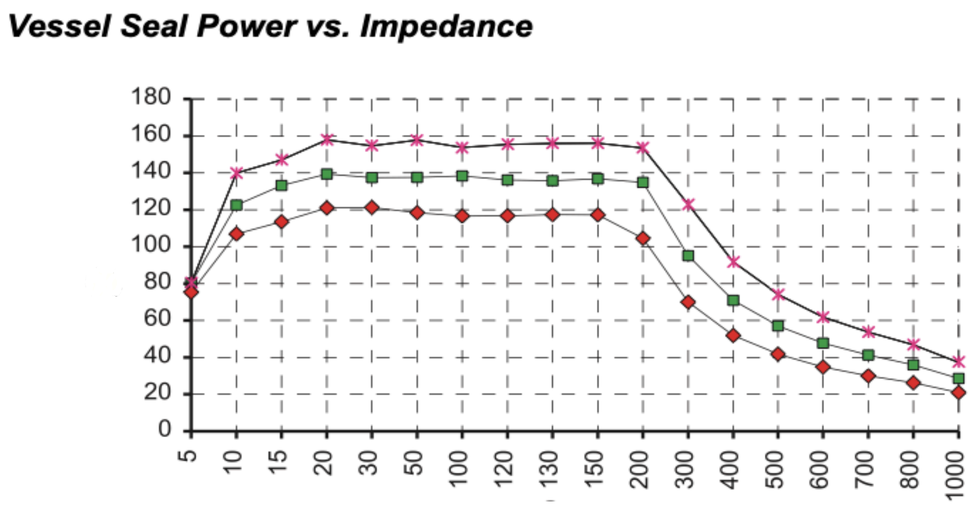


Figure 3: Relationship between the output power and the tissue impedance during seal cycle. [E]

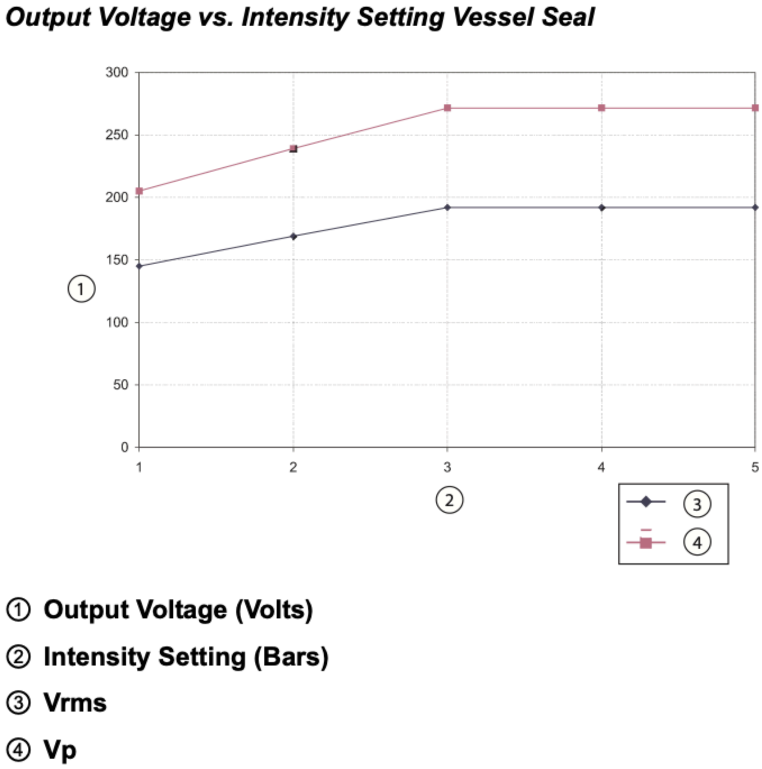


Figure 4: Relationship between the output voltage and the intensity setting during seal cycle. [E]

Ethicon Gen 11 Generator[F]

This device operates with a frequency range of 300-490 kHz. The maximum output power is 135 watts with a rated load of 15 ohms and maximum output voltage of 100 VAC RMS. The advantage of this unit is that it can be used to operate both Harmonic Ultrasound and EnSeal Advanced Bipolar devices.

Figure 5: Ethicon Gen 11 generator [F]

GYRUS ACMI- PlamsaKinetic SuperPulse Generator[B]

This unit is capable of identifying the type of instrument connected to the ESU and optimize the performance accordingly. It can be used for coagulation and cutting of tissue for open, endoscopic and laparoscopic surgery procedures. It also has an option of selecting the type of tissue, with high, medium or low impedance, to have the appropriate power intensity of the waveform. The RF output is a variable amplitude sinusoidal wave with frequency between 320-450 kHz. The maximum output power ranges between 90-120 W and the maximum voltage ranges between 100-480 V peak depending upon the mode and connected instrument.

Figure 6 shows the relationship between the RF output and the tissue impedance. Full Power Curve.

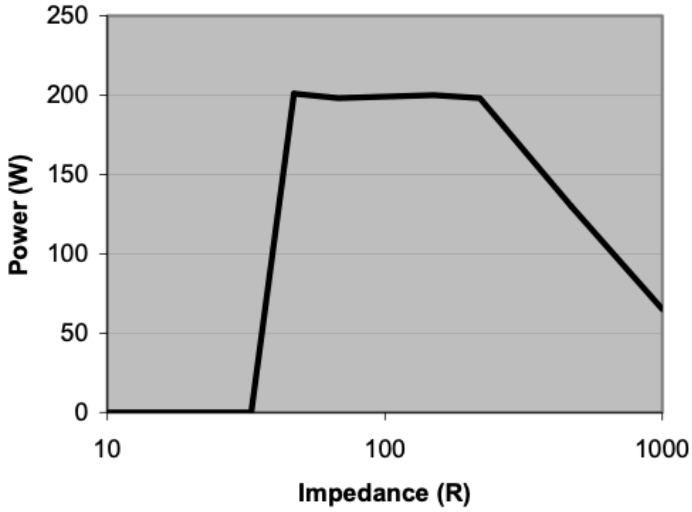


Figure 6: relationship between the RF output and the tissue impedance. Full Power Curve. [B]

Conclusion

From the information mentioned above, it can be noted that the output of a conventional ESU ranges in the frequency of 300-400kHz whereas the output frequency of vessel sealing system ranges between 300-500kHz. The maximum power wattage for a conventional ESU for cut mode is about 120W and for coagulation mode is about 300W. Since cut mode uses a high current/low voltage waveform it requires lower power than coagulation which uses high voltage/low current waveform.

The bipolar vessel sealing systems have a high-power output ranging between 90-150W due to its high current/low voltage. The graphs (Figure 3 & 6) displaying the relationship between the output power and tissue impedance shows that as energy is delivered the impedance of the tissue increases. After a certain value of impedance is reached, the applied energy starts to decrease and is finally terminated after the seal cycle is complete. They also indicate that the range of values considered for tissue impedance is 0-1000 ohms. [B][E]

This information will be used as the basis for the design module in the upcoming chapters.

Note: All the ESUs mentioned (ERBE ICC 300, ValleyLab Force FX, RDE Electrocut 100, LigaSure Vessel Sealing Generator, Ethicon Gen 11 Generator, GYRUS ACMI- PlamsaKinetic SuperPulse Generator) have an input of 100-240 V, 50/60Hz power supply.

5. Chapter V: List of requirements

General design considerations

In order to design an add-on module for an ESU based on a Low-and-Middle Income country setting, it is important to set a list of requirements. There are several articles that provide with design specifications for an ESU or a vessel sealing generator. The user-guide manual for various generators provide detailed technical specifications including power, operating temperatures etc. However, this circuit design only takes into account the output power specifications as the output of the module is expected to match the output of the sealing device.

The add-on module should have operating parameters of ambient room temperature and atmospheric pressure. Ideally, the module should draw power from the ESU but if there is a need for an external power supply, it should be able to draw power from the wall i.e. 120V/240V 50-60Hz supply. The module should not give out any output power if wires are missing. It is essential to take the cost of manufacturing of the module into account as this device is primarily targeted for Low-and-Middle Income setting which also indicates that it is essential to have easily available, replaceable and inexpensive components in the circuit so that the maintenance and repair of the device is easy.

Design requirements for the circuit

The circuit of the add-on module have the following design specifications:

1. The output power of the module should match the output energy delivery by a bipolar vessel sealing system which is 100-150W with frequency of 350-500kHz sinusoid.
2. The user should be able to vary the delivery of output power with intensities of low, medium and high.
3. The input to the circuit should be the output taken from a conventional ESU which is 150-160V with frequency of 300-450kHz sinusoid.
4. The duty cycle of the generator should not exceed more than 25%.
5. A potentiometer is used to mimic tissue impedance. When the value of potentiometer crosses 1000ohms, feedback is given to the user indicating completion of seal.
6. It will have an LED indictor and a buzzer alarm system to indicate completion of the seal.
7. The components used should be low-cost and easily available.
8. Ideally, the power supply would be given to a control board or a microcontroller which would be able to set desired output frequencies, voltage and power on the add-on module.
9. Ideally, the power supply must be cutoff automatically after the seal is complete.
10. Ideally, the feedback system should also be able to vary the power delivered to the tissue according to target tissue conditions.

This project does not cover the ideal requirements and is aimed at achieving the first 7 requirements. The ideal requirements are wishes which will be covered in discussion and future work in Chapter V.

6. Chapter VI: Design

6.1 Design

Common elements of any electrosurgical generator are power supply unit, frequency generator, signal modulator and an amplifier.[34] The design of the add-on module is based on the block diagram of a conventional ESU. It consists of a transformer, an RF oscillator, a signal modulator and a trigger circuit. The components required to build the circuit include resistors, capacitors, diodes, operational amplifiers, potentiometer, LED, buzzer, transformer and a signal modulator which are all easily available and replaceable parts.

Block diagram

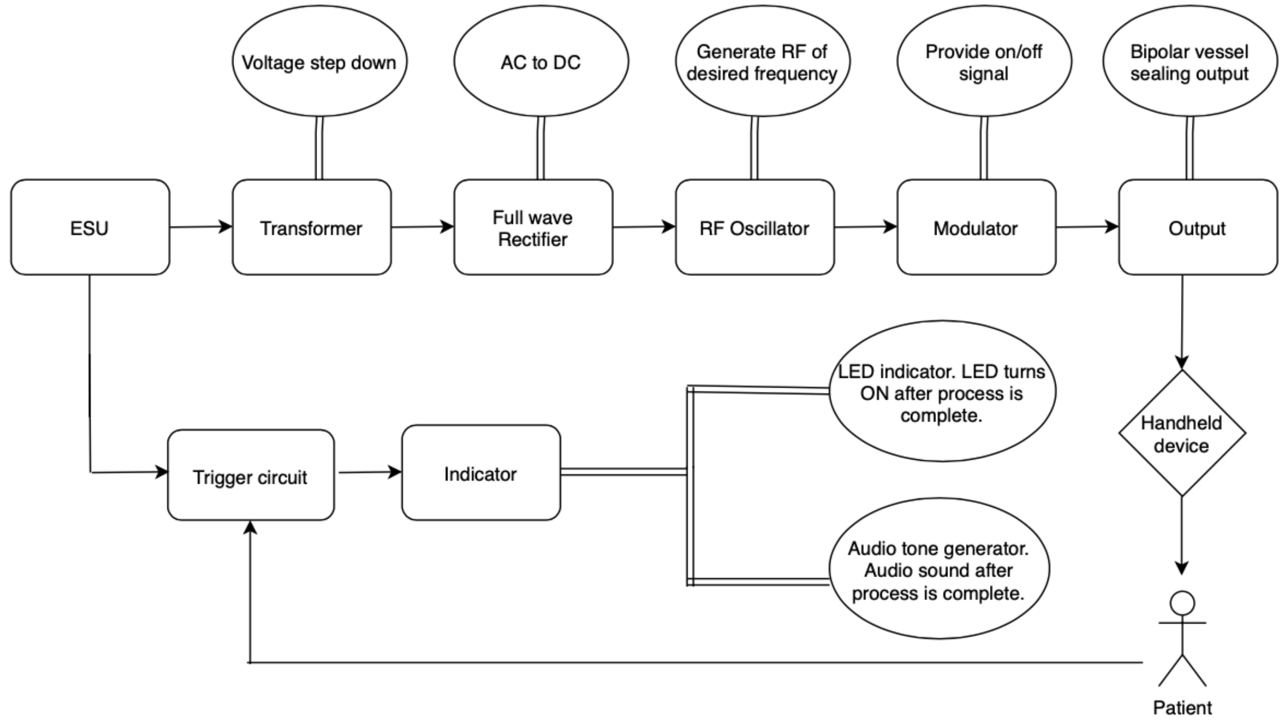


Figure 1: Block diagram

Figure 1 shows the block diagram of the add-on module. The power supply is taken from the conventional ESU which is around 150-160V, 350-450kHz ac source. Other components used are as follows:

Transformer

The transformer used in this circuit is a step-down transformer where the input voltage of 160V is converted into 15V to power the RF oscillator, 18V to power the signal modulator and 10V to power the trigger circuit. Since the step-down voltages are still AC, a full wave rectifier will be used in series to convert AC voltage to DC voltage.

A transformer is a passive device which is used to convert electric power in one circuit to electric power of the same frequency in another circuit. [35] It has two sets of windings, primary and secondary. See Figure 2. The input voltage is connected to the primary winding and the output voltage is connected to the secondary winding. The number of turns, in both primary and secondary winding, determines the amount of change from input voltage to output voltage. Therefore, the turns ratio is a very important aspect of a transformer. The relation between turns ratio and primary voltage (Vprimary) and secondary voltage (Vsecondary) is given by equation 1.

$$Turns\ ratio = \frac{Vprimary}{Vsecondary} \qquad \text{-Equation (1)}$$

The relation between the inductance of the two coils and turns ratio is given by equation 2.

$$(Turns\ ratio)^2 = \frac{Primaryinductance}{Secondaryinductance} \qquad \text{-Equation (2)}$$

From Equations (1) & (2) it can be noted that

$$\frac{Primaryinductance}{Secondaryinductance} = (\frac{Vprimary}{Vsecondary})^2$$

The input voltage is 160V and the output voltages are +15V , +18V and +10V for RF oscillator, modulator and trigger circuit respectively. The primary inductance is chosen to be 400µH. For this, the secondary inductances would be

$$\frac{400\mu H}{Secondaryinductance} = (\frac{160}{15})^2$$

Secondary inductance to get 15V output is approximately 3.5µH.

$$\frac{400\mu H}{Secondaryinductance} = (\frac{160}{18})^2$$

Secondary inductance to get 18V output is approximately 5µH.

$$\frac{400\mu H}{Secondaryinductance} = (\frac{160}{10})^2$$

Secondary inductance to get 10V output is approximately 1.7µH.

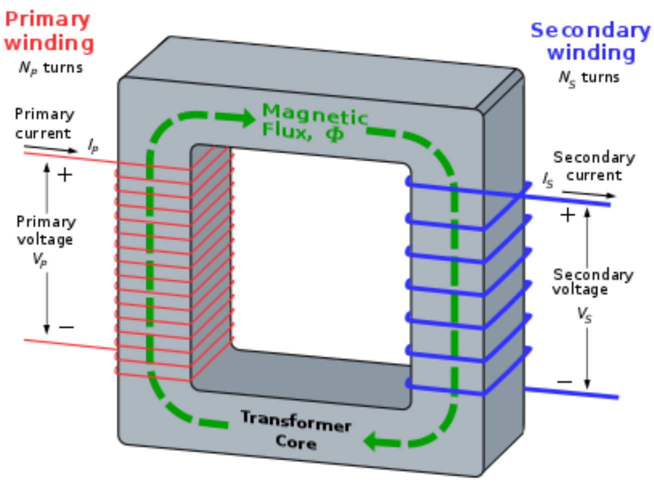


Figure 2: Transformer [36]

Full wave rectifier

A full wave rectifier is used to convert AC waveform into DC as it uses both halves of the input AC. There are 4 diodes which are connected in bridge arrangement. The diode bridge is used along with the transformer to get a DC voltage of +15V for the RF oscillator, +18V for the modulator and +10V for the trigger circuit . The negative DC voltage of -15V, for the RF oscillator, is obtained by changing the positions of all the diodes in the opposite direction.

During the first half of the input AC, diodes D1 and D3 are forward biased allowing the flow of current through the load whereas diode D2 and D4 are reversed biased which do not allow flow of current. Figure 3 [37] shows the flow of current during the first half cycle with green arrows indicating flowing current and red arrows showing returning current.

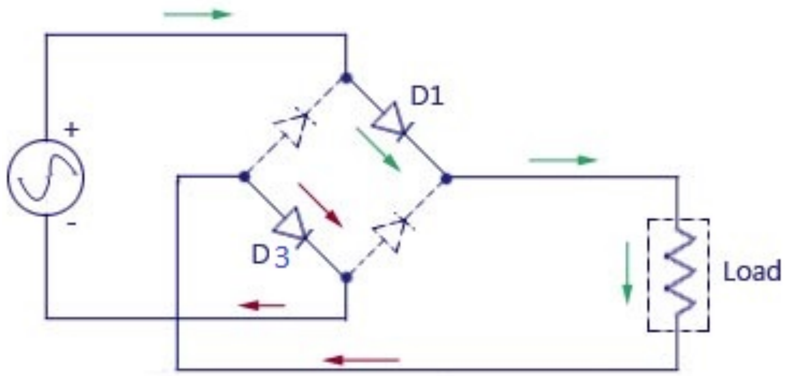


Figure 3: Active diodes in first half cycle of AC source [37]

Similarly, during the second half of the input AC, diodes D2 and D4 are forward biased allowing the flow of current through the load whereas diode D1 and D3 are reversed biased which do not allow flow of current. Figure 4 [37] shows the flow of current during the second half cycle with green arrows indicating flowing current and red arrows showing returning current.

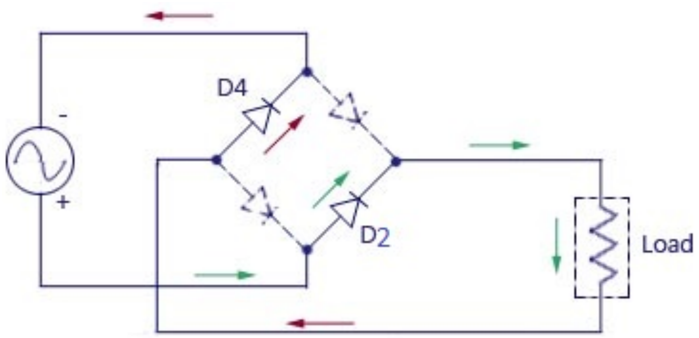


Figure 4: Active diodes in second half cycle of AC source [37]

During both the cycles, the current flows through the load and a DC output is obtained.

RF Oscillator

The type of RF oscillator used in the circuit is a wein bridge oscillator, Figure 5 [38]. A wein bridge oscillator is a type of oscillator which is capable of producing sine wave with a large range of frequencies. It consists of 4 resistors and 2 capacitors. The frequency of the sine wave depends on the value of R and C selected. The relation between frequency and R and C values is given by equation 3. Rf and Rs define the gain of the amplifier. The gain can be calculated by equation 4. The amplifier requires a power supply of DC voltage.

$$Frequency = \frac{1}{2\pi RC} \quad \text{-Equation (3)}$$

$$Gain = 1 + \frac{Rs}{Rf} \quad \text{-Equation (4)}$$

The required operating frequency is 480kHz. From equation (3), to get a frequency of 480kHz, and selected value of resistance R as 1000 ohms, the value of capacitor C is 0.33nF.

$$480{,}000 = \frac{1}{2\Pi(1000)C}$$

From equation (4),

$$Gain = 1 + \frac{2000}{500}$$

And the gain of the amplifier is 5.

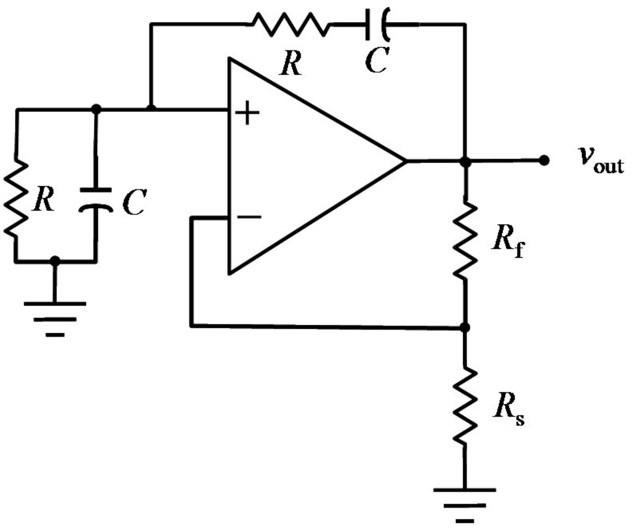


Figure 5: Wein Bridge Oscillator [38]

Modulator

A modulator is an electronic device which modulates the properties of an input signal, called the carrier signal, with help of another signal, called modulating signal. In this circuit, the carrier signal is the sine wave generated by the RF oscillator and the modulating signal is a square wave in form of pulses to convert periodic sine wave into a pulsed sine wave with a duty cycle of about 25%. The modulator generates a square wave signal with a frequency of 50Hz. The on time for the signal is 5ms and the total time period is 20ms. This makes the duty cycle of the pulsed sine wave to be 25%.

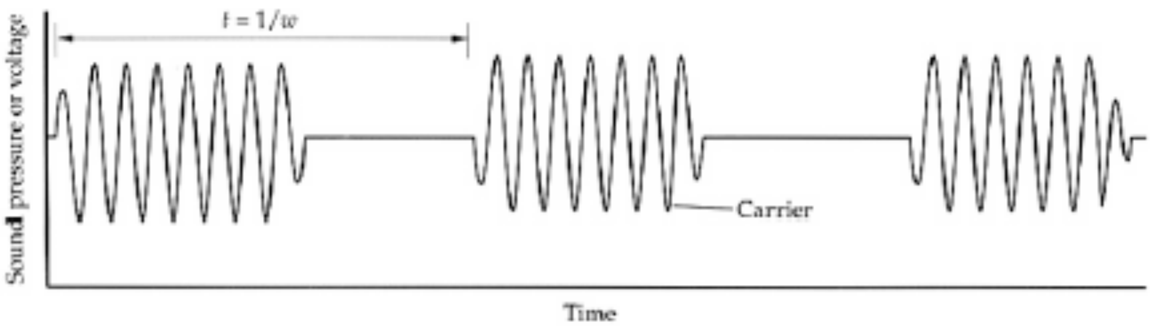


Figure 6: Pulsed sine wave [39]

The figure shows time domain image of a pulsed sine wave. The carrier signal is a pure sine wave of frequency f. The modulating signal is a square wave with frequency w.

Trigger Circuit

A voltage divider circuit is made with a 10k ohms potentiometer and 1k ohm resistor. The 10k ohms potentiometer acts as the changing impedance of the tissue which ranges from about 1-1000 ohms. The relation between input voltage and the output voltage of the voltage divider with the two resistors is given by equation 5.

$$Vout\ (voltage\ divider) = Vin\frac{R2}{R1+R2} \qquad \text{-Equation (5)}$$

Where R2 is the potentiometer and R1 is chosen constant value.

The output of this voltage divider is given to an Operational Amplifier. This op-amp functions as a comparator. It compares the output voltage of the voltage divider with a reference voltage. The output voltage of the voltage divider is connected to the non-inverting terminal and the reference voltage is connected to the inverting terminal of the op-amp. When Vout(voltage divider) is less than Vref, the output of the amplifier is 0 and when Vout(voltage divider) is greater than Vref, the output of the amplifier is Vdc.

$$Vout(voltage\ divider) < Vref; Vout(Opamp) = 0$$

$$Vout(voltage\ divider) > Vref; Vout(Opamp) = Vdc$$

This output is connected to an LED and a buzzer. When the potentiometer reaches the value of 1000ohms, which is expected to be the impedance of the tissue when sealing is complete, the output of the trigger circuit goes high. This turns the LED ON and the buzzer makes a sound, signaling the user of process completion.

For example, if the resistance of the potentiometer is 20ohms, from equation (5),

$$Vout\ (voltage\ divider) = Vin\frac{20}{1000+20}$$

Vout is about 0.2V which is lesser than Vref of 5V and the output of the op-amp is 0.

Another example, if the resistance of the potentiometer is 850ohms, from equation (5),

$$Vout\ (voltage\ divider) = Vin\frac{850}{1000+850}$$

Vout is about 4.59V which is still less than Vref of 5V and the output of the op-amp is 0.

When the value of the potentiometer is more than 1000 ohms, the output of voltage divider is higher than the reference voltage. For example, if the resistance of the potentiometer is 1150 ohms, from equation (5),

$$Vout\ (voltage\ divider) = Vin\frac{1150}{1000+1150}$$

Vout is about 5.35V which is more than Vref of 5V and the output of the op-amp is high. This will power the LED and the buzzer and will give an indication to the user to cut off power supply.

The dc voltages used in the circuit below are all taken from the transformer power supply.

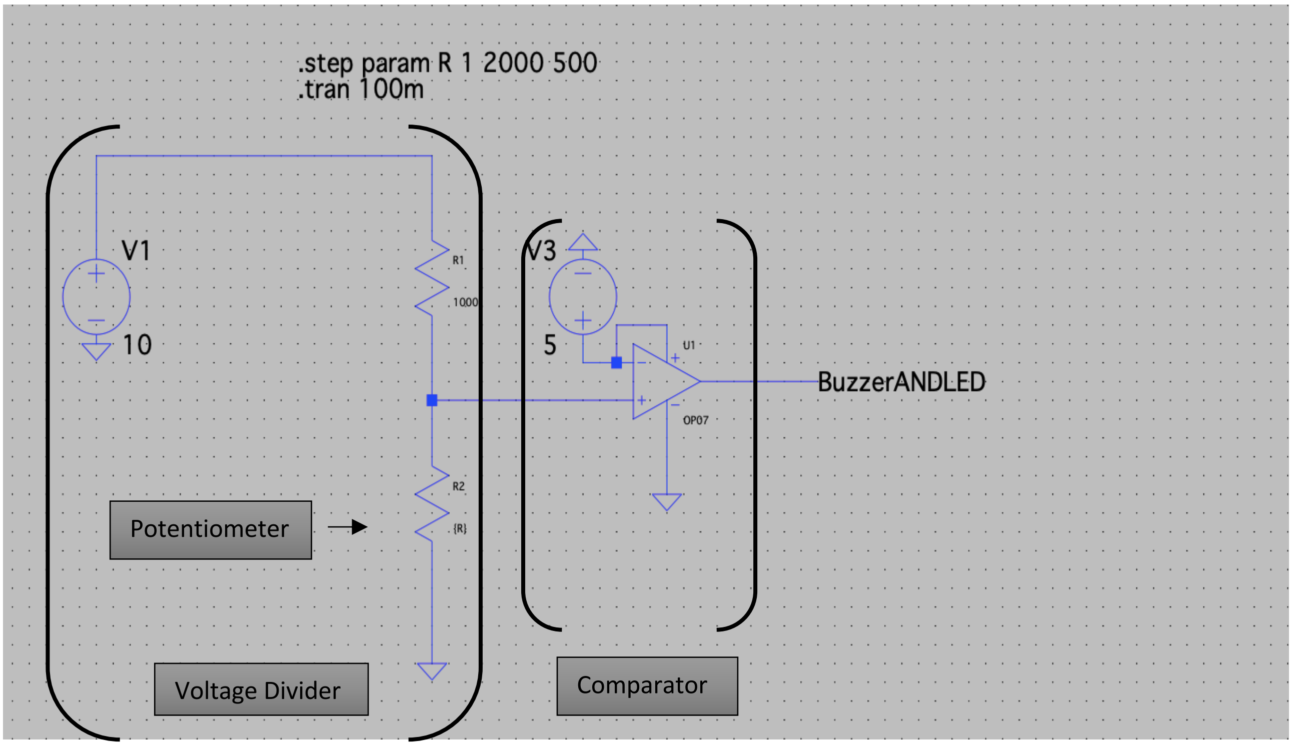


Figure 7: Trigger circuit

Circuit Diagram

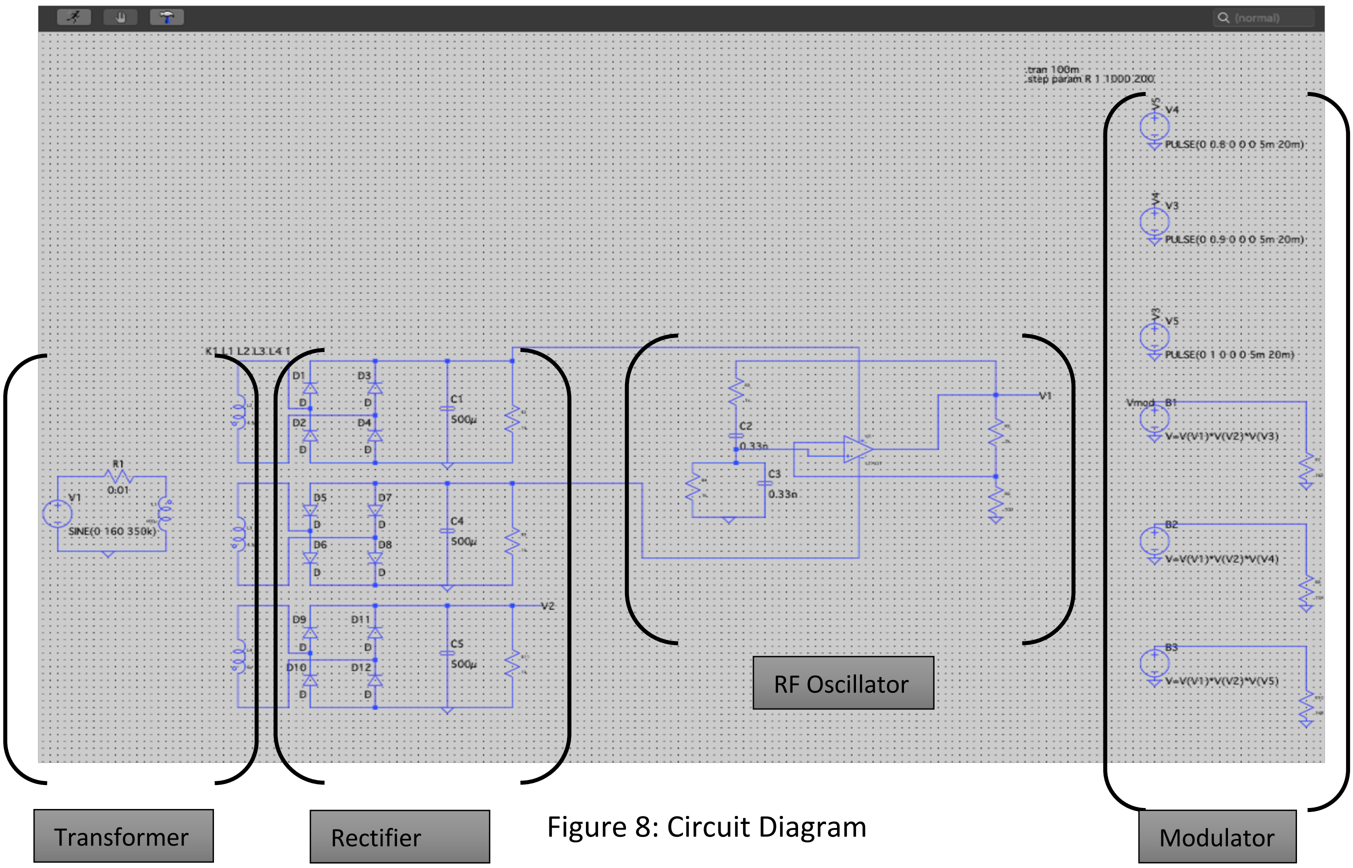


Figure 8: Circuit Diagram

7. Chapter VII: Results

Simulation Analysis

As mentioned in Chapter IV, Overview of current devices, a LigaSure vessel sealing system [E] has five varying intensities of power level in seal mode. Intensity level 1 has a power output of about 120W with peak voltage of 200V, intensity level 2 has a power output of about 140W with peak voltage of 220V and intensity levels 3, 4 and 5 have a power output of about 160W with peak voltage of 240V. The operating frequency of the output waveform is 472±5 kHz pulsed sinusoid. This seal mode power is applied to a tissue which in turn increases the impedance of the tissue. The tissue impedance is observed up to a value of 1000 Ohms after which the power supply is cut off, indicating that a seal has been created. It also has an audio tone generator which gives out two short beeps when vessel sealing cycle is complete.

The add-on module has 3 varying intensities of power supply. The graphs show the output waveform of the module. The first graph, Figure 1, shows high intensity power level with a voltage of 240V (peak voltage Vp) and power of 150W. The second graph, Figure 2, shows medium intensity power level with a voltage of 220V (peak voltage Vp) and power of 120W. And the third graph, Figure 3, shows low intensity power level with a voltage of 200V (peak voltage Vp) and power of 100W. The operating frequency is 480kHz pulsed sinusoid. It also has a trigger circuit which turns ON a buzzer (audio indication) and an LED (visual indication) when the simulated tissue impedance (potentiometer) reaches a value of 1000ohms. The relationship between output voltage of the trigger circuit and resistance of potentiometer can be seen in Figure 4. After the potentiometer crosses the value of 1000ohms, output at the opamp can be seen.

The add-on module shows similar output characteristics as of a LigaSure vessel sealing system. However, it is not an algorithm-controlled device and the disconnection of the power supply has to be done manually after the buzzer sound. The module does not sense the tissue impedance in real time and no computer-controlled algorithm is applied to alter the power delivery according to the tissue conditions.

High Intensity; Output Waveform: 250V, 480kHz power supply with duty cycle 25%. Output Power: 150W.

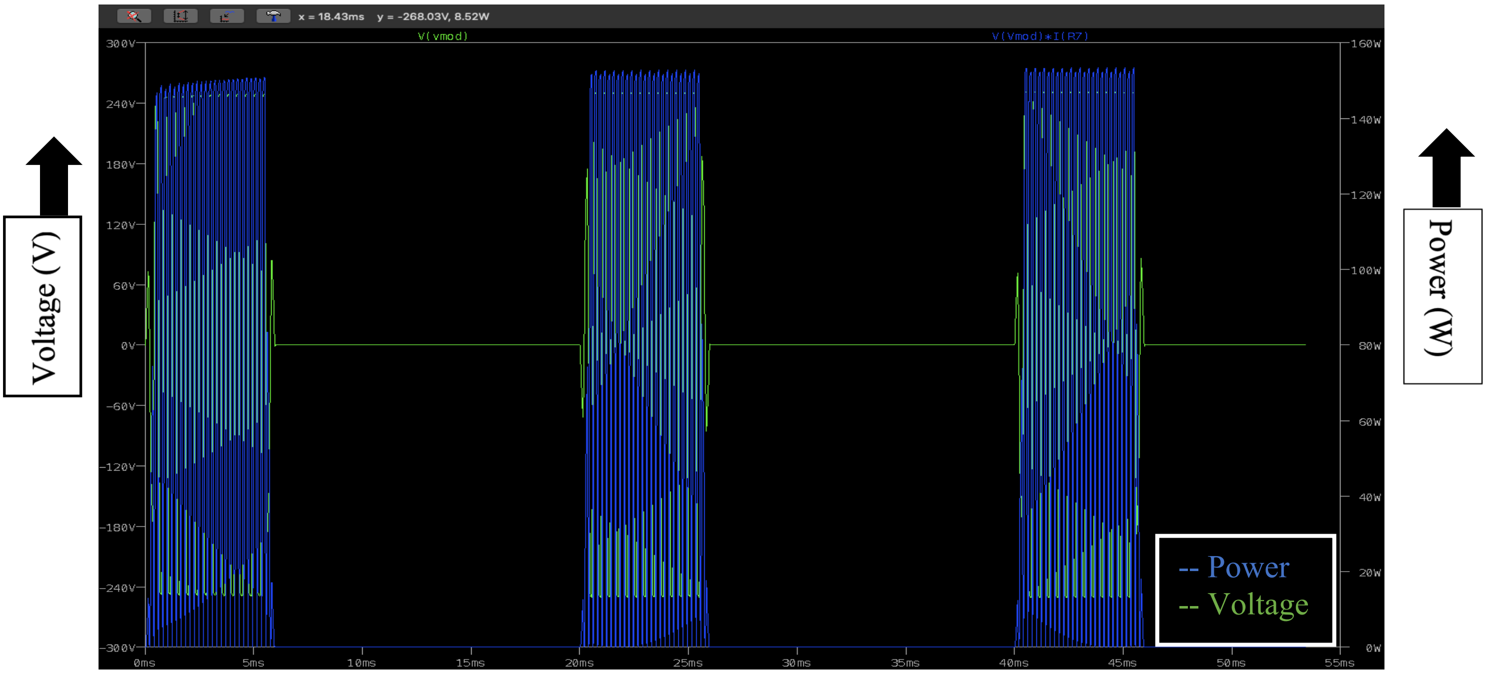


Figure 1: High intensity output

Medium Intensity; Output Waveform: 220V, 480kHz power supply with duty cycle 25%. Output Power: 120W.

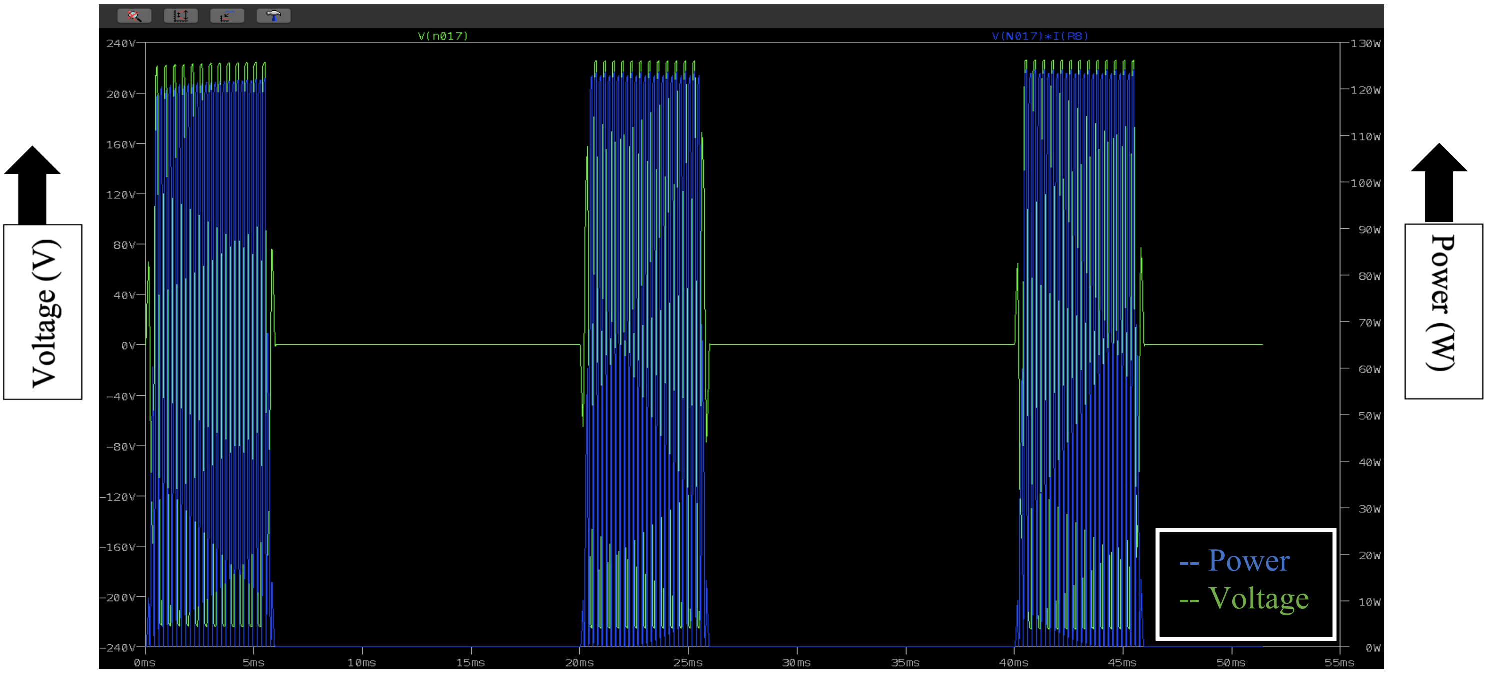


Figure 2: Medium intensity output

Output Waveform: 200V, 470kHz power supply with duty cycle 25%. Output Power: 100W.

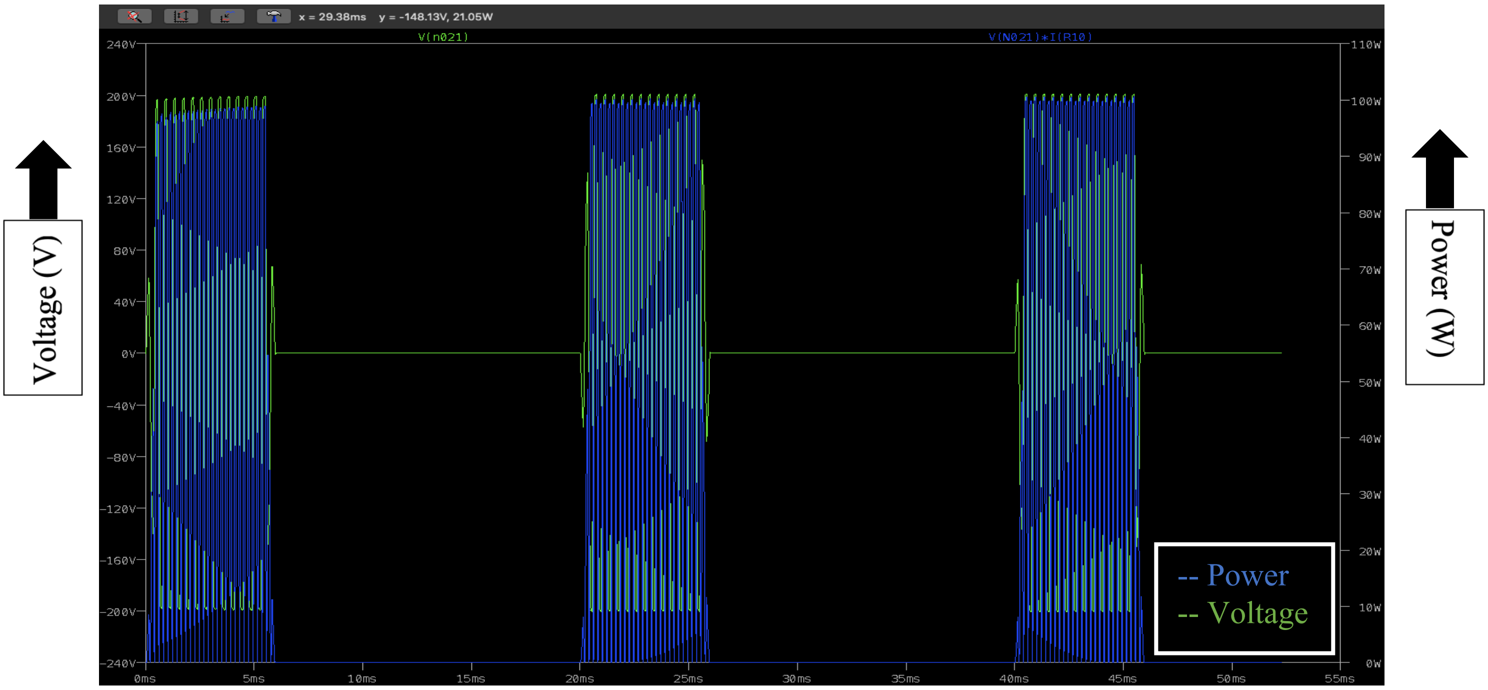


Figure 3: Low intensity output

Trigger Circuit Output voltage versus resistance graph

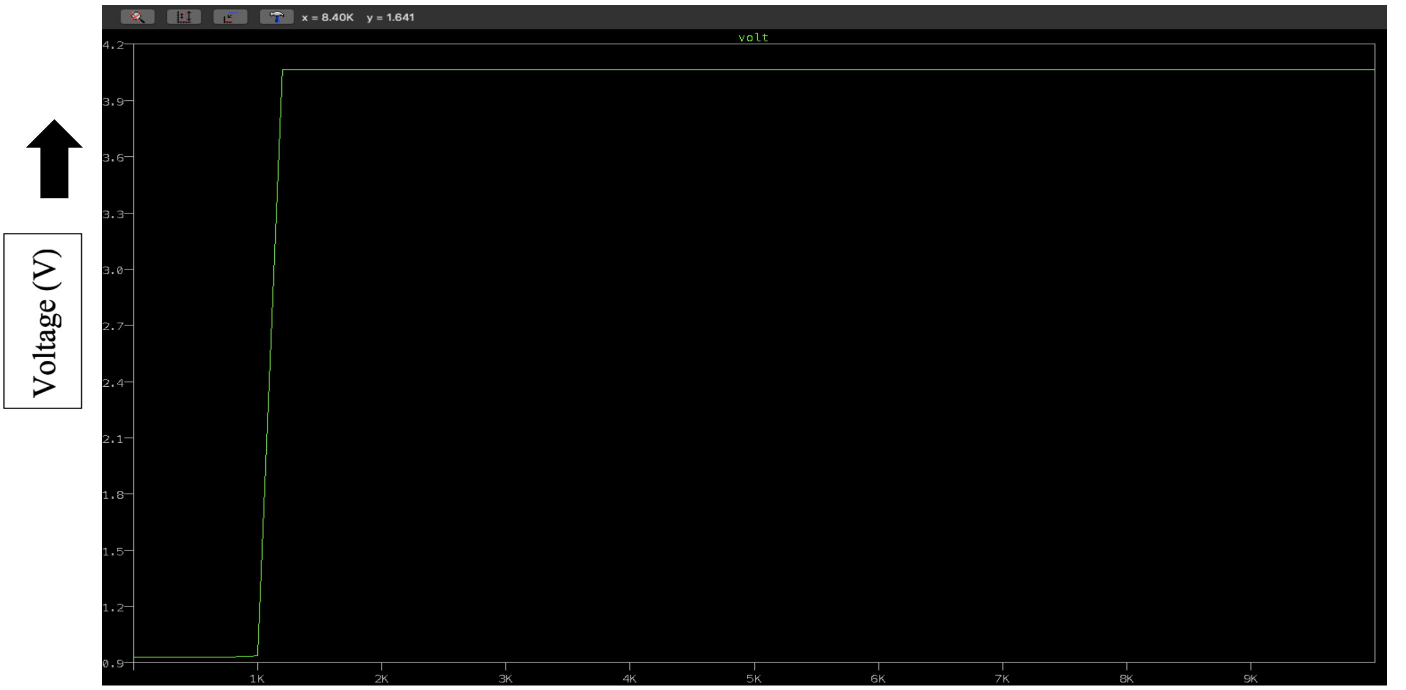


Figure 4: Trigger circuit output

8. Chapter VIII: Discussion and Conclusion

The aim of this project was to find a way to bridge the gap between the conventional ESUs and advanced bipolar vessel sealing devices for Low-and-Middle Income environment. To do so, an add-on module is designed which can be used along with a conventional ESU that will produce the output waveforms similar to the bipolar vessel sealing systems. This add-on module uses a conventional ESU as the power supply for its own RF oscillator and signal modulator circuit and successfully delivers the expected power output. An average ESU is able to produce 350-400kHz of high frequency alternating current of about 100W power while being used in cut or bipolar mode whereas, if used along with this add-on module, it should be able to produce 480kHz high frequency pulsatile alternating current with a duty cycle of 25% and a power output range of 100-150W. This power output is sufficient enough for efficiently sealing blood vessels as is evident by LigaSure vessel sealing system [E] which has a similar output and on which the outcome of the module is based.

A list of design requirements is listed in Chapter V. These requirements have been formulated based on the information collected from the manuals specifying technical details[A-F] and articles with experimental studies on all the ESU generators. On simulating the circuit in the software, it can be seen that the model successfully meets all the design requirements.

As mentioned in the introduction, the article by Oosting et al. [4] indicates some LMIC requirements and this add-on module checks quite a few of them. For example, it is a pure electronic circuit made of components which are easily available and replaceable. All the components including the diodes, op-amps, resistors and capacitors are inexpensive and can be replaced easily in case of a breakdown. The design of the circuit is also very simple and thus, the maintenance of the module should be very easy.

This study is limited due to certain factors. The circuit of the module has been designed and simulated on a software. It has not been physically built and experimented with and therefore, the results might vary in an actual situation. No ESU or vessel sealing system has been used for physical experimentations nor have real blood vessels been used to test the output of the add-on module. Since, it is only a circuit design the safety regulations by ISO to build an actual ESU, the one which has been approved to be used in a surgery, are not being taken into consideration.

Summary: This project has effectively developed a module to convert the power output of a conventional ESU to power output of a bipolar vessel sealing system with an indicator alarm system while using easily accessible, replaceable and inexpensive components in its circuit. It has achieved a possible solution that allows the use of vessel sealing with very low cost. There is still a lot of future research required to make this module highly efficient and put into practice for clinical applications.

9. Chapter IX: Future work

One of the most important things to accomplish will be to test the circuit in a physical environment, to establish the accuracy of the module. Once the testing is complete and approved, there can be a few additions that can be made to make the module more efficient, robust and safe. The ideal requirements, such as automated power supply regulation based on tissue condition or a microcontroller-based circuit to increase efficiency, might be achievable in accordance with LMIC requirements in the future. It would be nice if the user has an option to select the type of device the module is connected to so that it is compatible with all types of conventional ESU and has wider range of use. The figure below is a block diagram of how this module might perform if used with a microcontroller and what other functions can be achieved.

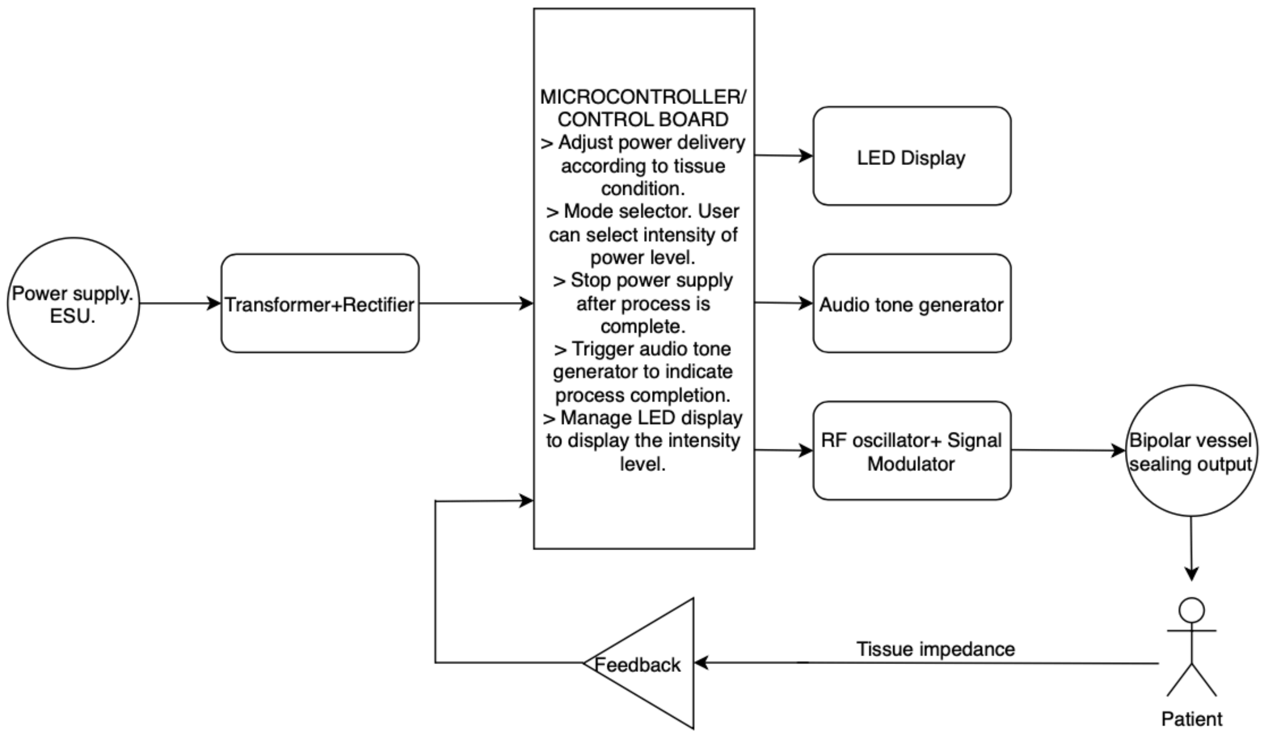


Figure 1: Block diagram of the add-on module with a microcontroller

In addition, it is vital to check the compatibility of the ESUs with the add-on module. The device must be reliable and give accurate output during a surgery. Research must be done to design an interface for this module and also to find a way to sterilize the device as everything in an operating theatre needs to be sterilized after every use. Since this module has only been created for *bipolar* vessel sealing system, further studies can be conducted to produce similar modules that give the output waveforms of other energy-based vessel sealing systems like ultrasound, hybrid, ferromagnetic, plasma and laser. Last but not the least, this module has been designed for LMIC uses, it is crucial that in future research it should be mass producible and that the costs of manufacturing are kept to a minimum.

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MANUALS

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C. Manual PK technology- https://www.olympus.pt/medical/rmt/media/en/Content/Content-MSD/Documents/Brochures/PK_TECHNOLOGY_Brochure_EN.pdf
D. Intelligent Ultrasonic energy- https://www.ethicon.com/na/system/files/2017-12/018618_140721_Springer_Healthcare_HARMONIC_ACE_7_Shears_Manuscript.pdf
E. https://cdn.shopify.com/s/files/1/1046/1086/files/ValleyLab-LigaSure-Vessel-Sealing-System-Users-Guide.pdf
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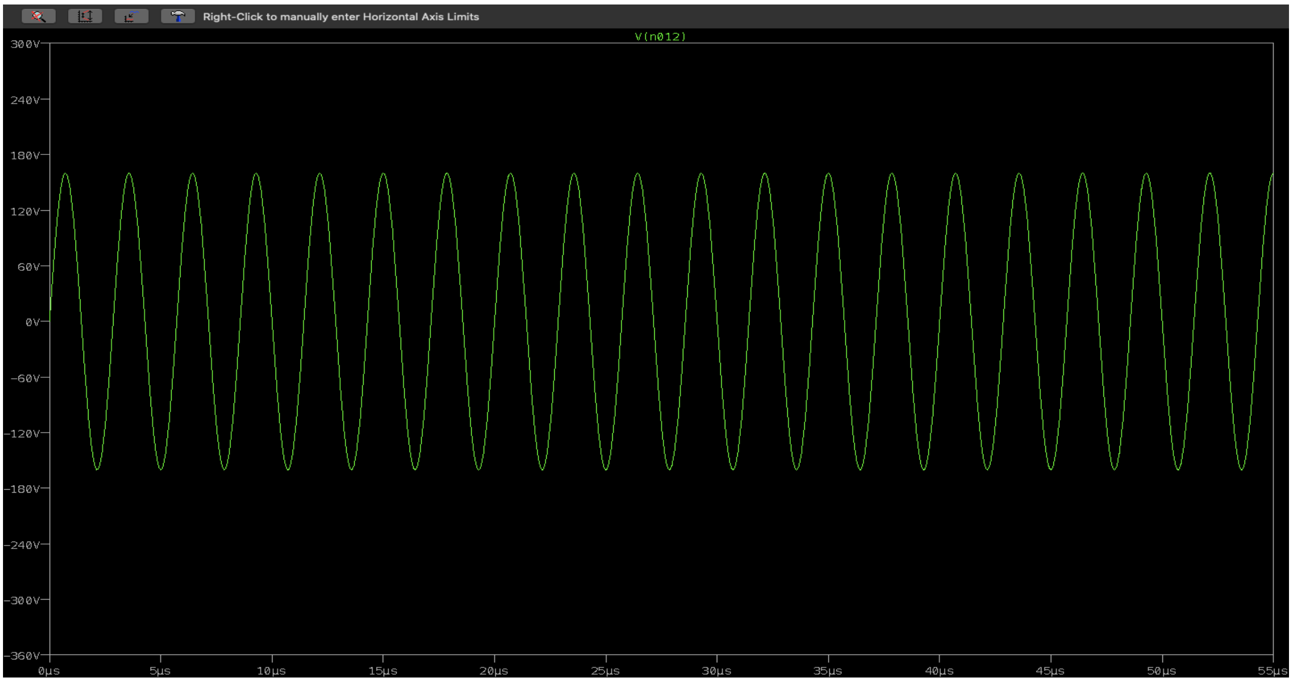
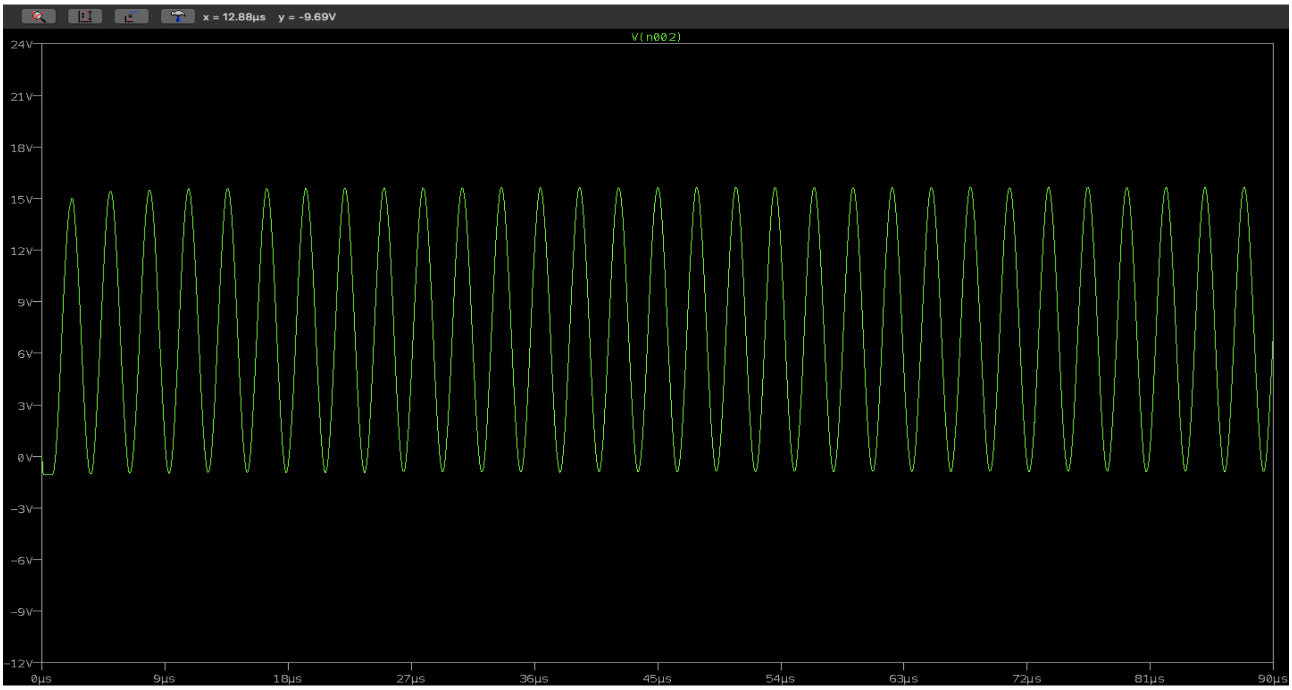
G. https://web.archive.org/web/20181203022221/https://www.analog.com/en/design-center/design-tools-and-calculators/ltspice-simulator.html

Appendix

Input Waveform: 160V, 350kHz power supply

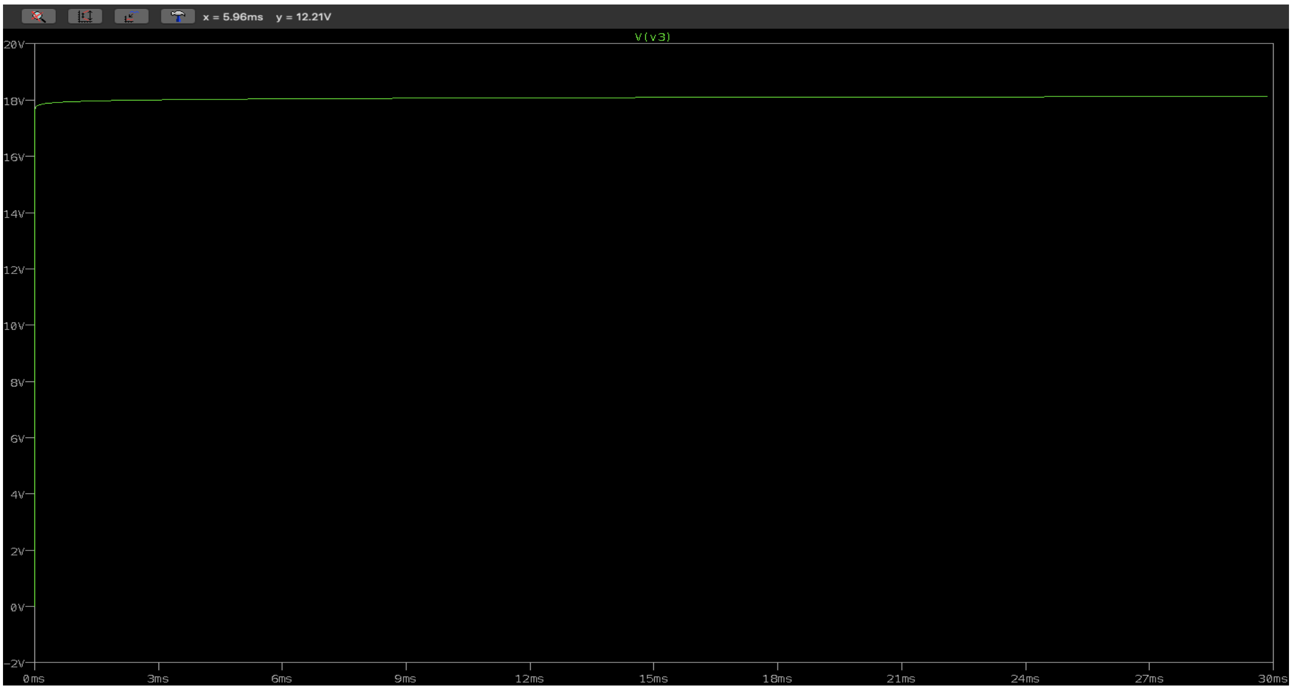


Transformer Output Waveform: 15V, 350kHz power supply

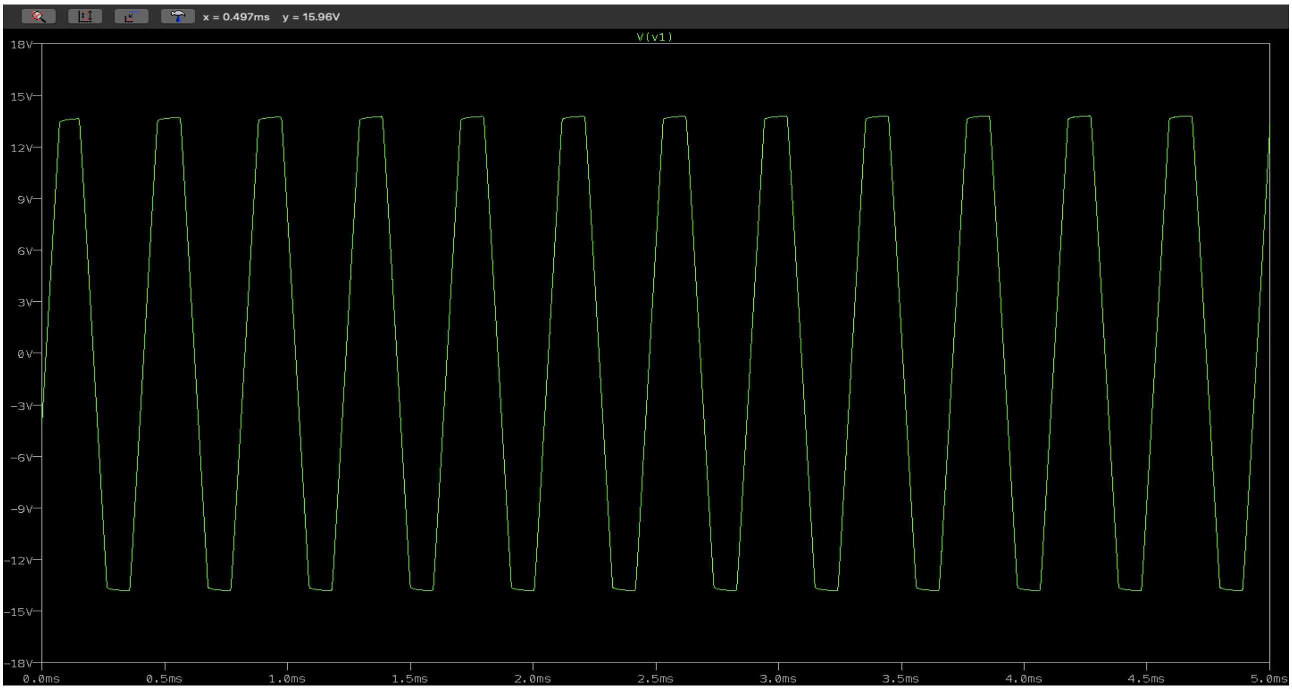


Rectifier output for RF Oscillator: 15V

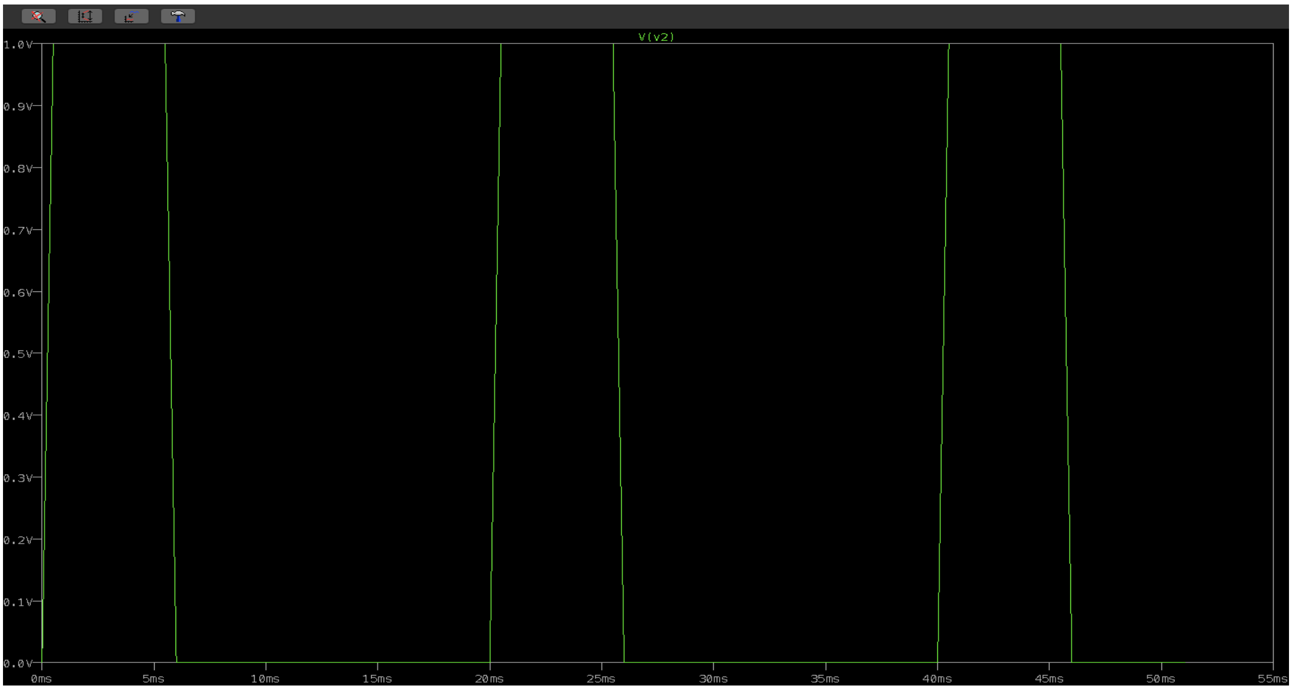
Rectifier output for Modulator: 18V



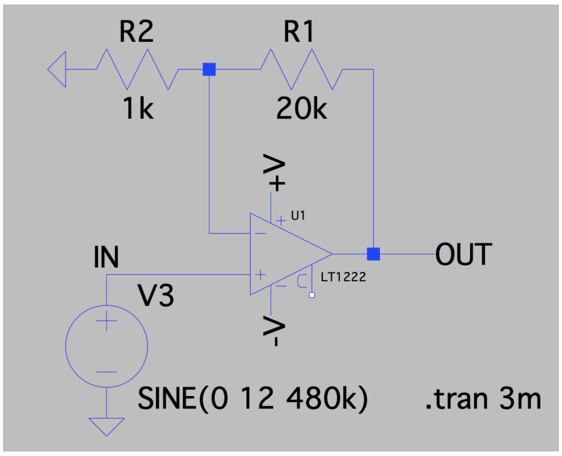
RF Oscillator Output to get 480kHz frequency

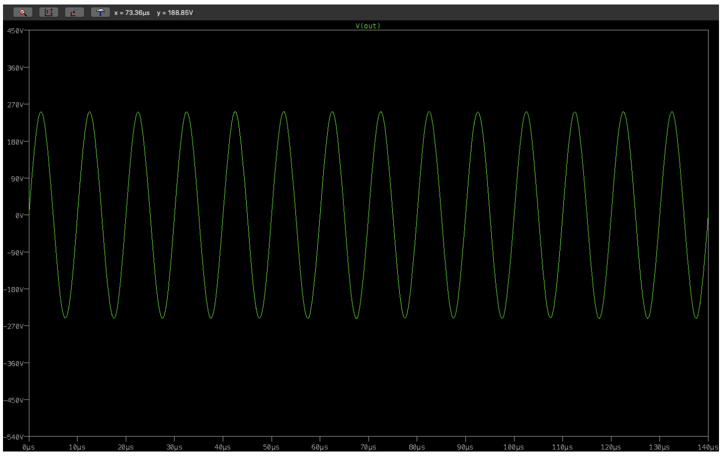


Modulating Signal for On/Off

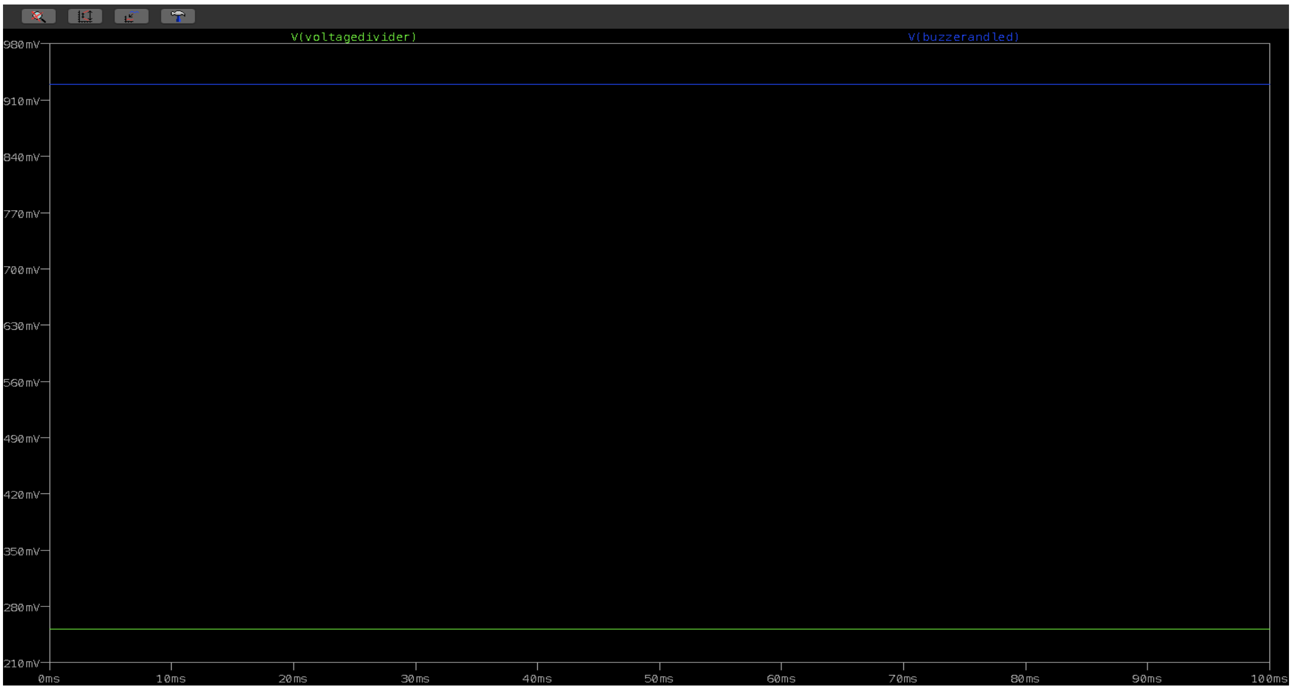


While assembling the circuit for testing, an amplifier can be used to amplify the output voltage of the RF oscillator to get the output voltage of 200-250V.





Voltage divider (green) and Op-amp (blue) output when potentiometer has value less than 1000 ohms. Potentiometer value at 20 ohms.



The graph shows that when the value of potentiometer is less than 1000ohms, there is no output at the op-amp since the output value of the voltage divider is less than the reference voltage of the op-amp.

Voltage divider (green) and Op-amp (blue) output when potentiometer has value less than 1000 ohms. Potentiometer value at 850 ohms.

The graph still shows that when the value of potentiometer is less than 1000ohms, there is no output at the op-amp, even though there is a significant amount of voltage at the voltage divider, since the output value of the voltage divider is less than the reference voltage of the op-amp.

Voltage divider (green) and Op-amp (blue) output when potentiometer has value more than 1000 ohms.

The graph shows that when the value of potentiometer is more than 1000ohms, there is an output at the op-amp since the output value of the voltage divider is more than the reference voltage of the op-amp. This output is used to light the LED and sound the buzzer.

Resistance values

```
.step r=1
.step r=201
.step r=401
.step r=601
.step r=801
.step r=1001
.step r=1201
.step r=1401
.step r=1601
.step r=1801
.step r=2001
.step r=2201
.step r=2401
.step r=2601
.step r=2801
.step r=3001
.step r=3201
.step r=3401
.step r=3601
.step r=3801
.step r=4001
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.step r=5401
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.step r=5801
.step r=6001
.step r=6201
.step r=6401
.step r=6601
.step r=6801
.step r=7001
.step r=7201
.step r=7401
.step r=7601
.step r=7801
.step r=8001
.step r=8201
.step r=8401
.step r=8601
.step r=8801
.step r=9001
.step r=9201
.step r=9401
.step r=9601
.step r=9801
.step r=10000
```

Output voltage values

```
Measurement: volt
  step          AVG(v(buzzerandled))
     1          0.929543        0
     2          0.929543        0
     3          0.929543        0
     4          0.929543        0
     5          0.931663        0
     6          0.937165        0
     7          4.06404         0
     8          4.06435         0
     9          4.06443         0
    10          4.06446         0
    11          4.06447         0
    12          4.06448         0
    13          4.06448         0
    14          4.06449         0
    15          4.06449         0
    16          4.06449         0
    17          4.0645          0
    18          4.0645          0
    19          4.0645          0
    20          4.0645          0
    21          4.0645          0
    22          4.0645          0
    23          4.06451         0
    24          4.06451         0
    25          4.06451         0
    26          4.06451         0
    27          4.06451         0
    28          4.06451         0
    29          4.06451         0
    30          4.06451         0
    31          4.06451         0
    32          4.06451         0
    33          4.06451         0
    34          4.06451         0
    35          4.06451         0
    36          4.06452         0
    37          4.06452         0
    38          4.06452         0
    39          4.06452         0
    40          4.06452         0
    41          4.06452         0
    42          4.06452         0
    43          4.06452         0
    44          4.06452         0
    45          4.06452         0
    46          4.06452         0
    47          4.06452         0
    48          4.06452         0
    49          4.06452         0
    50          4.06452         0
    51          4.06452         0


Date: Fri May  1 21:54:47 2020
Total elapsed time: 1.395 seconds.
```