

# BIPM Capacity Building & Knowledge Transfer Program 2024 BIPM TÜBİTAK UME Cycle 7 Project Placement REPORT

<b>Project Name</b>	Knowledge acquisition & transfer, capacity building and professional development in medical metrology measurements and calibration for homogeneity and traceability to Kenyan National Metrology Institute (NMI) – KEBS.
<b>Description</b>	Calibration and uncertainty calculation in medical metrology equipment according to the specific guidelines/standards and generating reports meeting the requirements of ISO/IEC 17025 standard and CIPM MRA Guidelines.
<b>Author, NMI</b>	Denish Omondi Ochieng, Kenya Bureau of Standards (KEBS), – KENYA.
<b>Mentor at TÜBİTAK UME</b>	Assoc. Prof. Dr. Baki KARABÖCE, Dr. Hüseyin Okan DURMUŞ, Mr. Gökhan GÜLER and Madam Elif BAŞARAN
<b>Date</b>	September 10 <sup>th</sup> , 2024 – November 28 <sup>th</sup> , 2024. (3 Months)

## Motivation & Introduction

The Kenya Bureau of Standards (KEBS) is the leading government agency responsible for Standards, Metrology, and Conformity Assessment (SMCA) in Kenya. Its metrology directorate, serving as the National Metrology Institute (NMI), ensures accurate measurements for sectors like industry, healthcare, and research.

A critical need exists for **medical metrology laboratory** for medical equipment calibration and traceability in Kenyan, especially in the context of vital machines such as ventilators, patient monitors, and defibrillators, which are crucial for saving lives and supporting the economy. Following the coronavirus pandemic, KEBS recognized the importance of improving its technical expertise in this area.

Though KEBS has acquired four of such necessary equipment, it still lacks sufficient personnel with the training and skills needed for the operation of this equipment. As a result, KEBS has struggled to expand its accreditation for medical metrology laboratory equipment calibration, testing and traceability.

A placement with **BIPM- TÜBİTAK UME** has provided valuable training, skills, and experience for KEBS personnel to address this gap and support not only KEBS operations but regional markets too with a goal of improving health sector with both equity and equality.

Therefore, the **BIPM- TÜBİTAK UME** placement was a perfect opportunity to help equip the KEBS personnel with the much-needed skills, firsthand calibration experience and technical proficiency in measurements and calibration of medical equipment, requisite for industry and economic support and growth for a better world. Undertaking this project shall help KEBS, Kenya, and regional countries within AFRIMET at large to improve their measurement capability in medical metrology measurements and calibration.

Eventually, this will result in improved manufacturing, better healthcare, increased economic gains, better responses to national pandemics and overall improved welfare of the Kenyan, African and the world people. I look forward to implementing this in my **NMI – KEBS** upon return.

## Project Objectives

The objectives of the research were.

1. To Acquire and advance both theoretical and practical medical metrology measurements and calibration. Understanding conditions of operations and basic troubleshooting, maintenance, and repair skills.
2. To help provide support and traceability to local and regional industries in medical device measurements, calibration, and maintenance by gaining the requisite training for accreditation.
3. To help **KEBS** towards the expansion of medical metrology calibration and measurements, scope, and capabilities within the country and regionally.
4. To help develop **KEBS** procedures on medical device measurements comparable to established and validated **NMI** procedures as of **BIPM- TÜBİTAK** and as per the **CIPM MRA** guidelines.
5. To develop measurement of uncertainty budgets in medical device measurements with strong endeavor to minimize the levels of such uncertainties.
6. To professionally develop opportunities through networking and collaborations, enhancing innovations in the research and development sectors of manufacturing, health, education, and agriculture.

## Project Methodology

I undertook the project through a combination of lectures and firsthand laboratory exercises and real calibration of both primary and secondary reference standards. The team in the **TUBİTAK UME Medical Metrology Laboratory** is very intensively organized with well-planned training schedules for us. Well informed and amazingly knowledgeable.

Daily, they make it very lively and interactive with more practical actions of calibrations especially when our trainers encouraged us (**BIPM Placements**) to get involved in the practical calibrations in their company and of course with their guidance. In the process, all questions raised we raised are adequately and extensively answered. This helped in building our confidence in handling machines and calibration with excellence.

**Assoc. Prof. Dr. Baki KARABÖCE** and **Dr. Hüseyin Okan DURMUŞ** in their separate lessons, first take you through all the concepts through interactive round table sessions that allowed us to understand the basics and principles behind every activity. They adequately tackled all questions, encouraged more questions, and the knowledge gained has been invaluable priceless.

The second part of each lesson involved the practical sessions in which we actively participated in the laboratory activities. We set up different measures, took reading and carried out analysis with the help of the Laboratory staff. The section below will outline brief samples of the activities that we conducted during the research and training period.

## 1. Infusion Pump and Infusion Pump Analyzer/Infusion Tester

### 1.1 Infusion Pump

An infusion pump is a medical device that delivers fluids, such as nutrients and medications, into a patient's body in controlled amounts. Infusion pumps are in widespread use in clinical settings such as hospitals, nursing homes, and in the home. These are high precision medical equipment mostly found and used in ICUs.



Figure 1: Infusion pump - Reference standard.



Figure 2: Infusion Pump Syringe Type

Only trained professionals run infusion pumps, who program the rate and duration of fluid delivery through a built-in software interface. Infusion pumps offer significant advantages over manual administration of fluids, including...

- Ability to deliver fluids in exceedingly small volumes
- Ability to deliver fluids at precisely programmed rates or automated intervals.

They can deliver nutrients or medications, such as insulin or other hormones, antibiotics, chemotherapy drugs, and pain relievers. There are several types of infusion pumps, including...

- Large volume,
- Patient-controlled analgesia.
- Elastomeric,
- Syringe, Enteral, and Insulin pumps.

Some are designed for stationary use at a patient's bedside. Others, called ambulatory infusion pumps, are designed to be portable or wearable.

## 1.2 Safety

Since infusion pumps administer critical fluids, including high-risk medications, pump failures can have significant implications for patient safety. Infusion pumps are equipped with safety features, such as alarms or other operator alerts that are intended to activate in case of a problem. For example, pumps are designed to alert users when air or another blockage is detected in the tubing that delivers fluid to the patient. Some newer infusion pumps, often called smart pumps, are designed to alert the user when there is a risk of an adverse drug interaction, or when the user sets the pump's parameters outside of specified safety limits.

### 1.3 Infusion Pump Analyzer/ Infusion Pump Tester

Is a medical machine used to periodically test infusion pumps to establish their functionality and performance within the recommended and expected ranges of operation by the manufacturer. The commonly used pumps that can be tested by the analyzers are drip rate pumps, volumetric pumps, syringe pumps, patient-controlled analgesia pumps, pumps for ambulatory use, and anesthesia pumps.



Figure 3: Infusion Pump Analyzer and Tester



Figure 4: Infusion Pump Analyzer and Tester

The above sample machines in Figures 3 & 4 are vital in analyzing and evaluating the suitability of infusion pumps in Figures 1 & 2.

Parameters Tested, Measured and Analyzed  
There are three parameters that are measurable by the infusion pump analyzers. They include...

- Flow rate (ml/h)
- Volume (ml)
- Pressure (psi)

The bellow tables (Table 1 to Table 3) are the sample practical of a calibration work we did under this research work.

Table 1: Volume Measurement Results.

Reference Volume (ml)	Reference Flow (ml/l)	Measured Volume (ml)					Tolerances
		1	2	3	4	Average	
15.00	400	14.95	14.94	14.97	14.96		2 % $\pm$ 1LSD
25.00	100	25.02	24.93	24.94	25.00		2 % $\pm$ 1LSD
30.00	800	29.67	29.70	29.68	29.70		1 % $\pm$ 1LSD
45.00	200	44.97	44.97	44.97	44.97		1 % $\pm$ 1LSD
50.00	1000	49.98	49.98	49.98	49.98		1 % $\pm$ 1LSD

As can be seen from the bellow analysis, the calibration test results were within the control bands. It is an exceptionally good result displayed by the analyzers, and it shows the equipment under test calibration passed the test.

We proceeded to prepare an uncertainty budget that resulted in the above table 1 values and the bellow graph figures 5 and 6.

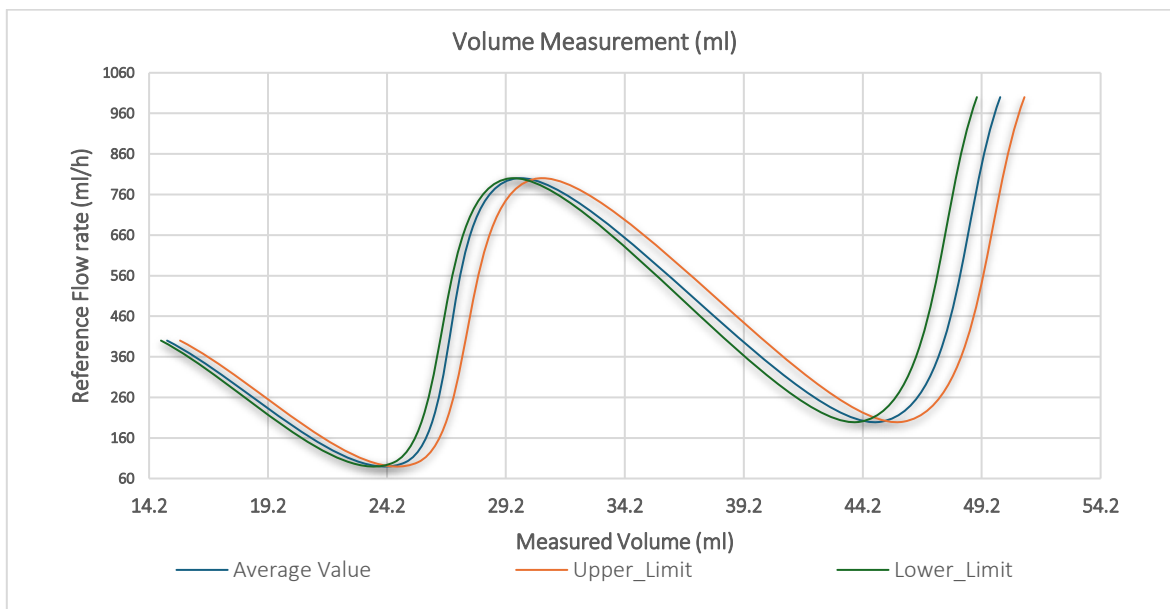


Figure 5: Line Graph Analysis.

Figure 6: Bar Graph analysis

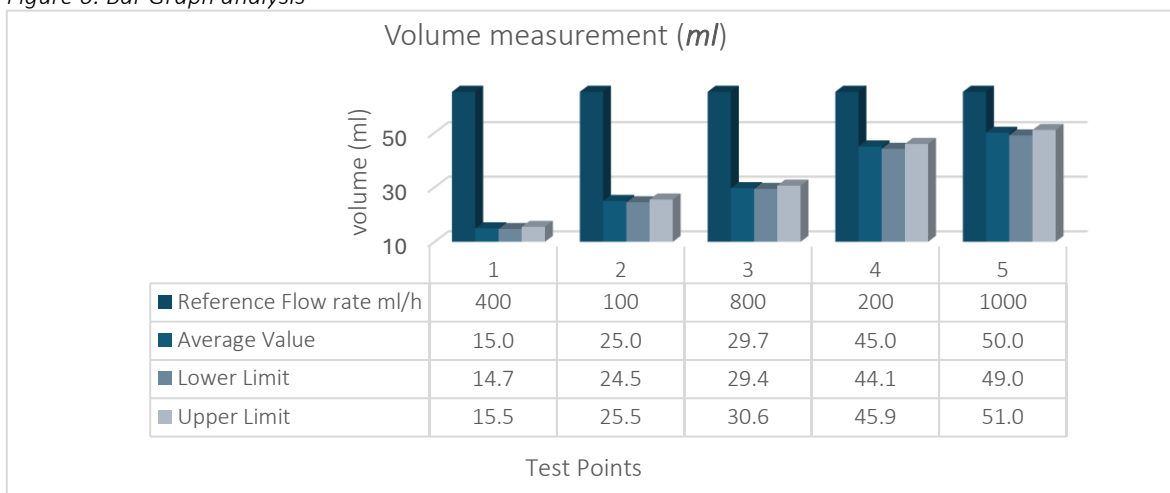


Table 2: Flow Rate Measurement results

Reference Flow (ml/l)	Reference Volume (ml)	Measured Volume (ml/l)					Tolerances (%)
		1	2	3	4	Average	
400	15.00	396.38	1397.12	397.17	396.98		2 % ± 1LSD
100	25.00	99.37	99.56	99.47	99.58		2 % ± 1LSD
800	30.00	795.22	796.43	795.78	796.53		1 % ± 1LSD
200	45.00	299.04	299.04	299.04	299.04		1 % ± 1LSD
1000	50.00	999.87	999.87	999.87	999.87		1 % ± 1LSD

Table 3: Pressure measurement

Reference Pressure (psi)	Measured Pressure (psi)					Tolerance % (psi)
	1	2	3	4	Average	
5.0	4.92	4.92	4.92	4.92	4.92	1 % ± 1 LSD
10.0	10.10	10.10	10.10	10.10	10.10	
20.0	19.92	19.92	19.92	19.92	19.92	
30.0	30.88	30.88	30.88	30.88	30.88	
40.0	39.87	39.87	39.87	39.87	39.87	
45.0	44.89	44.89	44.89	44.89	44.89	

The below graph figure 7 shows data analysis of pressure measurement for reference values against measured values for both measured and ideal values. It can be observed that the lines are almost similar with the blue indicating the measured values

while orange the ideal values. The expected graph should be a straight line with a positive gradient with zero origin. The graph shows we obtained exceptionally reliable results.

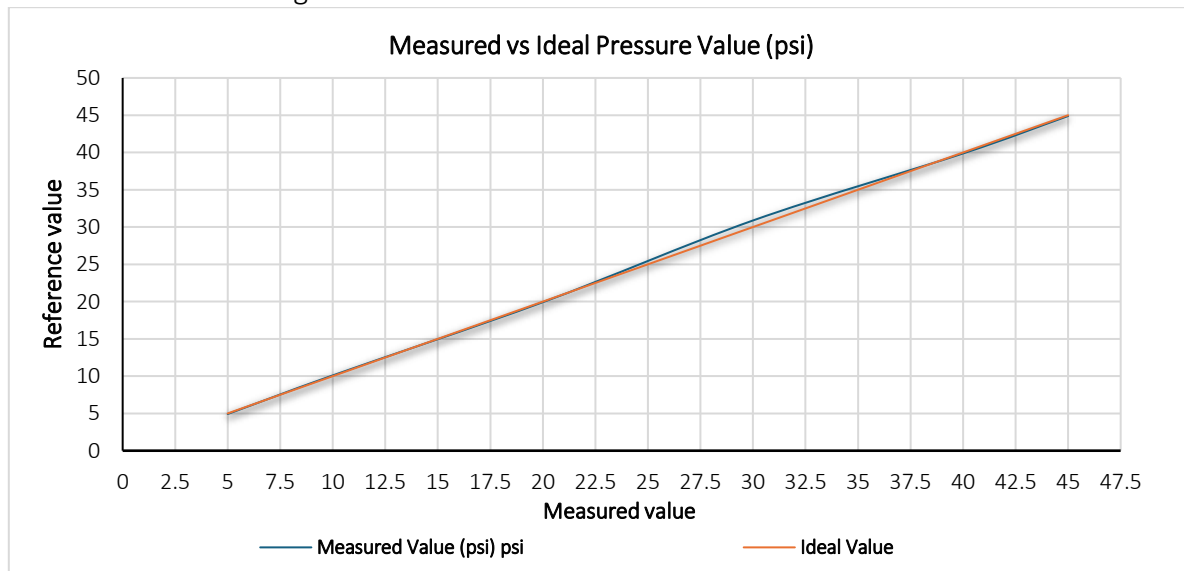


Figure 7: Pressure measurement

## 2. Gas flow Analyzer

### 2.1 Gas flow Analyzer

Meets the requirements for the calibration of both ventilators and anesthesia devices. Ventilators apply volume and pressure to a patient's lung, to deliver assisted breathing. They are a vital part of critical care, which means the accuracy of ventilation variables is fundamental to patient safety. Gas flow analyzers are capable of measuring flow, volume, pressure, and oxygen concentration over a wide range of values.

Measures gas flow (**forward & reverse**), volume measurements (**Inhale & Exhale**), pressure measurements (high - bar & low - mbar), oxygen concentration of the gas that flows (21% of air or 100% of pure oxygen gas) and gas concentration measurements. Some measure barometric pressure, temperature, and relative humidity. Of importance are discussions below in table 4.



Figure 8: Gas flow Analyzer zero



Figure 9: Gas Flow Analyzer

### 2.2 Oxygen concentration measurement results

#### 2.2.1 Tests are conducted using dry air.

We expect a reading of 21% since oxygen is about 21% by composition of air.

#### 2.2.2 Test done using pure dry oxygen.

A 100% reading expected.

Table 4: Percentage (%) Oxygen Test Measurements results

% Measure	Reference Volume (%)	Measured Volume (%)					Tolerance (%)
		1	2	3	4	Average	
21 % Oxygen Test	21.0	20.9	20.9	20.9	20.9	20.9	± 2.0
100 % Oxygen Test	100.0	100.0	100.0	100.0	100.0	100.0	± 2.0

## 2.3 Volume/Lung capacity measurements results

### 2.3.2 Inhale

Tests are done using three different test syringes of different capacities (small-100 ml, medium-1000 ml, and 3000 ml). Reading expected near test values.

### 2.3.3 Exhale

Tests are done using three different test syringes of different capacities (small-100 ml, medium-1000 ml, and 3000 ml). Reading expected near test values.



Figure 8: Calibrated Syringes for Lung Capacity Calibration

Table 5: Volume Measurement results

Input Type	Reference Volume (ml)	Measured Volume (Inhale & Exhale) (ml)					Tolerance (ml)
		1	2	3	4	Average	
Low Flow Input	100	98.9	98.9	98.9	98.9	98.9	± 3
	1000	100.3	100.3	100.3	100.3	100.3	± 30
High Flow Input	100	101.3	101.3	101.3	101.3	101.3	± 10
	1000	1013.5	1013.5	1013.5	1013.5	1013.5	± 30
	3000	3043.6	3043.6	3043.6	3043.6	3043.6	± 90

## 2.4 Pressure measurement results.

### 2.4.2 High pressure

We did a test in high pressure units e.g., bar measurements. Reading compared to setpoint readings.

Table 6: High pressure Gas (+) Measurement results

Reference Standard (psi)	Measured value (Psi)					Tolerances (psi)
	1	2	3	4	Average	
30.00	29.7	29.7	29.7	29.7	29.7	± 0.30
65.00	64.7	64.7	64.7	64.7	64.7	± 0.65
95.00	95.0	95.0	95.0	95.0	95.0	±0.95

Table 7: High pressure Gas (-) Measurement results

Reference Standard (psi)	Measured value (Psi)					Tolerances (psi)
	1	2	3	4	Average	
30.00	29.7	29.7	29.7	29.7	29.7	± 0.30
65.00	64.7	64.7	64.7	64.7	64.7	± 0.65
95.00	95.0	95.0	95.0	95.0	95.0	±0.95



### 2.4.3 Low pressure

Tests are conducted in low pressure units e.g., mmHg or cmH<sub>2</sub>O measurements. Reading compared to setpoint readings.

Table 8: Low pressure Gas (+) Measurement results

Reference Standard Value (cmH <sub>2</sub> O)	Measured value (cmH <sub>2</sub> O)					Tolerances (cmH <sub>2</sub> O)
	1	2	3	4	Average	
200.00	198.30	198.30	198.30	198.30	198.30	± 2.0
450.00	449.9	449.9	449.9	449.9	449.9	± 2.0
680.00	681.0	681.0	681.0	681.0	681.0	±3.4

Table 9: Low pressure Gas (-) Measurement results

Reference Standard Value (cmH <sub>2</sub> O)	Measured value (cmH <sub>2</sub> O)					Tolerances (cmH <sub>2</sub> O)
	1	2	3	4	Average	
-200.00	-198.30	-198.30	-198.30	-198.30	-198.30	± 2.0
-450.00	-449.90	-449.90	-449.90	-449.90	-449.90	± 2.0
-680.00	-681.00	-681.00	-681.00	-681.00	-681.00	±3.4

## 2.5 Flow channel measurement results.

### 2.5.2 Forward (+)

Set the flow in the positive going flow and the test done against the set flow point.

Table 10: Forward (+) Airway Pressure Flow Measurement results.

Reference Standard Value (cmH <sub>2</sub> O)	Measured value (cmH <sub>2</sub> O)					Tolerances (cmH <sub>2</sub> O)
	1	2	3	4	Average	
15.00	14.9	14.9	14.9	14.9	14.9	± 0.50
55.00	54.6	54.6	54.6	54.6	54.6	± 0.50
100.00	99.3	99.3	99.3	99.3	99.3	± 0.75

### 2.5.3 Reverse (-)

Set the flow in the negative going flow and the test done against the set flow point.

Table 11: Reverse (-) Airway Pressure Flow Measurement results.

Reference Standard Value (cmH <sub>2</sub> O)	Measured value (cmH <sub>2</sub> O)					Tolerances (cmH <sub>2</sub> O)
	1	2	3	4	Average	
-15.00	-15.1	-15.1	-15.1	-15.1	-15.1	± 0.50
-55.00	-55.2	-55.2	-55.2	-55.2	-55.2	± 0.50
-100.00	-100.5	-100.5	-100.5	-100.5	-100.5	± 0.75

## 2.6 Barometric Pressure Measure Measurement

Table 12: Barometric Pressure Measurement Results

Reference Standard Value (mmHg)	Measured value (mmHg)					Tolerances (mmHg)
	1	2	3	4	Average	
742.5	742.2	742.2	742.2	742.2	742.2	± 2.5

### 3. Electrosurgical Unit (ESU) and Electrosurgical Analyzer (ESA)

#### 3.1 Electrosurgical Unit (ESU)

An ESU is a medical instrument that uses high-frequency electrical currents to cut tissue and control bleeding by causing coagulation. The electrical current generates heat, which allows for precise cutting and coagulation of tissue during surgery.

It typically includes a generator, active electrode, and sometimes a dispersive electrode (grounding pad). The generator converts standard electrical frequencies to much higher frequencies to minimize nerve and muscle stimulation.



Figure 9: Electrosurgical Unit (ESU)\_Zero



Figure 10: Electrosurgical Unit (ESU)\_One

#### 3.2 Electrosurgical Analyzer (ESA)

An instrument intended for use in conducting performance tests on high

frequency electrosurgical units (ESUs). Electrosurgery is based on the transformation of a high frequency electrical current into heat, with the resulting effect of cutting, coagulating, desiccating, and fulguration of biological tissues at the point of current application.

The term *electrosurgery* refers to the use of high frequency, alternating electric current to produce heating in tissue. The heating is used to achieve the desired tissue effect such as cutting, tissue ablation, dedication, or a combination of effects. Electrosurgical units are commonly used by health officers in Gastroenterology, General Surgery, Ob-Gyn, ENT, Pulmonary Medicine, and Dermatology, to name b. Electrosurgery has been applicable in endoscopy since the 1970s. Its use in gastrointestinal endoscopy includes polypectomy and tissue resection procedures, hemostasis and ablation, and biliary and pancreatic endoscopy procedures.

Electrosurgery works by cutting or coagulating tissue via a high-frequency electrical current generated from an electrosurgical unit or ESU. The electrical current travels through an attached device (active electrode) and creates localized heating to allow for precise cuts or coagulation of the tissue which helps to reduce the risk of bleeding. By adjusting the method, mode, and power settings (wattage), physicians can customize the unit output setting for a variety of procedures. The commonly performed **tests** on **ESU** are as follows:

##### 3.2.2 High frequency (HF) power tests

Output current ( $I$ ), output voltage ( $V$ ), output Power ( $W$ ), Output resistance ( $\Omega$ ), crest factor (frequency) measurement using series of variable loads (Amplitude)

##### 3.2.3 High frequency leakage current tests/measurements

To ensure no hazardous currents are present and limit the amount of stray capacitive leakages. They ensure that if a failure in any electrode were to occur, patients should be shielded effectively from the leakages. The **IEC 60601** standard states that leakage should not exceed 150mA to earth ground through a **200  $\Omega$**  load.

### 3.2.4 Return electrode current monitoring tests.

Ensure that the alarms sound and ESU deactivates when the impedance of the patient plate exceeds specified values. The resistance limits should be stated in the performance schedule by the manufacturer. Typically, there are low resistance ( $\approx 10 \Omega$ ) and high resistance ( $\approx 250 \Omega$ ) alarm limits.

**NB:** In all the above tests, POWER applied constantly, and the results are prepared as below.

### 3.2.5 Resistance Measurement

#### 3.2.6 Fixed and variable Resistance Measurement results

Record measurement points from the bellow arrangement figure 13 and tabulated in table 13 below.

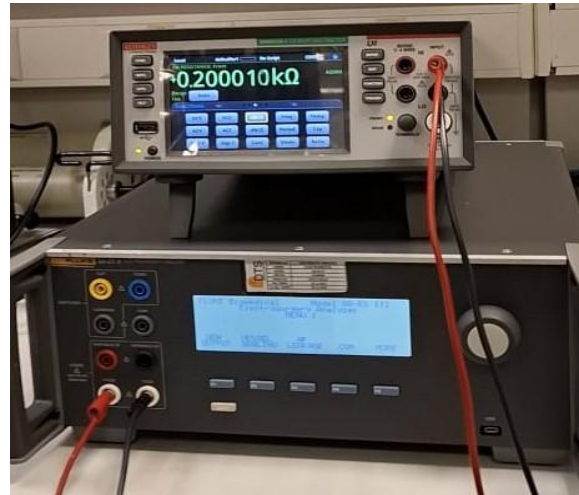


Figure 11: Resistance Measurement

Table 13: Fixed and variable Resistance Measurement results

Entry	Reference Standard Resistance $\Omega$	UUT Measured resistance $\Omega$					Tolerance %
		1	2	3	4	Average	
Fixed Resistance	200	200.014	200.013	200.013	200.014	200.0135	5
Variable Resistance	20	20.165	20.165	20.165	20.165	20.165	5
	50	49.996					5
	100	102.197					5
	150						5
	200						5
	300						5
	500						5
	750						5
	1000						5
	1500						5
	2000						5

### 3.2.7 Monopolar cut current and power measurement results

#### 3.2.7.1 Coagulation

In electrosurgery, **coagulation** refers to the process of using electric current to heat tissue, causing proteins to **Denature** and form a coagulated mass, thereby sealing blood vessels and reducing bleeding.

Also known as clotting, is the process by which blood changes from a liquid to a

gel, forming a blood clot. It results in hemostasis, the cessation of blood loss from a damaged vessel, followed by repair. The process of coagulation involves activation, adhesion, and aggregation of platelets, as well as deposition and maturation of fibrin.

#### 3.2.7.2 Denature

Refers to the process in which the natural structure or function of a biological

molecule, such as protein or nucleic acid, is altered or destroyed.

### 3.2.7.3 Cutting

Involves higher power levels that vaporize tissue rather than just heating it. This allows for incisions to be made while simultaneously minimizing blood loss. Both techniques utilize an electrosurgical generator to control the electric current, ensuring precision and effectiveness during surgical procedures.

### 3.2.7.4 Monopolar coagulation

A surgical technique that uses a single electrode to deliver electric current to tissue, causing it to heat and coagulate (solidify). This method is often used to control bleeding during surgeries by ensuring that tissues are sealed, reducing blood loss during procedures. It is commonly utilized in various surgical fields, including gynecology and laparoscopic surgery.

Table 14: Monopolar cut current and power measurement results

Load Resistance ( $\Omega$ )	Applied power (W)	Reference standard current (mA)	Calculated power (W) ( $P=I^2R$ )	UUT Measured current (mA)					UUT Measured power (W)	Tolerance (Current) %
				1	2	3	4	Average		
20	200	$100.66 \times 10 = 1006.6$	19.7	992	992	992	992	992	20.3	5
50	200	$100.67 \times 10 = 1006.7$	48.0	979	997	979	979	979	49.7	5
100	200									5
150	200									5
200	200									5
300	200									5
500	200									5
750	200									5
1000	200									5
1500	200	$24.61 \times 10 = 246.1$	84.3	237	237	237	237	237	86.3	5
2000	200	$18.34 \times 10 = 183.4$	60.0	173	173	173	173	173	62.2	5

$$P = I^2R, I = \text{AMPERE}_{\text{average}}, R = \text{Load Resistance}$$



Figure 12: Monopolar Cut current and Power Measurement Connection



Figure 13: Monopolar Cut current and Power Measurement Connection



Figure 14: Cut and coagulate foot run button.

**NB:** The Reference Standard Current value is taken from **mV** and then divided the current conversion factor (**0.1**) of the coil meter on the yellow cable, at the rate of **output volts per Amp** as shown in the below image.



Figure 15: Tx with k-factor as 0.1 output volts per Amp.

### 3.2.8 Monopolar coagulation current and power measurement results

#### 3.2.8.1 Coagulation

In electrosurgery, **coagulation** refers to the process of using electric current to heat tissue, causing proteins to **Denature** and form a coagulated mass, thereby sealing blood vessels and reducing bleeding.

Also known as **clotting**, is the process by which blood changes from a liquid to a gel, forming a blood clot. It results in hemostasis, the cessation of blood loss from a damaged vessel, followed by repair.



The process of coagulation involves activation, adhesion and aggregation of platelets, as well as deposition and maturation of fibrin.

generator to control the electric current, ensuring precision and effectiveness during surgical procedures.

### 3.2.8.2 Denature

Refers to the process in which the natural structure or function of a biological molecule, such as protein or nucleic acid, is altered or destroyed.

### 3.2.8.3 Cutting

Involves higher power levels that vaporize tissue rather than just heating it. This allows for incisions to be made while simultaneously minimizing blood loss. Both techniques utilize an electrosurgical

### 3.2.8.4 Bipolar coagulation

A surgical technique that uses two electrodes to deliver electric current to tissue controlling bleeding during procedures by passing electrical heat and coagulates it. This method uses two electrodes, which helps to minimize thermal injury and preserve surrounding tissues compared to traditional monopolar coagulation. It is commonly employed in laparoscopic surgeries and other minimally invasive procedures.

Table 15: Monopolar coagulation current and power measurement results

Load Resistance ( $\Omega$ )	Applied power (W)	Reference Standard current (mA)	UUT Measured current (mA)					UUT Measured power (W)	Tolerance (Current) %
			1	2	3	4	Average		
10	200	$65.18 \times 10 = 651.8$	642	642	642	642	642	4.2	5
20	200	$65.0 \times 10 = 650.0$	640	640	640	640	640	8.2	5
50	200								5
100	200								5
150	200								5
200	200								5
300	200								5
500	200								5
750	200								5
1000	200								5
1500	200								5
2000	200								5



Figure 16: Monopolar Coagulation test end cable connection.

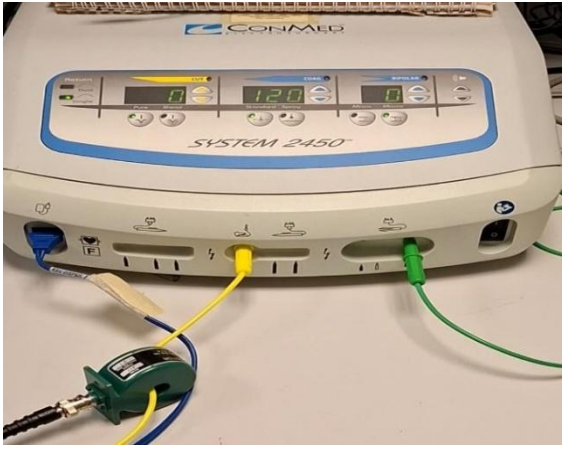


Figure 17: Monopolar Coagulation test starts cable connection.



Figure 21: Cut and coagulate foot run button.

## 4. Bipolar coagulation current and power measurement results

Table 16: Bipolar coagulation current and power measurement results

Load Resistance ( $\Omega$ )	Applied power (W)	Reference Standard current (mA)	Measured current (mA)					Measured power (W)	Tolerance Current (%)
			1	2	3	4	Average		
20	50	107.5 = 1075.0	1063	1065	1064	1063	1063.75	22.63	5
50	50	99.32 = 993.2	994	994	994	994	994	98.80	5
100	50								5
150	50								5
200	50								5
300	50								5
500	50								5
750	50								5
1000	50								5
1500	50	5.310 = 53.10	51	51	51	51	51	3.90	5
2000	50	3.993 = 39.93	38	38	38	38	38	2.89	5

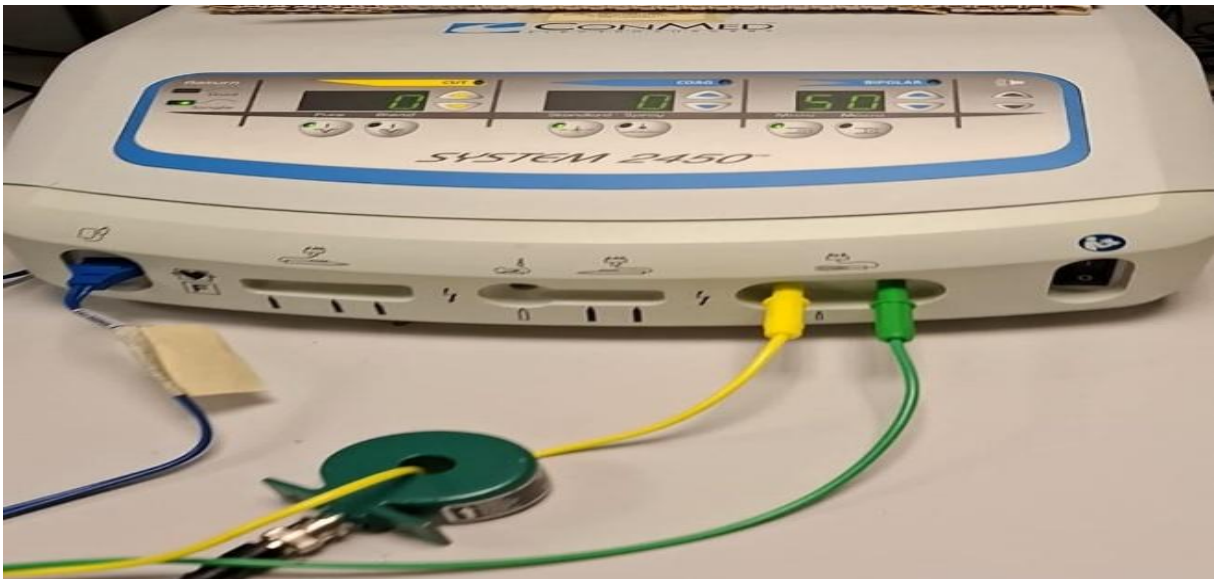


Figure 18: Bipolar coagulation test starts cable connection.



Figure 19: Bipolar coagulation test end cable connection.



Figure 20: Bipolar Run Button

Modern ESU analyzers have built in variable load resistances with automated power test procedures. An ESU performance maintenance schedule can be programmed into the analyzer for ease of use and uniform testing. Performance testing of electrosurgical units (ESUs) relies on three crucial tests.

I.HF Power tests measure the **current output**, **voltage**, **wattage**, and **crest factor** using a series of variable loads. Checks are always conducted on available modes and maximum power. The performance schedule from the manufacturer will state which loads are required, plus any additional power levels. Specifications for output power are usually around +/-10%.

II.HF leakage current tests ensure that the ESU is limiting the amount of stray capacitive leakage. It must be assessed in all available

modes and under faulty conditions. Tests are conducted from the active and dispersive electrodes in monopolar mode, and from both electrodes in bipolar mode.

**Note:** The difference between *Electrosurgery Analyzer* and *Electrical safety tester*

An Electrosurgery Analyzer and an Electrical Safety Tester serve different purposes in medical equipment testing.

#### 4.1 Electrosurgery Analyzer

##### 4.1.2 Purpose

Specifically designed to assess electrosurgical units (ESUs), which use high-frequency electrical currents for cutting tissue and controlling bleeding.

##### 4.1.3 Functions

Measures parameters like power output, current, voltage, and frequency to ensure the ESU is performing correctly and safely.

##### 4.1.4 Usage

Essential for verifying the performance and safety of ESUs, ensuring they meet manufacturer specifications and regulatory standards.

#### 4.2 Electrical Safety Tester

##### 4.2.2 Purpose

Used to perform general electrical safety tests on a wide range of medical devices.

##### 4.2.3 Functions

Tests for ground wire resistance, chassis leakage, insulation resistance, and other safety parameters to ensure the device does not pose an electrical hazard.

##### 4.2.4 Usage

It is crucial for routine safety inspections of various medical equipment to prevent electrical shock and fire hazards.

In summary, while an Electrosurgery Analyzer specializes in assessing the performance of electrosurgical units, an Electrical Safety Tester is used for broader safety checks on various medical devices. Both are important for maintaining the safety and efficacy of medical equipment.



## 5. Patient analyzer/Monitor/Simulator

Patient simulators use advanced simulation tools that mimic human physiological responses to evaluate the equipment, confirming that patient monitors are fully operational and conducting thorough and correct readings.

Patient monitor testing is imperative to ensure patient monitors are functioning as they should be. These devices are one of the most common and essential medical devices because they give healthcare staff a clear overview of the well-being of each patient. Testing patient monitors is not a one-size-fits-all approach mainly because patient monitors do not have just one function.

The below Rigel Uni-Sim's monitors are checked with physiologically correct and synchronized simulations, the closest thing to a human being. These sampled devices measure varieties of parameters including but not limited to:



Figure 21: Rigel Uni-Sim Patient Simulator/monitor/analyzer\_1.



Figure 22: Patient Simulator/monitor/analyzer\_2.



Figure 23: Patient simulator/monitor/analyzer\_3.

### 5.1 Non-invasive Blood Pressure (NIBP)

It refers to the use of Oscillo-metric monitoring equipment to measure blood pressure without the need for invasive procedures.

NIBP monitors are widely used in operating rooms and critical care units (ICUs) to closely monitor blood pressure in patients. Technology is based on indirect measurement of cuff pressure oscillations caused by changes in arterial volume during cuff deflation.

Table 17: Pulse Control Measurement Results using **Nellcor**.

Reference Value <i>bpm</i>	Measured Value <i>bpm</i>	Deviation (%)	Tolerance (%)	Conformity <i>Pass/Fail</i>
30	30	0.0	± 1.0	pass
60	60	0.0		pass
65	65	0.0		pass
80	80	0.0		pass
100	100	0.0		pass
120	120	0.0		pass
150	150	0.0		pass
180	180	0.0		pass
240	240	0.0		pass

Table 18: Pulse Control Measurement Results using **Masimo Radical 7**

Reference Value <i>bpm</i>	Measured Value <i>bpm</i>	Deviation (%)	Tolerance %	Conformity <i>Pass/Fail</i>
30	30	0.0	± 1.0	pass
60	60	0.0		pass
65	65	0.0		pass
80	80	0.0		pass
100	100	0.0		pass
120	120	0.0		pass
150	150	0.0		pass
180	180	0.0		pass
240	240	0.0		pass

Table 19: Manometer Pressure Measurement Results

Reference Value (mmHg)	Measured Value (mmHg)	Deviation (%)	Tolerance	Conformity (Pass/Fail)
10.0	10.1	1.0	± (1% of reading + 1 mmHg)	Pass
25.0	25.0	0.0		Pass
50.0	50.0	0.0		Pass
75.0	75.0	0.0		Pass
100.0	100.1	0.1		Pass
200.0	199.8	-0.1		Pass
300.0	299.5	-0.2		Pass
400.0	398.6	-0.3		Pass

Table 20: Direct Pressure Measurement Results

Reference Value (mmHg)	Measured Value (mmHg)	Deviation %	Tolerance	Conformity Pass/Fail
0.0	0.0	0.0	± (1% of reading + 1 mmHg)	Pass
8.0	81.3	1.6		Pass
160.0	161.4	0.9		Pass
250.0	251.0	0.4		Pass

## 5.2 Invasive Blood Pressure (IBP)

IBP monitoring involves inserting an arterial catheter (also known as an A-line) into a suitable artery.

This catheter allows continuous access to arterial blood and provides real-time BP values.

**NB:** We shall only simulate and analyze without invasion. It uses precision multimeter, DC supply source of 10mV with different sensitivity values e.g., **5  $\mu$ V/V/mmHg** and **40  $\mu$ V/V/mmHg** for a static pressure measurement and recorded on tables as bellow.

Table 21: Sensitivity - 5  $\mu\text{V/V/mmHg}$

Setpoint (mmHg)	Measured values (mA)	Converted Measured values (mV)	Results after calculation (mmHg)
0	0	0	0
10	0.514	0.0514	10.28
25	1.265	0.1265	25.30
50	2.501	0.2501	50.02
100	5.003	0.5003	100.06
150	7.506	0.7506	150.12
200	10.008	1.0008	200.16

**Result** =  $\frac{\text{Measure Value} \times k\text{-Factor}}{\text{Sensitivity}}$  (mmHg).....Equation 1

Since  $K=0.1$ , Conversion from **mA** to **mV** you multiply measured value by **k**-factor. Conversion from **mV** to **mA** you divide measured value by **k**-factor.

**Note:** Sensitivity of the Standard dictates the use of k-factor.

The below **figure 27** show that the measurement taken are within the accepted tolerances – both the upper and lower limits of a  $5\mu\text{V/V/mmHg}$  sensitivity IBP UUT.

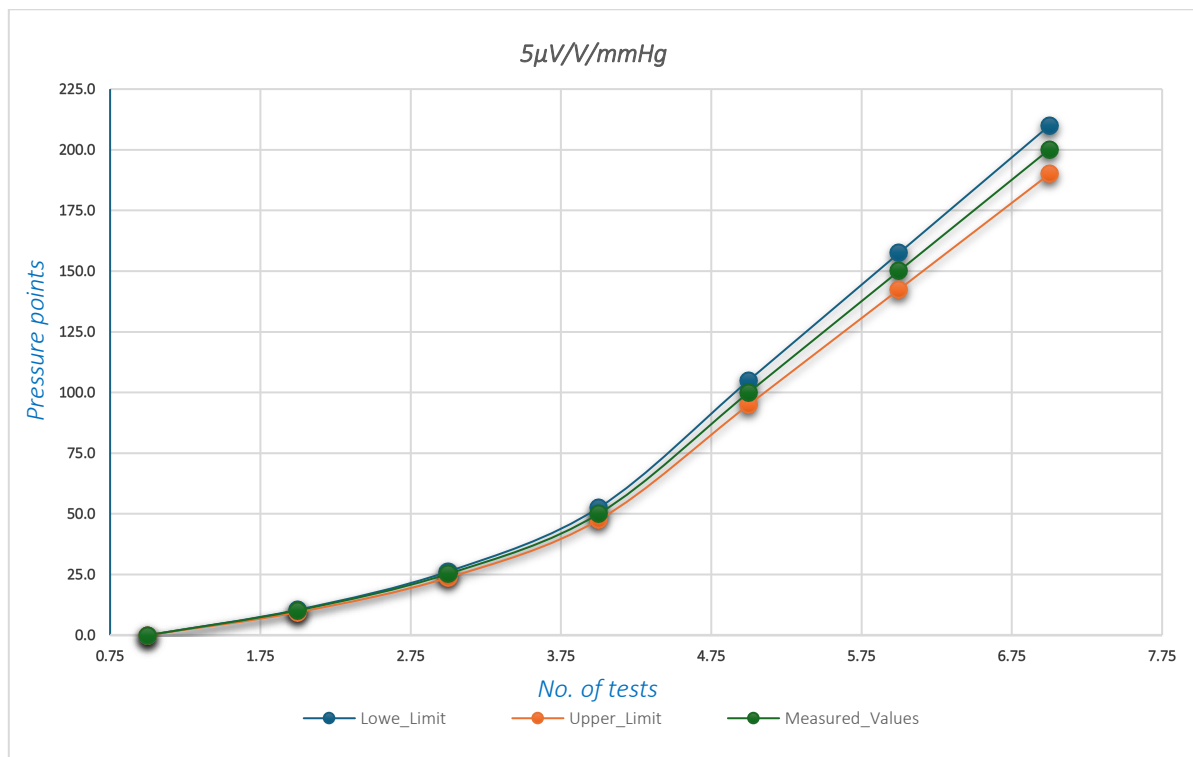


Figure 24: Graph of  $5\mu\text{V/V/mmHg}$  IBP Sensitivity machine

Table 22: Sensitivity - 40  $\mu\text{V/V/mmHg}$

Setpoint (mmHg)	Measured values (mV)	Converted Measured values. (mV)	Results after calculation (mmHg)
0	0	0	0
10	3.990	0.3990	9.98
25	9.982	0.9982	24.96
50	19.846	1.9846	49.62
100	39.808	3.9808	99.52
150	59.791	5.9791	149.48
200	79.753	7.9753	199.38

Since  $K=0.1$ , Conversion from mA to mV you multiply measured value by k-factor. Conversion from mV to mA you divide measured value by k-factor.  
 Note: Sensitivity of the Standard dictates the use of k-factor.

### 5.3 Electrocardiogram (ECG)

It is a quick test *to check the heartbeat*. It records the electrical signals in the heart. Test results can help diagnose heart attacks and irregular heartbeats, called arrhythmias. ECG machines can be found in medical offices, hospitals, operating rooms, and ambulances. Some personal devices, such as smartwatches, can do simple ECGs.

Table 23: ECG Waveform Verification Measurement Results

Reference Value (bpm)	Measured Value (bpm)	Deviation %	Tolerance %	Conformity (Pass/Fail)
30	30	0.0	± 1.0	Pass
60	60	0.0		Pass
80	80	0.0		Pass
90	90	0.0		Pass
120	121	0.8		Pass
150	151	0.7		Pass
180	181	0.6		Pass
210	210	0.0		Pass
240	240	0.0		Pass
270	270	0.0		Pass
300	300	0.0		Pass
320	320	0.0		Pass

Table 24: ECG Performance Verification Measurements

Nominal Value (mV)	ECG Deviation	Percentage Rate	Reference Value (mV)	Measured Value (mV)	Deviation %	Tolerance %	Conformity
1	Lead I	70	0,70	0,71	1,4	± 5,0 (Lead II for setting)	Pass
1	Lead II	100	1,00	0,98	-2,0		Pass
1	Lead III	30	0,30	0,29	-3,3		Pass
1	Lead V1	24	0,24	0,25	4,2		Pass
1	Lead V2	48	0,48	0,49	2,1		Pass
1	Lead V3	100	1,00	1,03	3,0		Pass
1	Lead V4	120	1,20	1,22	1,7		Pass
1	Lead V5	112	1,12	1,15	2,7		Pass
1	Lead V6	80	0,80	0,82	2,5		Pass

#### 1.1 Oxygen saturation (SpO<sub>2</sub>)

SpO<sub>2</sub> Is a measurement of how much oxygen your blood is carrying as a percentage of the maximum it could carry. It is also known as **oxygen saturation**.

A pulse oximeter reading indicates what percentage of your blood is saturated. For a healthy individual, the **normal SpO<sub>2</sub> should be between 96% to 99%**. High altitudes and other factors may affect what is considered normal for a given individual.

Table 25: SpO2 Measurement Results Using **Nellcor**

Reference Value (%)	Measured Value (%)	Uncertainty (%)	Deviation %	Tolerance %	Conformity
70	70	2	0	± 3.0	Pass
75	75	2	0		Pass
80	80	2	0		Pass
85	85	2	0		Pass
90	90	2	0		Pass
95	95	2	0		Pass
97	97	2	0		Pass
98	98	2	0		Pass
99	99	2	0		Pass
100	100	2	0		Pass

Table 26: SpO2 Measurement Results Using **Masimo Radical 7**

Reference Value (%)	Measured Value (%)	Uncertainty (%)	Deviation %	Tolerance %	Conformity
70	69	2	-1	± 3.0	Pass
75	74	2	-1		Pass
80	79	3	-1		Pass
85	84	3	-1		Pass
90	90	3	0		Pass
95	95	3	0		Pass
97	97	3	0		Pass
98	98	3	0		Pass
99	99	3	0		Pass
100	100	3	0		Pass

**Note:** Accuracy; Saturation within UUT

specific range..... was given as  $\pm$  (1 count + specified accuracy of the UUT). One count means 1 count. For example, if the result is 60, it means 1 less and 1 more. The specified accuracy of the UUT means the specified accuracy of the Unit/Device Under Test. From this test, the accuracy of the device under the test was Pros-Sim 4 with. These devices are gold standard devices in the sector, with devices such as **Nellcor** and Masimo Radikal 7, which we also have.

Here are the accuracies of **Nellcor** and **Masimo Radikal 7**. For Nellcor, the Pulse Oximeter accuracy is 2 digits/points/counts/percentage between 70% and 100%.

For Masimo, it is 2 digits/points/counts/percentage between 70% and 100%. In this case,  $\pm$  (1 count + specified accuracy of the UUT) means  $\pm$  (1 count + 2 counts) =  $\pm 3$  counts. or  $\pm 3\%$ .

The Patient Simulator device's pressure measurement uncertainty is 0.38 mmHg, voltage uncertainty is 0.1 mV, pulse measurement uncertainty is 1 bpm and SpO<sub>2</sub> measurement uncertainty is given in the tables.

Other factors that simulators are capable of measuring are...

- i. Temperature
- ii. Cardiac Output
- iii. Fetal Heart Rate (FHR)

## 6. Defibrillators/ Pacemaker Analyzers

Are critical resuscitation devices that apply an electric charge (Q) or current (I), voltage (V) and energy (J) to the heart to restore a normal heartbeat. If the heart rhythm stops due to cardiac arrest, also known as sudden cardiac arrest (SCA). Some implantable or wearable defibrillators can also correct certain dangerous arrhythmia, which are problems with the rate or rhythm of your heartbeat. Hospitals and medical centers must ensure that their critical medical devices are **safe, accurate, dependable, and operational** at the required level of performance.

The use of reliable defibrillators has led to more effective treatments and improved patient safety through better control and management of complications during Cardiopulmonary Resuscitation (CPR).

### 6.1 Defibrillator Voltage, Current, and Joules

When it comes to defibrillators, the parameters measured are **voltage, current** and **joules**. In defibrillation, joules (J) represent the amount of energy delivered to a patient's heart from a shock. For instance, an adult patient would receive a shock with more joules than a pediatric patient would. Voltage measured (V), determines the strength of the shock from an Automated External Defibrillator or Automatic Electronic Defibrillator (AED) and we take measurements in joules.

The higher the voltage, the greater the capacity to push electric charges through a circuit. A **current (A)** is the rate at which electric charges move in a circuit, or the flow of energy. In the context of defibrillation,

joules represent the energy of the shock, voltage is the intensity or “push” of the shock, and current is the actual flow of electric charges during defibrillation, working together to restore the heart to its normal rhythm (*sinus rhythm*) from the abnormal rhythm (*sinus arrhythmia*).

#### 6.1.1 Importance of Defibrillator Voltage

Most Automated External Defibrillator or Automatic Electronic Defibrillator (AEDs) have a fixed number of joules they will deliver to the patient when a shock is advised. Typically, their energy level is somewhere **between 120-360 joules**. For instance, the capacitor in the Avive connects AED stores 2,000 V so that it can deliver a 150-joule shock to an adult patient and a 50-joule shock to a pediatric patient.

Advanced life support (ALS) defibrillators are designed for use by medical professionals because the joules in each shock can be manually adjusted depending upon varied factors that can be assessed through analyzing an *electrocardiogram (ECG or EKG)* and considering patient specifics. Public access AEDs do not have this feature, because they are designed for use by untrained bystanders.

Biphasic (double phased) shocks of **150 joules** are just as effective in restoring a heart rhythm as higher energy shocks, and they typically cause less harm to the patient *because* there is less energy being administered. All modern AEDs deliver Biphasic (double phased), shocks which allow for a safe, effective shock via lower energy levels.





Figure 25: Defibrillator/Transcutaneous Pacer Analyzer (Reference Standard)



Figure 27: Defibrillator/Monitor



Figure 26: Defibrillator/Pacemaker Analyzer (UUT)



Figure 28: Defibrillator Analyzer variable load module.



Figure 29: Calibration set of Standard Reference and UUT Defibrillators with charge pads and load module and a laptop.

## 6.2 Types of defibrillators

### 6.2.1 Automated external defibrillators (AEDs)

They are found in many public spaces. They can save the lives of people who are in cardiac arrest. The unit tells the operator what to do. Even untrained people can use an AED in an emergency. Healthcare providers sometimes recommend keeping an AED at home if someone has an elevated risk for cardiac arrest.



Figure 30: Automated external defibrillators (AEDs)\_0



Figure 31: Automated external defibrillators (AEDs)\_1

### 6.2.2 Implanted cardioverter defibrillators (ICDs)

Are small devices surgically placed on chest. They are preprogrammed to automatically detect cardiac arrest or a life-threatening **arrhythmia**. They then send a high-energy electric charge to stop the arrhythmia or restart the heart after cardiac arrest. Some ICDs also function as **pacemakers** by giving low-energy electrical pulses to help the heartbeat at a normal rhythm. Others can send pulses of electricity to synchronize the rhythm of the heart's lower chambers.

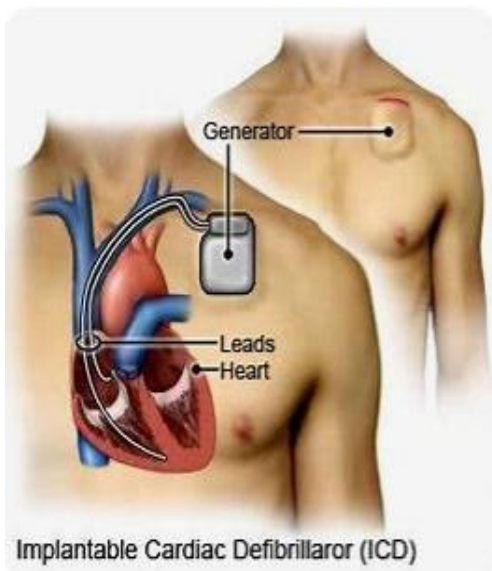


Figure 32: Implanted cardioverter defibrillators (ICDs)



Figure 33: Implanted cardioverter defibrillators (ICDs)



Figure 34: Implanted cardioverter defibrillators (ICDs)

### 6.2.3 Wearable cardioverter defibrillators (WCDs)

Are vests with a rechargeable battery. Like the ICD, they automatically detect a life-threatening rhythm and send an electrical charge to restore a normal rhythm. WCDs are usually for short-term use.



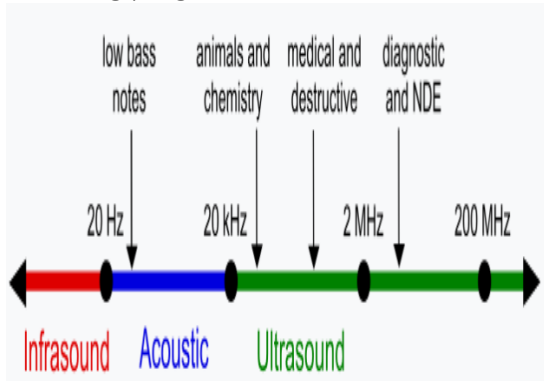
Figure 35: Wearable cardioverter defibrillators (WCDs)



## 7. Ultrasound and Ultrasonic Power

### 7.1 Ultrasound

Ultrasound wave frequencies typically range from 20 kHz to several gigahertz (GHz), i.e.,  $f > 20\text{kHz}$ . In medical imaging, common frequencies are between (1 – 20) MHz. Ultrasound is a medical imaging technique that uses high-frequency sound waves to create visual images of organs, tissues, and other structures inside the body. It is used by health professionals in prenatal monitoring, assessing heart conditions, and guiding certain medical procedures. Unlike X-rays, ultrasound does not use ionizing radiation, making it a safer option for patients, including pregnant women.



#### 7.1.1 Measurement and determination of sound speed, attenuation coefficient, acoustic Impedance, and density in Human tissue through mimicking materials – Phantoms.

**Phantoms** - In ultrasound, phantoms are specially designed objects that simulate or mimics human tissue properties and can help in evaluating the performance of ultrasound equipment or training practitioners in ultrasound imaging techniques. These are models or representations used for calibration, training, or research work. In this research work, we used varied materials such as:



Figure 36: Agar Phantom



Figure 37: Muscle Phantom



Figure 38: Zerdine Phantom

## A. Sound Speed Measurements

In this experiment we utilized the following equipment.

- Oscilloscope (Up to 70MHz capacity)
- Ultrasonic probe with an operating frequency of 1MHz.
- Signal (Frequency) Generator
- Phantom (Different types – Agar, Muscle and Zerdine)

We used a pulse-echo method to determine and measure the speed of sound in different phantoms above in figures 39, 40 and 41. Using an ultrasonic probe with an operating frequency of 1MHz (an NDT Systems Immersion Ultrasonic Transducer). We use the bellow equation 2 to determine the speed.

$$V = \frac{x}{t} \text{ms}^{-1} \dots\dots\dots \text{Equation 2}$$

$$x = 2d \dots\dots\dots \text{Equation 3}$$

$d$  = Distance from the probe to the base of the phantom.

$X$  = One complete cycle distance.

## B. Attenuation Coefficient Measurements and Calculations

Involves the use of two ultrasonic transducers working at the same frequencies, placed parallel to one another on the opposite surface sides of the sample phantom. We observed that the amplitude of the signal reaching the receiver transducer decreased exponentially. Using the bellow equations 3 and 4, we obtained the attenuation coefficient as.

$$I = I_0 e^{-\mu x} \dots\dots\dots \text{Equation 4}$$

$$\mu = -\frac{1}{2} \ln\left(\frac{I}{I_0}\right) \dots\dots\dots \text{Equation 5}$$

$$x = 2d \dots\dots\dots \text{Equation 6}$$

$I$  = Final amplitude  
 $I_0$  = Initial amplitude  
 $\mu$  = Attenuation coefficient

## C. Acoustic Impedance Measurements Calculations.

We calculated the acoustic impedance using the bellow equation 5.

$$z = \rho c \dots\dots\dots \text{Equation 7}$$

Where;  $z$  = *Acoustic impedance*

$(\text{Kg}/\text{m}^2 \cdot \text{s})$

$\rho$  = *Density of the phantom*

$(\text{Kg}/\text{m}^3)$

$c$  = *Speed of sound (m/s)*

## D. Density Measurements

Density is the ratio of the mass to volume of an object. The volume of each object cube is initially determined by Archimedes principle, which states that, “An object fully or partially submerged in a fluid experience an upward buoyant force equal to the weight of the fluid that the object displaces.”

We weighed the mass of the phantom object and measured the volume of the displaced distilled water by the same phantom object, and we calculated the density using the below equation 8.

$$\rho = \frac{M}{V} \dots\dots\dots \text{Equation 8}$$

$\rho$  = *Density of phantom (Kg/m<sup>3</sup>)*

$M$  = *Mass of phantom (Kg)*

$V$  = *Volume of phantom (m<sup>3</sup>)*

## 7.2 Ultrasonic Power

The amount of **energy** delivered by ultrasonic waves per unit of time, typically measured in **watts (W)**. Ultrasonic waves are sound waves with frequencies above the range of human hearing (typically above 20 kHz) and are used in applications that involve precise energy transfer, such as cleaning, medical imaging, and industrial processes.



Figure 39: Ultrasonic Power in use.



Figure 40: Ultrasonic in Use

In applications:

### 7.2.2 Medical and Therapeutic Uses

In medical devices, ultrasonic power helps create detailed images (ultrasound) by emitting high-frequency waves and measuring how they reflect off tissues. Therapeutic ultrasound, for instance, uses

controlled ultrasonic power to treat injuries by increasing blood flow and tissue heating.

### 7.2.3 Ultrasonic Cleaning:

In ultrasonic cleaners, ultrasonic power is used to create microscopic bubbles in a liquid through a process called **cavitation**. When these bubbles collapse, they produce tiny shock waves that dislodge dirt and contaminants from surfaces like jewelry, metals, and delicate instruments.

### 7.2.4 Material Processing and Sonochemistry

Ultrasonic power is applicable in processes such as welding plastics, dispersing nanoparticles, or in chemical reactions to increase reaction rates (sonochemistry). The high-intensity sound waves create rapid vibrations, which can help in breaking down materials or mixing substances effectively.

***NB:** The strength of ultrasonic power applied in any device or process influences the intensity of the effect, with higher power leading to stronger ultrasonic effects but also **increased heating** and potential **wear on materials**.*

## 7.3 Factors and key parameters considered when measuring Ultrasonic power.

When analyzing ultrasonic power, key parameters considered to ensure accurate, effective, and safe application of ultrasound in various fields include:

### 7.3.2 Frequency: Measured in kilohertz (kHz) or megahertz (MHz)

Frequency determines the energy and penetration depth of the ultrasound waves. Lower frequencies (20-100 kHz) are used in industrial applications (e.g., cleaning, welding), while higher frequencies (1-15 MHz) are used in medical imaging.

### 7.3.3 Power Output (Wattage)

This is the amount of energy delivered by the ultrasonic device, usually measured in watts

(W). Power output affects the intensity of ultrasonic waves and is crucial for controlling the effectiveness of processes like cleaning, sonochemistry, or therapeutic treatments.

### **7.3.3 Intensity**

Ultrasonic intensity is the power per unit area, typically expressed in watts per square centimeter ( $\text{W}/\text{cm}^2$ ). It affects how ultrasound energy interacts with materials, with higher intensities leading to stronger effects, such as deeper heating or more aggressive cleaning.

### **7.3.4 Duty Cycle**

In pulsed ultrasound applications, the duty cycle is the percentage of time the ultrasound is actively "on" during a treatment cycle. It is essential in controlling the thermal effects of ultrasound, especially in therapeutic applications where tissue overheating must be avoided.

### **7.3.5 Amplitude**

This is the peak displacement or pressure variation of the ultrasound waves, measured in microns or decibels. Higher amplitude increases the power delivered to the medium, enhancing effects like cavitation (useful in cleaning) but also increasing the risk of material damage.

### **7.3.6 Waveform Type**

Ultrasonic waves can be continuous or pulsed. Continuous waves deliver a steady output, while pulsed waves provide intermittent energy. Pulsed waves help manage heat buildup in therapeutic or sensitive applications.

### **7.3.7 Temperature**

The temperature of the medium or surrounding area can affect the efficiency of ultrasound. For example, in sonochemistry, temperature control is essential because temperature changes can alter reaction rates and cavitation effects.

### **7.3.8 Cavitation Threshold**

In applications that use cavitation (e.g., cleaning or sonochemistry), the cavitation threshold is the minimum intensity needed to produce cavitation bubbles in the medium. This threshold depends on factors like frequency, medium composition, and temperature.

### **7.3.9 Impedance Matching**

To optimize power transfer from the ultrasonic transducer to the medium, impedance matching is used to reduce energy loss. Proper matching ensures efficient transmission of ultrasonic waves and reduces unwanted reflections.

## **7.4 Beam Profile**

The shape and distribution of the ultrasound beam (e.g., focused, unfocused) determines the area affected by the ultrasonic energy. Focused beams concentrate power in a small area, while unfocused beams cover a larger area with lower intensity.

## Conclusions and Future Work

CIPM - MRA Training - During my UME training, I had the privilege of receiving additional instruction from BIPM representatives concerning the CIPM MRA and its significance in the field of metrology. I gained insights into the origins of the CIPM MRA, its launch rationale, and its overarching functions and objectives.

This encompassed a comprehensive understanding of how a National Metrology Institute (**NMI**) can engage in comparisons within the CIPM MRA framework, ensuring the publication of its calibration measurement capabilities (**CMCs**) in the **BIPM** key comparison database (**KCDB**). Further, I delved into the procedural aspects, including the requisite peer reviews—namely, intra-regional assessments and inter-regional reviews conducted by the Joint Committee for Traceability in Metrology (**JCRB**).

Additionally, it became evident that CIPM MRA frameworks mandate NMIs to establish and sustain a quality management system (**QMS**). CIPM MRA entrusts the approval and ongoing monitoring of this **QMS** to the respective regional metrology organizations (**RMOs**). The speakers and trainers also emphasized the paramount importance of maintaining metrological traceability and the strategies employed to uphold it. This

training has been very instrumental in shaping my understanding of medical metrology, measurement, and calibration. I have gained the requisite knowledge required to transform our measurement capability at **KEBS** to a globally recognized level. The ties I made at the Laboratory are promising and I look forward to fostering the relationship between our laboratory and **TÜBİTAK UME**'s laboratories with the aim of improving our capabilities.

I was able to not only achieve my intended technical objectives, but also gained important management and research and development skills. I was overly impressed by the dedication and the work ethic of the team at TÜBİTAK UME. Throughout the period I was there, the team was engaged in various Research Projects that they worked tirelessly on. They put in extra hours and produced innovative ways of dealing with the challenges faced.

The team had custom made solutions that suited their applications perfectly. These are things that I hope to take back with me. Soon, we hope to increase our accreditation scope to include all the measurands covered during the placement project. The process is at its infant stage, and we hope to expand it within the next few years going forward.

## Acknowledgements

The training has been instrumental in advancing my understanding of Medical Metrology. I acquired essential knowledge needed to elevate **KEBS's** measurement capabilities to global standards. I am profoundly grateful to the government of **Kenya**, our NMI, KEBS CEO **Madam Esther NGARI**, the Director of Metrology and Testing **Dr. Henry ROTICH**, and my HOL, **Mr. George MASWAI**, for both their unwavering support and strong belief on me throughout my three-month research period from the initial stages of application. Thank you my wonderful familiy. *Asanteni sana!*

I cherish the time spent in Türkiye and the invaluable knowledge I gained, which is not only beneficial to me but to Kenya as well. My heartfelt thanks go to the incredible team at TÜBİTAK UME Medical Laboratories, led by **Assoc. Prof. Dr. Baki KARABÖCE**, **Dr. Hüseyin Okan DURMUŞ**, **Mr. Gökhan GÜLER**, and **Madam Elif BAŞARAN**. You are such a wonderful team that went beyond to guide me through each concept, often sacrificing your time to ensure the success of my research project. Your hospitality was exceptional, far exceedingly massive. I am sincerely grateful to you all.

The relationship I built at the TÜBİTAK UME Laboratory holds great. I also extend my thanks to the **Turkish Government**, through TÜBİTAK UME Deputy Director **Assoc. Prof. Dr. Mustafa ÇETİNTAŞ**, the entire management, and staff of TÜBİTAK UME, for accepting and facilitating this unique opportunity.

This training is crucial in helping develop metrology and enhancing capacity building globally. I am particularly grateful to the program coordinator -

**Dr. Enver SADIKOĞLU**, the International Liaisons Office, **Madam Atam MÜGE**, **Mr. Mehmet EKINCI**, and everyone in that office for providing exceptional support from our arrival to our departure.

Their dedication inspires hope for the future of young metrologists worldwide. *Hepinizi selamlıyorum, güzel insanlar!*

My gratitude also goes to BIPM, led by **Mr. Chingis KUANBAYEV** and **Mr. Anderson MAINA**, for granting us with the research opportunity as the Cycle 7, 2024 cohort. We deeply appreciate this opportunity and are committed to applying the knowledge gained in our respective NMIs. Thank you as well for the CIPM MRA training, it was invaluable. *Merci beaucoup!*

Finally, I thank God for enabling us a healthy life to seize this opportunity and complete it successfully. Throughout the training, I did not only achieve my technical goals but also gained invaluable soft skills geared towards my career growth. The TÜBİTAK UME team's dedication and work ethic left an impression on my way of thinking and action.

Throughout my time here, they were deeply engaged in research projects, consistently going an extra mile to produce innovative solutions for the challenges they faced. Their custom-made approaches tailored perfectly to their applications, insights I plan to bring back to my home **NMI-KEBS**. We are now in the initial stages of expanding our accreditation scope to cover all measurands from this project, and we hope to progress significantly in the coming years with the main goal being good health provision to the Kenyan people. *Thank you all and be blessed!*