BIPM Capacity Building & Knowledge Transfer Programme

2025 BIPM - TÜBİTAK UME Project Placement

REPORT

Project Name	Studies of measurements parameters of critical medical devices and definition of the ultrasound power standard
Description	Reliability in medical measurements and medical device calibrations has a direct impact on treatment processes. Medical device calibration and test are one of the important and critical issues in the field of metrology. The approach of traceability in medical devices and measurements is not as strong as in other areas of metrology. Ultrasound has many applications in diagnostics and therapy. The development of the mentioned directions is in the interest of the Azerbaijan Institute of Metrology and newly established the related systems. This project will increase the staff capacity of the laboratory.
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Motivation & Introduction

Being accepted for an internship at the Medical Metrology Laboratory of TÜBİTAK UME is a highly significant opportunity for me in terms of both scientific and professional development. One of the main factors that increases the value of this experience is the extensive work Azerbaijan has been carrying out in recent years to strengthen its national metrology system. Our country is taking serious steps to improve national measurement standards, align calibration procedures with international requirements, and ensure the reliability and traceability of measurement results. At such an important stage, completing an internship at TÜBİTAK UME—one of the leading institutions in this field worldwide—offers me the chance to gain firsthand experience with the most advanced technologies, cutting-edge methodologies, and internationally recognized professional practices. I am eager to apply this knowledge and these skills in the future to contribute to the development of Azerbaijan's metrology infrastructure.

Furthermore, medical metrology is a highly specialized and critically important field for any healthcare system. The accuracy of measurements performed with medical devices directly influences the correctness of diagnoses, the effectiveness of treatment decisions, and, ultimately, overall patient safety. In Azerbaijan, increasing the quality of medical services, ensuring that healthcare institutions use equipment compliant with international standards, and improving the reliability of measurement systems are among the national priorities. Therefore, acquiring skills such as medical device calibration, measurement uncertainty evaluation, and performance assessment of measurement systems is extremely valuable—not only for my personal career growth but also for the advancement of this field in my country.

This internship will not only allow me to apply my theoretical knowledge in a real laboratory environment but will also help me gain international collaboration experience, laying a strong foundation for my future work in metrology on a broader scale.

Project methodology

The research aimed to acquire and enhance both theoretical and practical knowledge in the field of medical metrology. This involved developing the ability to perform accurate measurements and calibrations of medical equipment, as well as understanding how these devices operate under various environmental and functional conditions.

Another key objective was to contribute to the development of standardized procedures for medical device measurements that align with internationally recognized practices used by institutions such as BIPM–TÜBİTAK and comply with the technical requirements of the CIPM MRA. In addition, the study focused on establishing detailed and well-structured measurement uncertainty budgets for calibration processes, placing particular emphasis on identifying potential sources of uncertainty and implementing strategies to minimize their impact on measurement results.

Beyond the technical goals, the project also aimed to support professional development by fostering collaboration and building strong networks, thereby promoting innovation and advancement in sectors such as manufacturing, healthcare, education.

1. Calibration System for Medical Ultrasound Systems

The ultrasonic power emitted by an ultrasonic transducer is an important measurand characterizing the strength of ultrasonic field. Ultrasound has a wide usage in medical applications, non-destructive testing, underwater acoustical measurements, cleaning and monitoring.

Figure 1. Ultrasonic power measurement device

- Two ultrasonic transducers (labeled UME-LNB1M and UME-LNB5M) were fabricated using lithium niobate ($LiNbO_3$) crystals. These were housed in stainless-steel enclosures, designed to operate at fundamental and overtone frequencies to allow resolution of multiple harmonics.
- The measurement system uses the radiation force balance method recommended by the international standard IEC 61161.
- Measurements were done in water (to simulate acoustic propagation in tissue — given that human body is ≈ 65% water).
- The system components include a high-precision balance to detect force induced by ultrasound on an absorbing target submerged in water, a signal generator, a power amplifier, and a voltage measurement setup using a thermal converter + DC voltage calibrator.
- Resonance frequencies were determined by scanning around nominal crystal frequencies, acknowledging that actual resonance might shift; for example, fundamental and odd harmonics were identified (e.g. 0.9322 MHz fundamental, 3.1423 MHz third harmonic, 4.6720 MHz for the second transducer).

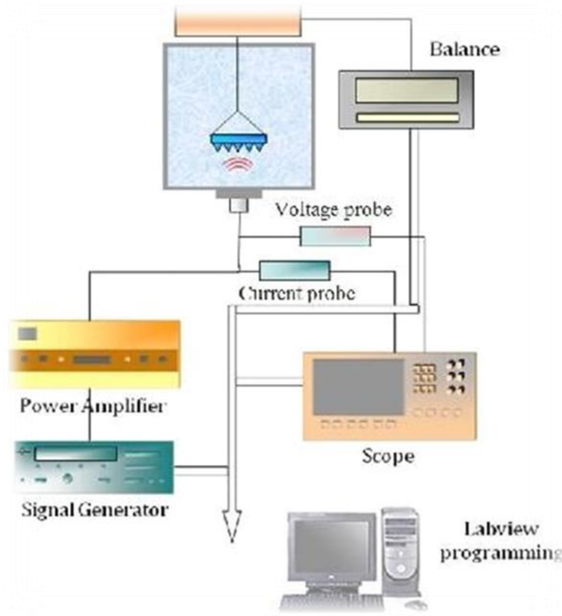

Figure 2. Ultrasonic power measurement device scheme

Calculations:

Ultrasonic power for an ideal absorbing target,

$$P = c \times F = c \times m \times g$$

For an ideal reflective target, ultrasonic power,

$$P = \frac{c \times F}{2\,cos^2\alpha} = \frac{c \times m \times g}{2\,cos^2\alpha}$$

c: Ultrasonic velocity (1491.19 m/s at 23 °C) [m/s]
m: Weight change measured on a precision scale [g]
g: Gravitational acceleration (9.8023 m/s^2)
a: The angle between the direction of the ultrasonic wave and the normal of the reflective target surface (45°)

Radiation Conductance

The most characteristic feature of an ultrasonic transducer is the measurement of the radiation scattering value. The radiation emission is determined by G, Eq.

$$G = \frac{P}{U^2}$$

G: Radiation emission [S]
P: Measured power [W]
U: Applied voltage [V].

2. Patient Simulator System (ECG Simulator included)

An electrocardiogram (ECG or EKG) 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.

This system is used for calibrating the patient simulator, and the calibration process is carried out with Fluke Corporation's MET/CAL software.

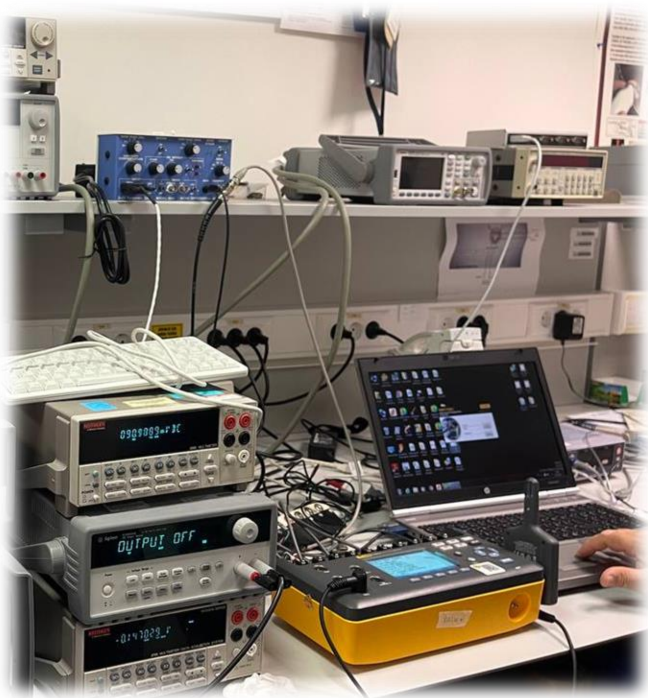

Figure 3. Patient simulator calibration system

Figure 4. Patient simulator

Calibration results:

Table 1. ECG waveform verification measurement

Reference Value (bpm)	Measured Value (bpm)	Uncertainty (bpm)	Error (%)	Tolerance (%)
30,0	30,0	1,0	0,0	± 1,0
60,0	60,0		0,0	
80,0	80,0		0,0	
90,0	90,7		0,8	
120,0	121,0		0,8	
150,0	151,0		0,7	
180,0	180,3		0,2	
210,0	210,0		0,0	
240,0	240,0		0,0	
270,0	270,0		0,0	
300,0	300,0		0,0	
320,0	319,3		-0,2	

Table 2. ECG performance verification measurement

Nominal Value (mV)	ECG Derivation	Percentage Rate	Reference Value (mV)	Measured Value (mV)	Uncertainty (mV)	Error (%)	Tolerance (%)
1	Lead I	70	0,70	0,71	0,02	1,4	± 5,0 (Lead II ayarı için)
1	Lead II	100	1,00	1,01		1,0	
1	Lead III	30	0,30	0,30		0,0	
1	Lead V1	24	0,24	0,25		4,2	
1	Lead V2	48	0,48	0,50		4,2	
1	Lead V3	100	1,00	1,02		2,0	
1	Lead V4	120	1,20	1,21		0,8	
1	Lead V5	112	1,12	1,15		2,7	
1	Lead V6	80	0,80	0,82		2,5	

Table 3. SpO_2 measurement using nellcor

Reference Value (% SpO_2)	Measured Value (% SpO_2)	Uncertainty (% SpO_2)	Absolute Difference (% SpO_2)	Tolerance (% SpO_2)
70,0	69,7	1,7	0,3	± 3,0*
75,0	74,7	1,7	0,3	
80,0	80,0	1,7	0	
85,0	85,0	1,8	0	
90,0	90,0	1,9	0	
95,0	95,0	2,0	0	
97,0	97,0	2,0	0	
98,0	98,0	2,0	0	
99,0	99,0	2,1	0	
100,0	100,0	2,1	0	

Table 4. Pulse control measurement using nellcor

Reference Value (bpm)	Measured Value (bpm)	Uncertainty (bpm)	Absolute Difference (bpm)	Tolerance (bpm)
30,0	30,0	1,1	0,0	± 1,0
60,0	60,0	1,9	0,0	
80,0	80,0	2,5	0,0	
100,0	100,0	3,1	0,0	
120,0	120,0	3,6	0,0	
150,0	150,0	4,5	0,0	
180,0	179,7	5,5	0,3	
240,0	239,7	7,3	0,3	

Table 5. SpO_2 measurement using masimo radical 7

Reference Value (% SpO_2)	Measured Value (% SpO_2)	Uncertainty (% SpO_2)	Absolute Difference (% SpO_2)	Tolerance (% SpO_2)
70,0	69,0	1,5	1,0	± 3,0*
75,0	75,0	1,6	0,0	
80,0	80,0	1,7	0,0	
85,0	85,0	1,8	0,0	
90,0	90,0	1,9	0,0	
95,0	95,0	2,0	0,0	
97,0	97,0	2,0	0,0	
98,0	98,0	2,0	0,0	
99,0	99,0	2,1	0,0	
100,0	100,0	2,1	0,0	

Table 6. Pulse control measurement using masimo radical 7

Reference Value (bpm)	Measured Value (bpm)	Uncertainty (bpm)	Absolute Difference (bpm)	Tolerance (bpm)
30,0	30,0	1,1	0,0	± 1,0
60,0	60,0	1,9	0,0	
80,0	80,0	2,5	0,0	
100,0	100,0	3,1	0,0	
120,0	120,0	3,6	0,0	
150,0	150,0	4,5	0,0	
180,0	180,0	5,4	0,0	
240,0	240,0	7,2	0,0	

Table 7. Manometer pressure measurement

Reference Value (mmHg)	Measured Value (mmHg)	Uncertainty (mmHg)	Error (%)	Tolerance
10,0	10,5	0,2	5,0	± (1% of reading + 1 mmHg)
25,0	25,7		2,8	
50,0	50,8		1,6	
75,0	75,6		0,8	
100,0	100,6		0,6	
200,0	200,3		0,2	
300,0	300,1		0,0	
400,0	400,0		0,0	
300,0	300,0		0,0	
200,0	200,3		0,2	
100,0	100,6		0,6	
50,0	50,6		1,2	
25,0	25,7		2,8	

Table 8. Direct pressure measurement

Reference Value (mmHg)	**Measured Value (mmHg)**	**Uncertainty (mmHg)**	**Error (%)**	**Tolerance**
0,0	0,0	0,2	0,00	± (1% of reading + 1 mmHg)
80,0	80,6		0,75	
160,0	160,5		0,31	
250,0	250,1		0,04	

3. Gas flow analyzer system (Anesthetic agent and oxygen analyzer included)

A gas flow analyzer is a tool that measures and analyzes the flow rate, volume, pressure, and sometimes the composition of a gas. These devices are crucial for testing, calibrating, and maintaining medical equipment like ventilators, anesthesia machines, and other respiratory devices to ensure they function correctly and safely.

Figure 5. Gas flow analyzer

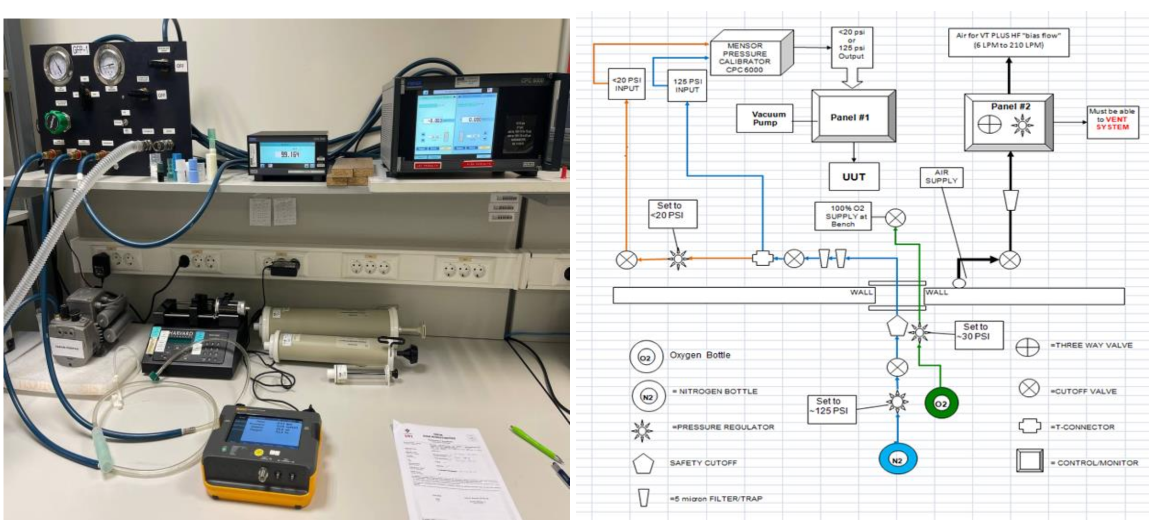

Figure 6. Gas flow analyzer calibration system and scheme

Calibration results:

Table 9. Flow measurement

Reference Flow (LPM)	Measured Flow (LPM)	Uncertainty (LPM)	Error (%)	Tolerance (%)
2,00	2,00	0,1	0.00	± 1,9
5,00	4,93	0,1	-1.33	
8,00	8,00	0,1	0.00	
10,00	10,00	0,1	0.00	
20,00	19,80	0,2	-1.00	
30,00	30,00	0,3	0.00	
40,00	40,00	0,4	0,00	
50,00	50,37	0,5	0,73	
60,00	60,43	0,5	0,72	
70,00	70,57	0,6	0,81	
80,00	80,67	0,7	0,83	
90,00	91,33	0,8	1,48	
100,00	100,87	0,8	0,87	
125,00	126,10	1,0	0,88	
150,00	151,23	1,3	0,82	
200,00	201,97	1,6	0,98	
250,00	252,43	2,0	0,97	

Table 10. High pressure measurement

Reference Pressure (bar)	Measured Pressure (bar)	Uncertainty (bar)	Error (%)	Tolerance (%)
1,00	1,00	0,02	0,27	± 1,0
2,00	2,00		0,02	
3,00	3,00		-0,03	
4,00	4,00		-0,07	
5,00	5,00		-0,07	
6,00	5,99		-0,09	
7,00	6,99		-0,11	
8,00	7,99		-0,11	
9,00	8,99		-0,12	
9.90	9,89		-0,12	

Table 11. Pressure measurement in the flow channel

Reference Pressure (mbar)	Measured Pressure (mbar)	Uncertainty (mbar)	Error (%)	Tolerance (%)
-50,00	-49,80	0,8	-0,41	± 0,75
-30,00	-29,96		-0,13	
-15,00	-14,98		-0,13	
-5,00	-5,01		0,20	
5,00	5,01		0,20	
10,00	10,06		0,60	
25,00	25,07		0,28	
50,00	50,07		0,13	
100,00	100,05		0,05	
125,00	125,18		0,14	
137,00	137,29		0,21	

Table 12. Differential pressure measurement (1st channel (left side) open, 2nd channel pressurized)

Reference Pressure (mbar)	Measured Pressure (mbar)	Uncertainty (mbar)	Error (%)	Tolerance (%)
5,00	5,03	0,8	0,67	± 0,75
10,00	10,03		0,30	
20,00	20,04		0,20	
50,00	50,02		0,04	
100,00	100,03		0,03	
150,00	150,36		0,24	
200,00	199,97		-0,01	

Table 13. Differential pressure measurement (channel 1 pressurized, channel 2 (right side) open)

Reference Pressure (mbar)	Measured Pressure (mbar)	Uncertainty (mbar)	Error (%)	Tolerance (%)
5,00	4,99	0,8	-0,13	± 0,75
10,00	10,00		0,03	
20,00	20,01		0,07	
50,00	49,92		-0,15	

100,00	100,13		0,13	
150,00	150,57		0,38	
200,00	200,00		0,00	

Table 14. Differential pressure measurement in vacuum (1st channel (left side) open, 2nd channel pressurized)

Reference Pressure (mbar)	Measured Pressure (mbar)	Uncertainty (mbar)	Error (%)	Tolerance (%)
-5,00	-5,03	0,8	0,53	± 0,75
-10,00	-10,05		0,53	
-20,00	-20,00		0,02	
-50,00	-49,86		-0,27	
-100,00	-100,09		0,09	
-137,00	-137,34		0,25	

Table 15. Differential pressure measurement in vacuum (channel 1 pressurized, channel 2 (right side) open)

Reference Pressure (mbar)	Measured Pressure (mbar)	Uncertainty (mbar)	Error (%)	Tolerance (%)
-5,00	-5,03	0,8	0,60	± 0,75
-10,00	-10,02		0,17	
-20,00	-20,02		0,08	
-50,00	-50,04		0,08	
-100,00	-99,96		-0,04	
-137,00	-137,11		0,08	

Table 16. Volume measurement

Reference Volume (mL)	Measured Volume (mL)	Uncertainty (mL)	Error (%)	Tolerance (%)
100,00	100,90	0,9	0,90	± 2,0
1000,00	1006,30	7,9	0,63	
3000,00	3003,40	25,8	0,11	

Table 17. Oxygen (O_2%) Measurement

Reference Oxygen	Measured Oxygen	Uncertainty (%)	Error (%)	Tolerance (%)
%21,0	%21,0	1,0	0,0	± % 1
%100,0	%100,0	1,0	0,0	

Table 18. Atmospheric pressure measurement

Reference Atmospheric Pressure (mbar)	Measured Atmospheric Pressure (mbar)	Uncertainty (%)	Error (%)	Tolerance
982,35	984,00	1,0	0,17	± % 1

4. Electrosurgery Analyzer System

Electrosurgery - uses high-frequency electrical current to cut tissue, stop bleeding, or destroy abnormal tissue by generating heat. A healthcare provider directs the electricity to a surgical site using an active electrode, while a return electrode ensures the current completes a circuit, controlling the effects based on the waveform, power, and technique. This method is versatile, commonly used in various surgical specialities, and distinct from electrocautery, where heat is generated on the electrode tip itself.

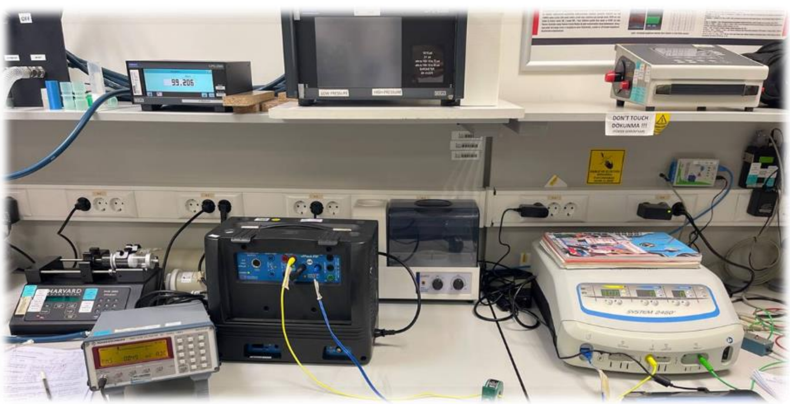

Figure 7. Electrosurgery analyzer system

Monopolar coagulation is a surgical technique using a high-frequency electrical current to stop bleeding by sealing blood vessels. In this method, a single active electrode held by the surgeon delivers the current to the target tissue, which travels through the patient's body to a separate grounding pad placed on the skin, completing the circuit. The high concentration of current at the tip of the active electrode heats and coagulates the tissue, with the effect becoming deeper when the energy is applied for longer periods.

Bipolar coagulation is a surgical technique that uses an electrical current to stop bleeding by coagulating blood vessels. It works by passing the current between the two tips of a special forceps, so it only flows through the tissue held between them. This makes it a precise method that limits damage to surrounding areas compared to monopolar coagulation, which requires a grounding pad.

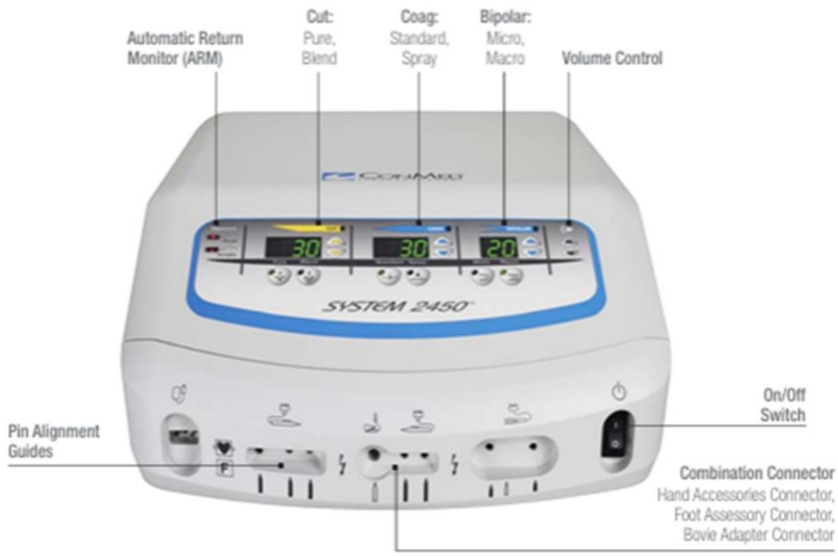

Figure 8. Electrosurgical device

Calibration results:

Table 19. Fixed and variable resistance measurement

Exit	Reference resistance Ω	Measured resistance Ω	Error %	Tolerance
Fixed Resistance	200,0	200,0	0,0	± % 5
Variable Resistor	10,0	10,2	1,3	
	50,0	50,2	0,3	
	100,0	100,1	0,1	
	150,0	150,0	0,0	
	200,0	200,1	0,0	
	300,0	299,9	-0,0	
	500,0	499,7	-0,0	
	750,0	749,5	-0,1	
	1000,0	997,0	-0,3	
	1500,0	1496,4	-0,2	
	2000,0	1998,7	-0,1	

Table 20. Monopolar cut current and power measurement

Load resistance Ω	Applied power W	Reference current mA	Calculated power W	Measured current mA	Measured power W	Current Error %	Tolerance (current)
10,0	120,0	1010,0	10,4	996,0	10,0	-1,4	± % 5
50,0	120,0	994,5	49,6	979,0	48,0	-1,6	
100,0	120,0	974,7	95,1	973,0	94,7	-0,2	
150,0	120,0	920,0	127,0	891,0	119,0	-3,2	
200,0	120,0	771,3	119,0	769,0	118,0	-0,3	
300,0	120,0	634,1	120,6	631,0	119,0	-0,5	
500,0	120,0	494,2	122,0	486,0	118,0	-1,7	

750,0	120,0	413,5	128,1	404,0	122,0	-2,3	
1000,0	120,0	353,0	124,2	345,0	119,0	-2,3	
1500,0	120,0	246,1	90,6	237,0	84,3	-3,7	
2000,0	120,0	182,1	66,3	174,0	60,3	-4,5	

Table 21. Monopolar cut power measurement uncertainty

Load resistance Ω	**Reference current mA**	**Measured power W**	**Uncertainty W**
10,0	1010,0	10,0	1,2
50,0	994,5	48,0	1,2
100,0	974,7	94,7	1,1
150,0	920,0	119,0	1,0
200,0	771,3	118,0	0,8
300,0	634,1	119,0	0,6
500,0	494,2	118,0	0,4
750,0	413,5	122,0	0,4
1000,0	353,0	119,0	0,4
1500,0	246,1	84,3	0,3
2000,0	182,1	60,3	0,3

Table 22. Monopolar coagulation current and power measurement

Load resistance Ω	**Applied power W**	**Reference current mA**	**Calculated power W**	**Measured current mA**	**Measured power W**	**Current Error %**	**Tolerance (current)**
10,0	120,0	651,8	4,3	642,0	4,2	-1,5	± % 5
50,0	120,0	642,8	20,7	633,0	20,0	-1,5	
100,0	120,0	631,5	39,9	621,0	38,6	-1,7	
150,0	120,0	620,1	57,7	610,0	55,7	-1,6	
200,0	120,0	609,4	74,3	599,0	71,7	-1,7	
300,0	120,0	588,0	103,7	582,0	102,0	-1,0	
500,0	120,0	491,0	120,5	480,0	115,0	-2,2	
750,0	120,0	412,7	127,7	401,0	120,0	-2,8	
1000,0	120,0	351,1	122,9	341,0	116,0	-2,9	
1500,0	120,0	296,6	131,6	284,0	120,0	-4,3	
2000,0	120,0	256,0	131,0	244,0	119,0	-4,7	

Table 23. Monopolar coagulation power measurement uncertainty

Load resistance Ω	Reference current mA	Measured power W	Uncertainty W
10,0	651,8	4,2	0,6
50,0	642,8	20,0	0,6
100,0	631,5	38,6	0,5
150,0	620,1	55,7	0,5
200,0	609,4	71,7	0,5
300,0	588,0	102,0	0,5
500,0	491,0	115,0	0,4
750,0	412,7	120,0	0,4
1000,0	351,1	116,0	0,4
1500,0	296,6	120,0	0,4
2000,0	256,0	119,0	0,4

Table 24. Bipolar coagulation current and power measurement

Load resistance Ω	Applied power W	Reference current mA	Calculated power W	Measured current mA	Measured power W	Current Error %	Tolerance (current)
20,0	50,0	1078,0	11,8	1065,0	11,4	-1,2	± % 5
50,0	50,0	993,0	49,5	994,0	49,4	0,1	
100,0	50,0	709,9	50,4	710,0	50,4	0,0	
150,0	50,0	493,1	36,5	488,0	35,6	-1,0	
200,0	50,0	374,7	28,1	370,0	27,4	-1,3	
300,0	50,0	253,8	19,3	250,0	18,8	-1,5	
500,0	50,0	153,4	11,8	149,0	11,1	-2,9	
750,0	50,0	104,2	8,1	102,0	7,9	-2,1	
1000,0	50,0	77,18	5,9	75,0	5,6	-2,8	
1500,0	50,0	53,1	4,2	51,0	3,9	-4,0	
2000,0	50,0	39,9	3,2	38,0	2,9	-4,8	

Table 25. Bipolar coagulation power measurement uncertainty

Load resistance Ω	Reference current mA	Measured power W	Uncertainty W
10,0	1078,0	11,4	1,4
50,0	993,0	49,4	1,2
100,0	709,9	50,4	0,7
150,0	493,1	35,6	0,4
200,0	374,7	27,4	0,3
300,0	253,8	18,8	0,2

500,0	153,4	11,1	0,2
750,0	104,2	7,9	0,1
1000,0	77,2	5,6	0,1
1500,0	53,1	3,9	0,1
2000,0	39,9	2,9	0,1

5. Infusion Pump Analyzer System

An infusion pump is a medical device that precisely delivers fluids, medications, or nutrients into a patient's body over a specific time. Unlike manual gravity-fed IVs, pumps offer greater control and accuracy, which is crucial for administering drugs like insulin, chemotherapy, or antibiotics, as well as for providing nutrition or pain relief. These devices come in many forms, from stationary bedside pumps to portable, wearable "ambulatory" pumps.

Figure 9. Infusion Pump Analyzer System

Calibration results:

Table 26. Volume measurement

Reference Volume (mL)	Reference Flow (mL/h)	Measured Volume (mL)	Uncertainty (mL)	Tolerance
25,00	200,00	24,89	0,19	% 1 ± 1 LSD
45,00	800,00	44,37	0,33	% 2 ± 1 LSD

Table 27. Flow measurement

Reference Flow Rate (mL/h)	Reference Volume (mL)	Measured Flow Rate (mL/h)	Uncertainty (mL/h)	Tolerance
800,0	45,0	803,3	6,5	% 1 ± 1 LSD
200,0	25,0	200,4	1,7	% 2 ± 1 LSD

Table 28. Pressure measurement

Reference Pressure (psi)	Measured Pressure (psi)	Uncertainty (psi)	Tolerance
5,00	4,97	0,03	% 1 ± 1 LSD
10,00	9,99		
15,00	15,00		
20,00	19,95		
25,00	24,98		

6. Pulse Oxymetry Analyzer System (Pulse Oxymetry Simulator included)

Pulse oximetry is a quick, non-invasive medical test that uses a small clip-like device to measure the amount of oxygen in your blood, also known as oxygen saturation (SpO_2). The device shines light through a finger or earlobe and detects how much light passes through to calculate how much hemoglobin in your red blood cells is saturated with oxygen. Normal readings are typically 95–100% for healthy individuals, but it can be lower for those with lung or heart problems.

Figure 10. Pulse Oxymetry Analyzer

Calibration results:

Table 29. SpO2 Measurement Results Using Nellcor

Reference Value (% SpO2)	Measured Value (% SpO2)	Uncertainty (% SpO2)	Error (% SpO2)	Tolerance (% SpO2)
30,0	29,7	1,1	-0,3	± 3,0
50,0	49,0	1,2	-1,0	
60,0	59,7	1,6	-0,3	
70,0	69,0	1,6	-1,0	
80,0	80,0	1,9	0,0	
85,0	85,0	2,0	0,0	
90,0	90,0	2,1	0,0	
93,0	93,0	2,1	0,0	
97,0	97,0	2,2	0,0	

7. Electrical Safety Analyzer System

An electrical safety analyzer is a test instrument used to ensure electrical devices and equipment comply with safety standards by performing tests like ground continuity, insulation resistance, and leakage current measurements. These systems can range from portable, user-friendly models for on-site testing to comprehensive, automated systems for high-volume production, with many models complying with specific international and national standards like *IEC 60601-1*, *IEC 62353*, and *AAMI ES1*.

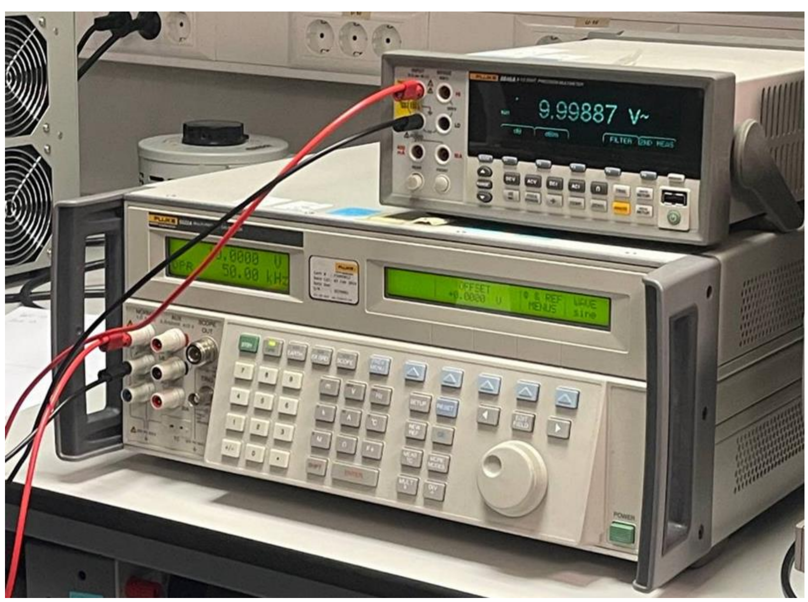

Figure 11. Calibration of a multimeter in an electrical safety system

As part of the electrical safety system, we performed the calibration of the multimeter to ensure accurate and reliable measurements, which are essential for both system functionality and human safety.

Calibration results:

Table 30. DC voltage

Measurement Range	Applied Value	Measured Value
10 V	10 V	10,00001 V
	-10 V	-10,00002 V
100 V	100 V	100,002 V

Table 31. DC current

Measurement Range	Applied Value	Measured Value
10 mA	10 mA	10,00110 mA
100 mA	100 mA	100,0036 mA

Table 32. AC voltage

Measurement Range	Applied Value	Frequency	Measured Value
100 mV	100 mV	1 kHz	100,13 mV
		50 kHz	97,28 mV
1 V	1 V	1 kHz	0,99987 V
		50 kHz	0,99902 V
10 V	10 V	1 kHz	9,99812 V
		50 kHz	9,99890 V
100 V	100 V	1 kHz	100,004 V
		50 kHz	99,883 V
300 V	300 V	1 kHz	299,972 V
		50 kHz	299,907 V

Table 33. AC current

Measurement Range	Applied Value	Frequency	Measured Value
100 mA	100 mA	1 kHz	99,994 mA

8. Defibrillator Analyzer System (Pacemaker analyzer included)

A defibrillator analyzer is a precision testing instrument used by trained technicians to ensure that defibrillators and AEDs (Automated External Defibrillators) are working correctly and meet manufacturer specifications. These analyzers measure energy output in joules, test charge time, synchronized mode operation, and can sometimes simulate ECG signals and check pacemaker functions. This process is crucial for maintaining patient safety and the reliability of life-support equipment.

As a result of the stimulation of the heart at the wrong time and the random stimulation of the stimulating signals, the heart muscles begin to contract irregularly and faster than normal. This state in which the heart enters is called “fibrillation”. If the heart can not get rid of this situation through the body's feedback control systems, these irregular contractions should be stopped and the heart should start to contract regularly. For this, a shock called "counter shock" is applied to the heart . This process is called defibrillation, and the device used is called as a defibrillator.

The defibrillator consists of an adjustable high voltage source and electrodes called spoons designed to apply this high voltage to the patient's body without harming the user. It is usually kept ready to transport to the patient's location with its rechargeable batteries and charging unit.
The device works synchronously with an EKG device that monitors the heart signals and detects the appropriate time to discharge the stored energy. This synchronization prevent the random arrival of the shock. Defibrillators, depending on their attachment to the patient are divided into two. The one is external defibrillators and the other is internal defibrillators.

Figure 12. External Defibrillators

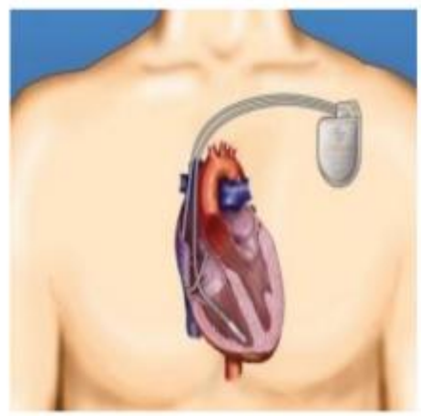

Figure 13. Internal (Implant) Defibrillators

Defibrillation should be performed by specially trained people and physicians. Generally, defibrillator devices are available in emergency rooms, ambulances, intensive care units, and airplanes.
Attention should be paid to setting errors in the defibrillator. If the output of the defibrillator device is not set correctly, it should be noted that the output power of the device is higher than the selected value and situations that may cause the death of the patient may occur during the intervention . Likewise, if the output value is smaller than the selected one, similar situations may occur.
Defibrillators are sensitive devices used on a mobile basis. The reliability of the device should be maintained by frequent preventive maintenance. The following procedures are applied using the defibrillator analyzer to test the device.

- Electrodes of the defibrillator are placed in the test holder circuit.
- Line voltage is turned on.
- Energy selection button of the defibrillator is set to the highest level.
- Press the charging button of the device.
- Electrodes are discharged into the test holder circuit.
- The given energy is read from the indicator of the test holder circuit.

- Battery is tested.

The Defibrillator Analyzer is used to test whether defibrillators and pacemakers are working safely and effectively. It measures the energy at the defibrillator outputs by simulating human body resistance. It then measures the current through this resistor. The standard resistance value is 50 ohms. The defibrillator is also used in transthoracic pacemaker calibrations.

Figure 14. Calibration of defibrillator

It should be checked whether the defibrillator (Electro-shock) devices measure correctly. In other words, the calibration of defibrillator devices should be done with specified periods. Defibrillator devices are calibrated by 2nd level calibration laboratories with Defibrillator analyzers.

It measures the energy at the defibrillator outputs by simulating human body resistance. It then measures the current through this resistor, the standard resistor value is 50 ohms. The defibrillator is also used in Transthoracic Pacemaker calibrations. The images below show a picture of three different defibrillator analyzers.

Calibration results:

Table 34. Energy measurement

Energy Produced by the LifePak Defibrillator (J)	Energy Measured with the Gold Standard (J)	Energy Measured by Device (J)	Uncertainty Value Calculated for the Device (J)	Error (%)	Tolerance
2,0	2,0	2,0	0,1	0,0	0.1 J to 360 J ± (1% of reading + 0.1 J)
5,0	5,0	5,0	0,1	0,0	
10,0	10,0	10,0	0,2	-0,3	
20,0	20,1	20,0	0,4	0,0	
30,0	30,3	30,1	0,6	0,3	
50,0	50,6	50,1	1,0	0,3	
70,0	70,5	70,0	1,4	0,0	
100,0	101,0	100,1	2,0	0,1	
150,0	152,1	150,8	3,0	0,5	

200,0	202,0	200,5	4,0	0,2	
250,0	252,8	250,8	5,0	0,3	
300,0	304,4	302,2	6,0	0,7	
360,0	364,6	362,0	7,2	0,5	

Table 35. ECG waveform verification measurement (with LEAD)

3-Way Connection	Value Measured with Lifepack	Value Measured by the Device	Uncertainty Value	Error (%)	Tolerance (%)
RA-LL-LA	30,0 bpm	30,0 bpm	1,0 bpm	0,0	± 1,0
	60,0 bpm	60,0 bpm		0,0	
	90,0 bpm	90,0 bpm		0,0	
	120,0 bpm	120,0 bpm		0,0	
	150,0 bpm	150,0 bpm		0,0	
	180,0 bpm	180,0 bpm		0,0	
	240,0 bpm	240,0 bpm		0,0	
	300,0 bpm	300,0 bpm		0,0	
	360,0 bpm	360,0 bpm		0,0	

Table 36. Waveform verification

Waveform	Expected Frequency (Hz)	Measured Frequency (Hz)
Waveform: Sine Amplitude: 1 mV Measurement point: Lead II	0,05	0,05
	0,5	0,5
	10	10
	40	40
	50	50
	60	60
	100	100
	150	150
	200	200
Waveform: Triangle Amplitude: 1 mV Measurement point: Lead II	2,0	2,0
	2,5	2,5
Waveform: Square Amplitude: 1 mV Measurement point: Lead II	0,125	0,125

Conclusion

In this work, we studied the calibration of various critical medical equipment, including medical ultrasound systems, patient simulators (with ECG simulation), electrical safety analyzers, defibrillator analyzers (including pacemaker analyzers), gas flow analyzers (including anesthetic agent and oxygen analysis), electrosurgery analyzers, pulse oximetry analyzers (with pulse oximetry simulation), and infusion pump analyzers. We learned how to perform precise calibration procedures and how to calculate the associated uncertainties, which is essential for ensuring the reliability, accuracy, and safety of these medical devices. The knowledge gained from this study has enhanced our understanding of quality assurance in medical instrumentation and will be directly applicable in professional practice. By implementing these calibration and uncertainty assessment techniques, we can contribute to maintaining high standards in healthcare environments, ensuring that medical devices function accurately and safely for patient care.

Future Work

In the future, this work can be extended to include the development of automated calibration protocols for these systems, integration with digital record-keeping for traceability, and the exploration of advanced uncertainty quantification methods to further enhance measurement accuracy. Additionally, applying these calibration practices across a wider range of medical devices can improve overall hospital equipment reliability and patient safety. Continuous professional development and practical application of these skills in real-world healthcare settings will ensure that the theoretical knowledge is effectively translated into operational excellence.

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