BIPM Capacity Building & Knowledge Transfer Programme

2025 BIPM - TÜBİTAK UME Project Placement

REPORT

Project Name	Precision, Traceability, and Quality in Healthcare Measurements"
Description	Enhancement of accuracy, reproducibility, and traceability of measurements in medical applications; reduction of measurement uncertainties; and compliance with international metrological standards. Development of technical competencies and laboratory experience, including project planning, execution of measurements, data analysis, calibration of medical instruments, and quality assurance of measurements.
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Date	September 1st 2025 – October 31st 2025 (2 month)

Motivation & Introduction

Doing an internship in the medical metrology laboratory of TÜBİTAK UME represents a meaningful opportunity for me for several reasons. First, Uzbekistan is actively developing its metrological infrastructure, strengthening the status of national standards and the quality base in measurement and calibration. Participating in an internship in one of the leading institutes in this field allows me to acquire the best international practices and advanced methods, which can then be adapted at home.

Second, medical metrology is an area with high social and practical importance: the accuracy and reliability of medical measurements directly affect diagnosis, treatment, and patient safety. As a researcher from Uzbekistan, where efforts are being made to improve the quality of medical services and meet international standards, skills such as calibrating medical devices, estimating measurement uncertainty, verifying measurement systems are very valuable.

Third, collaborating with the TÜBİTAK UME laboratory — which participates in international projects (for example under EURAMET / the international metrology system) and offers services in design of calibrators, manufacture of phantoms, calibration of high-precision medical devices — gives the opportunity to deeply study standards, norms, technologies and methods which are not always widely used in Uzbekistan.

My goal is to use the internship to gain practical skills that will help me:

- improve the quality of metrological services and calibration of medical equipment in Uzbekistan;
- participate in development or implementation of regulatory documents / standards in medical metrology;
- contribute to strengthening international cooperation and knowledge exchange between the Uzbek National Institute of Metrology and overseas laboratories.

The **Medical Metrology Laboratory of TÜBİTAK UME** was formally established after the conclusion of the "Medical Metrology Feasibility" Project, and has been operating since December 2014. Its mission is to establish the traceability of measurement quantities relevant to medicine, integrate these measurement quantities into the international metrology system through international comparisons, and ensure measurement unity by disseminating traceability to lower level laboratories within the country or abroad through calibration, measurement and test services.

Key activity areas of the laboratory include:

- Design and manufacture of calibrators for medical devices.

- Calibration and verification of measurement systems of medical devices such as patient simulators, NIBP simulators, defibrillator/pacer analyzers, SpO_2 analyzers, infusion pump analyzers, gas flow analyzers, etc.
- Development of phantoms and reference materials (tissue-like materials) for preclinical research, and development of ultrasonic and thermal measurement devices.
- Performance testing of hearing aids and headphones.
- Training professionals in calibration of medical devices.

For my country, the significance of such a laboratory and the competencies it offers are especially high in the context of reforms in the metrological service, improving standardization, enhancing export potential, and ensuring high quality of medical equipment and services.

Research

Methodology

The project was executed through an integrated approach of theoretical lectures and hands-on laboratory exercises. The team at the TÜBİTAK UME Medical Metrology Laboratory provided an intensively organized and well-planned training schedule. Daily sessions were highly interactive, emphasizing practical calibration activities where trainees were actively involved in the procedures under expert guidance.

Assoc. Prof. Dr. Baki Karaböce and Dr. Hüseyin Okan Durmuş led theoretical sessions through interactive round-table discussions, ensuring a deep understanding of the fundamental concepts and principles. All inquiries were addressed comprehensively, fostering a robust learning environment. The practical segments involved active participation in laboratory setups, data acquisition, and analysis with the support of laboratory staff.

Infusion Pump Calibration & Metrology in a Medical-Metrology Laboratory Context

Overview

An infusion pump is a medical-electrical device that delivers fluids (medications, nutrients, etc.) into a patient's body at a controlled flow rate and volume. In a medical-metrology laboratory (such as your role in the TÜBİTAK UME Medical Metrology Laboratory), infusion pumps represent a critical class of equipment because the accuracy of delivered fluid volume and flow directly impacts patient safety. Calibration, traceability, uncertainty quantification, and metrological best practices are essential.

Figure 1: Infusion pump - Reference standard

Figure 2: Infusion Pump Analyzer

Relevant Standards and Traceability

- The standard IEC 60601-2-24 ("Medical electrical equipment — Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers") specifies performance and safety requirements for infusion pumps and volumetric infusion controllers.
- Other standards and guidance address measurement of low flow rates, traceability and calibration for drug-delivery systems (e.g., the EMPIR project MeDD / MeDDII).
- Establishing traceability means the calibration results link to the International System of Units (SI) via primary or secondary standards. For example, gravimetric methods converting mass to volume/flow.

Calibration Methodology

Preparation of the system

- Setup the infusion pump under test with the appropriate infusion set, tubing, reservoir and fluid. Remove air bubbles, prime the line, ensure stable temperature/humidity conditions.
- Allow equipment and fluid to stabilise thermally (for example 10 minutes or more) so drift is minimal.

Selection of calibration points

- Select at least three flow-rate points to cover the expected working range of the pump (for example low, medium, high). This ensures characterization of performance across the range.
- For each point record the indicated flow rate (on the infusion pump) and the reference measurement (obtained via the calibrator or gravimetric method).

Reference measurement method

- Gravimetric method: The pump delivers fluid into a precision balance. The mass collected over known time gives a mass flow; using the fluid density at the measurement temperature, you convert to volumetric flow. This method gives lab-level accuracy and is often used by National Metrology Institutes.
- Comparative (analyzer) method: In situ (e.g., hospital environment) calibrations may use an Infusion Pump Analyser device as reference. It may be less accurate than gravimetric but practical.

Data collection and error calculation

- For each flow point, log the indicated flow rate from the pump, the reference value, time period, volume delivered, environmental conditions.
- Compute the error (indicated minus reference) and possibly percentage error (error/reference × 100%). Also assess repeatability by performing multiple runs.
- Document any alarms (occlusion detection, air-in-line) or deviations (e.g., tubing compliance, back-pressure effects).

Uncertainty estimation and conformity assessment

- Develop an uncertainty budget: identify and quantify all relevant sources of measurement uncertainty (e.g., balance resolution, fluid density variation, temperature fluctuations, timing accuracy, operator effect, tubing compliance).
- Combine uncertainties (e.g., via root-sum-square) to get an expanded uncertainty (typically for $k = 2$). Ensure that the measurement uncertainty is acceptable compared to the manufacturer's specification or clinical requirement.
- Compare errors and uncertainties to acceptance criteria (e.g., manufacturer tolerance, hospital policy). If outside tolerance, the pump may need adjustment, maintenance or decommissioning.

Here, using reference equipment, after performing calibration, we obtained the following data:

Table 1. Volume Measurement Results,

Reference Volume (*ml*)	Reference Flow (mL/h)	Measured Volume (ml)	Uncertainty (ml)	Deviation (%)	Tolerans	Conformity Pass/Fail
5	25	4,92	0,71	-1,6	% 2 ± 1 LSD	Passed
15	400	14,91	0,71	-0,6	% 2 ± 1 LSD	Passed
30	800	29,49	0,71	-1,7	% 2 ± 1 LSD	Passed
25	100	24,84	0,79	-0,64	% 1 ± 1 LSD	Passed
45	200	44,65	0,7	-0,78	% 1 ± 1 LSD	Passed
50	1000	49,55	0,82	-0,9	% 2 ± 1 LSD	Passed

Table 2. Flow Rate Measurement results

Reference Flow (mL/h)	Reference Volume (*ml*)	Measured Flow (mL/h)	Uncertainty (ml)	Deviation (%)	Tolerans	Conformity Pass/Fail
5	2	4,99	0,04	-0,2	% 2 ± 1 LSD	Passed
25	5	25,03	0,2	0,12	% 2 ± 1 LSD	Passed
100	25	100	0,8	0	% 1 ± 1 LSD	Passed
400	15	395,9	3,2	-1,03	% 2 ± 1 LSD	Passed
800	30	784,8	6,5	-1,9	% 2 ± 1 LSD	Passed
1000	50	987	11	-1,3	% 2 ± 1 LSD	Passed

Table 1. Pressure measurement

Reference Pressure (psi)	Measured Pressure (psi)	Uncertainty (psi)	Deviation (%)	Tolerans	Conformity Pass/Fail
5	5,01	0,08	0,2	% 1 ± 1 LSD	Passed
10	10,05		0,5		Passed
20	19,99		-0,05		Passed
30	29,96		-0,13		Passed
40	39,9		-0,25		Passed
45	44,9		-0,22		Passed

Gas flow Analyzer

The gas flow analyzer is a critical instrument for the calibration of ventilators and anesthesia devices. Ventilators, which are essential in critical care, operate by delivering specific volumes and pressures to a patient's lungs to provide assisted breathing. Consequently, the accuracy of these ventilation parameters is paramount for ensuring patient safety.

Gas flow analyzers are designed to measure a comprehensive set of parameters across a wide operational range. Their capabilities include the measurement of gas flow (in both forward and reverse

directions), volume (for both inhalation and exhalation phases), and pressure (across high ranges in bar and low ranges in mbar). Furthermore, these analyzers verify oxygen concentration—typically 21% in ambient air or 100% for pure oxygen—and other gas concentrations. Advanced models may also measure ambient conditions such as barometric pressure, temperature, and relative humidity. The measurement results for oxygen concentration are detailed in Table 4 below.

Calibrated measurement functions:

Low-pressure gas

High-pressure gas

Airway pressure

Barometric pressure

Oxygen testing

Volume measurement

Figure 3. Gas flow analyzer

Figure 4. Calibration process

Oxygen Concentration Measurement Results

Test Medium: Dry Air

The measured oxygen concentration is expected to be 21.0%, reflecting the typical volumetric composition of oxygen in dry air.

Test Medium: Pure Dry Oxygen

The measured oxygen concentration is expected to be 100.0%.

Table 4. Percentage (%) Oxygen Test Measurements results

% Measure	Reference (%)	Measured (%)	Uncertainty (%)	Tolerans (%)
% 21 Oksijen Testi	21,0	21,0	1,0	± 1,0
% 100 Oksijen Testi	100,0	99,9		± 1,0

Table 5. Low Pressure Gas (+) Measurement Results

Reference (cmH_2O)	Measured (cmH_2O)	Uncertainty (cmH_2O)	Tolerans (%)
5,00	4,99	0,08	± 1,0
25,00	24,97		± 1,0
50,00	49,95		± 1,0
100,00	99,90		± 1,0
150,00	149,83		± 1,0

Table 6. Low Pressure Gas (-) Measurement Results

Reference (cmH_2O)	Measured (cmH_2O)	Uncertainty (cmH_2O)	Tolerans (%)
5,00	5,01	0,08	± 1,0
25,00	25,00		± 1,0
50,00	50,01		± 1,0
100,00	99,96		± 1,0
150,00	149,95		± 1,0

Table 7. High Pressure Gas Measurement Results

Reference (psi)	Measured (psi)	Uncertainty (psi)	Tolerans (%)
30,00	29,96	0,01	± 1,0
50,00	49,96		± 1,0
65,00	64,96		± 1,0
75,00	74,97		± 1,0

Table 8. Airway Pressure (+) Measurement Results

Reference (cmH_2O)	Measured (cmH_2O)	Uncertainty (cmH_2O)	Tolerans (%)
5,00	5,00	0,08	± 0,50
25,00	24,95		± 0,50
50,00	49,91		± 0,50
100,00	99,86		± 0,50
140,00	139,81		± 0,50

Table 9. Airway Pressure (-, Vacuum) Measurement Results

Reference (cmH_2O)	Measured (cmH_2O)	Uncertainty (cmH_2O)	Tolerans (%)
- 5,00	-4,99	0,08	± 0,50
-25,00	-24,97		± 0,50
-50,00	-49,93		± 0,50
-100,00	-99,85		± 0,50
-140,00	-139,78		± 0,50

Inhalation Volume Measurement

Testing was performed using three calibrated syringes of distinct nominal volumes: 100 mL (low capacity), 1000 mL (medium capacity), and 3000 mL (high capacity). The measured values are expected to correspond closely to the reference volumes of the syringes used.

Exhalation Volume Measurement

Testing was performed using the same set of three calibrated syringes with nominal volumes of 100 mL, 1000 mL, and 3000 mL. The measured values are expected to correspond closely to the reference volumes of the syringes used.

Table 10. Volume Measurement Results

Reference volume (mL)	Measured volume (mL)	Uncertainty (mL)	Tolerans (%)
3000	3018	32	± 2
1000	1000	11	± 2
100,0	99,7	1,1	± 2

Patient Simulator

Patient simulators employ sophisticated technology to replicate human physiological signals, enabling the verification of patient monitor functionality and measurement accuracy. Ensuring the correct operation of these monitors is critical, as they provide vital clinical data for patient assessment and are among the most fundamental devices in healthcare settings.

Figure 5. Patient simulator

The calibration of patient monitors requires a multifaceted approach, as these devices integrate multiple measurement functions. The Rigel Uni-Sim simulator, referenced below, provides physiologically accurate and synchronized waveforms, offering the highest fidelity simulation of a human patient for performance testing.

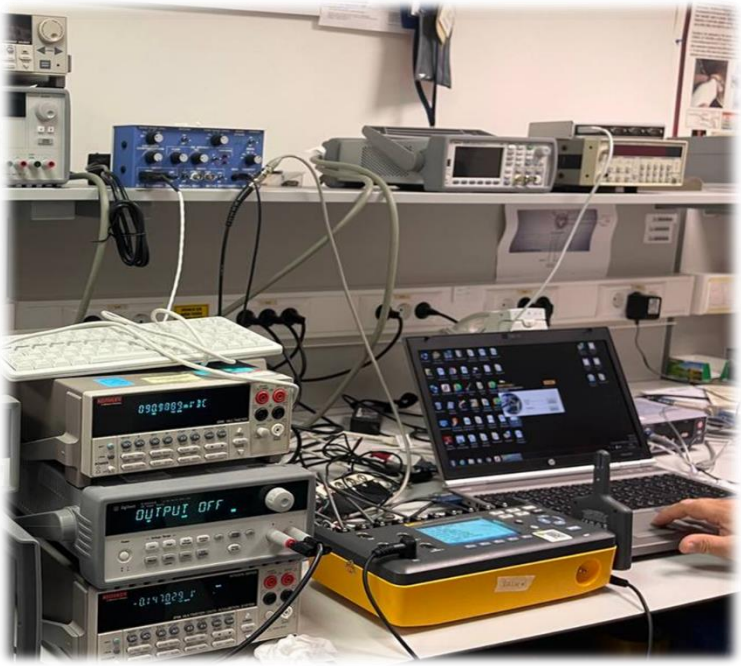


Figure 6. Calibration process.

Calibrated measurement functions:

Sine wave frequency measurement
Square wave frequency measurement
Triangle wave frequency measurement
Voltage measurement on a sine wave
Voltage measurement on a triangle wave
Voltage measurement on a square wave
Frequency measurement on a triangle wave at different points
Voltage measurement on a triangle wave

Electrocardiogram (ECG)

An Electrocardiogram (ECG) is a diagnostic procedure that records the electrical activity of the heart. This test is instrumental in detecting and diagnosing cardiac conditions such as myocardial infarction (heart attacks) and arrhythmias (irregular heartbeats). ECG equipment is standard in various clinical settings, including medical offices, hospitals, operating rooms, and emergency vehicles. Furthermore, basic ECG monitoring functionality is now integrated into certain personal wearable devices, such as smartwatches.

Table 11. ECG Output Verification Lead I Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
LA-RA (mV)	1.00	1.00	0.01	0.00	± 0.07	Passed
	-0.10	-0.10	0.01	0.00	± 0.05	Passed
	-50.00	-49.87	0.09	0.13	± 1.05	Passed
	500.00	500.14	0.30	0.14	± 10.05	Passed

Table 12 (Continued). ECG Output Verification Lead I Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
Voltage Ratio Test (V)	10.00	10,12	0.15	0.12	± 0.30	Passed
Respiratory Resistance Values (Ω)	500.0	495.1	2.2	4.9	± 25.00	Passed
	1000.0	1000.7	2.2	0.7	± 50.00	Passed
	1500.0	1506.2	3.3	6.2	± 75.00	Passed
	2000.0	2013.4	5.2	13.4	± 100.00	Passed
Respiratory Resistance Change (Ω)	0,000	-0,000	0.004	0,000	± 0.05	Passed
	5.00	4.95	0.16	0.050	± 0.20	Passed
	0,000	0,000	0.004	0,000	± 0.05	Passed
	1,000	0.999	0.012	0.001	± 0.08	Passed
	0,000	-0,000	0.004	0,000	± 0.01	Passed
	0.100	0.095	0.009	0.005	± 0.07	Passed

Table 13. ECG Output Verification Lead II Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
LA-RA (mV)	3.00	3.01	0.01	0.01	± 0.11	Passed
	-0.30	-0.29	0.01	0.01	± 0.06	Passed
	-70.00	-70.15	0.01	0.15	± 1.45	Passed
	700.00	699.98	0.02	0.02	± 14.05	Passed
Voltage Ratio Test (V)	10.00	10.06	0.02	0.06	± 0.30	Passed
Respiratory Resistance Values (Ω)	500.0	498.9	1.3	1.1	± 25.00	Passed
	1000.0	1003.6	1.8	3.6	± 50.00	Passed
	1500.0	1508.7	3.7	8.7	± 75.00	Passed
	2000	2017	4	17	± 100.00	Passed
Respiratory Resistance Change (Ω)	0,000	-0,000	0.005	0,000	± 0.01	Passed
	5.00	4.96	0.16	0.040	± 0.20	Passed
	0,000	0,000	0.005	0,000	± 0.05	Passed
	1,000	1,001	0.021	0.001	± 0.08	Passed
	0,000	0,000	0.005	0,000	± 0.05	Passed
	0.100	0.096	0.025	0.004	± 0.05	Passed

Table 14. ECG Output Verification Lead III Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
LL-LA (mV)	2.00	2.01	0.02	0.01	± 0.09	Passed
	-0.20	-0.19	0.03	0.01	± 0.05	Passed
	-20.00	-20.29	0.65	0.29	± 0.45	Passed
	200.00	199.83	0.33	0.17	± 4.05	Passed
Voltage Ratio Test (V)	10.00	10.00	0.26	0.00	± 0.30	Passed
Respiratory Resistance Values (Ω)	500.0	494.3	1.3	5.7	± 25.00	Passed
	1000.0	998.4	3.9	1.6	± 50.00	Passed
	1500	1505	6	5	± 75.00	Passed
	2000	2012	4	12	± 100.00	Passed

Table 15. ECG Output Verification Lead V1 Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
V1-RL (mV)	3.00	3.01	0.02	0.01	± 0.11	Passed
	-0.30	-0.30	0.03	0.00	± 0.06	Passed
	-70.00	-69.93	0.36	0.07	± 1.45	Passed
	700.00	700.11	0.28	0.11	± 14.05	Passed
Voltage Ratio Test (V)	10.00	10,11	0.07	0.11	± 0.30	Passed
Respiratory Resistance Control (Ω)	1000.0	995.3	1.9	4.7	± 50.00	Passed

Table 16. ECG Output Verification Lead V2 Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
V2-RL (mV)	3.00	3.00	0.04	0.00	± 0.11	Passed
	-0.30	-0.30	0.03	0.00	± 0.06	Passed
	-70.00	-70.00	0.18	0.00	± 14.05	Passed
	700.0	700.1	0.5	0.1	± 70.40	Passed
Voltage Ratio Test (V)	10.00	10.05	0.03	0.05	± 0.30	Passed
Respiratory Resistance Control (Ω)	1000.0	996.6	1.9	3.4	± 50.00	Passed

Table 17. ECG Output Verification Lead V3 Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
V3-RL (mV)	3.00	3.01	0.03	0.01	± 0.11	Passed
	-0.30	-0.29	0.03	0.01	± 0.06	Passed
	-70.00	-69.99	0.48	0.01	± 1.45	Passed
	700.0	700.1	0.3	0.1	± 14.05	Passed
Voltage Ratio Test (V)	10.00	10.05	0.03	0.05	± 0.30	Passed
Respiratory Resistance Control (Ω)	1000.0	999.4	5.3	0.6	± 50.00	Passed

Table 18. ECG Output Verification Lead V4 Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
V4-RL (mV)	3.00	3.00	0.03	0.00	± 0.11	Passed
	-0.30	-0.30	0.03	0.00	± 0.06	Passed
	-70.00	-69.98	0.44	0.02	± 1.45	Passed
	700.0	700.1	0.3	0.1	± 14.05	Passed
Voltage Ratio Test (V)	10.00	10,11	0.09	0.11	± 0.30	Passed
Respiratory Resistance Control (Ω)	1000.0	996.4	2.6	3.6	± 50.00	Passed

Table 19. ECG Output Verification Lead V5 Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
V5-RL (mV)	3.00	3.01	0.03	0.01	± 0.11	Passed
	-0.30	-0.29	0.03	0.01	± 0.06	Passed
	-70.00	-69.99	0.40	0.01	± 1.45	Passed
	700.0	700.1	0.3	0.1	± 14.05	Passed
Voltage Ratio Test (V)	10.00	10.05	0.09	0.05	± 0.30	Passed
Respiratory Resistance Control (Ω)	1000.0	996.3	5.7	3.7	± 50.00	Passed

Table 20. ECG Output Verification Lead V6 Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
V6-RL (mV)	3.00	3.01	0.03	0.01	± 0.11	Passed
	-0.30	-0.29	0.03	0.01	± 0.06	Passed
	-70.00	-70.41	0.56	0.41	± 1.45	Passed
	700.0	699.8	0.4	0.2	± 14.50	Passed
Voltage Ratio Test (V)	10.00	10.16	0.15	0.16	± 0.30	Passed
Respiratory Resistance Control (Ω)	1000.0	996.2	6.1	3.8	± 50.00	Passed

Table 21. Waveform Verification Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
60 Hz Sine	60.00 Hz	60.00 Hz	0.06 Hz	0.00 Hz	± 0.60 Hz	Passed
2.5 Hz Frame	2,500 Hz	2,500 Hz	0.006 Hz	0.000 Hz	± 0.03 Hz	Passed
2.5 Hz Triangle	2,500 Hz	2,500 Hz	0.002 Hz	0.000 Hz	± 0.03 Hz	Passed
LL-RA 60 Hz Sine Amplitude (pp)*	5.00 mV	5.00 mV	0.18 mV	0.00 mV	± 0.15 mV	Passed
LL-RA 2.5 Hz Square Amplitude (pp)**	5.00 mV	5.08 mV	0.12 mV	0.08 mV	± 0.15 mV	Passed
LL-RA 2.5 Hz Triangle Amplitude (pp)**	5.00 mV	5.08 mV	0.12 mV	0.08 mV	± 0.15 mV	Passed

*: Average of 10 measurements.

**: Average of 36 measurements.

Table 22. High-Level Waveform Verification Measurement Results

Measured Parameter	Reference Value	Measured Average Value	Uncertainty	Absolute Difference	Tolerance	Conformity
High Level Output 60 Hz Sine Amplitude Vp-p*	2.50 V	2.47 V	0.03 V	0.03 V	± 0.13 V	Passed

*: Average of 10 measurements.

Non-invasive Blood Pressure (NIBP)

NIBP refers to the measurement of blood pressure using oscillometric monitoring equipment, eliminating the need for invasive procedures. This technique is widely employed in operating rooms and intensive care units (ICUs) for continuous patient monitoring. The method is based on the indirect measurement of pressure oscillations within a cuff, which are caused by arterial volume changes during controlled deflation.

Invasive Blood Pressure (IBP)

IBP monitoring involves the direct measurement of blood pressure via a catheter inserted into an artery (commonly referred to as an arterial line or A-line). This technique provides continuous, real-time blood pressure readings.

Note: For the purpose of this calibration, the IBP function is simulated and analyzed non-invasively. The simulation utilizes a precision multimeter and a DC source set at 10 mV, applying different sensitivity values (e.g., 5 µV/V/mmHg and 40 µV/V/mmHg) for static pressure measurement. The resulting data is recorded in the tables below.

Table 23. IBP 1st Channel, 5 µV/(V/mmHg) Measurement Results

Supply: 10 V DC

Reference Value (mmHg)	Measured Value (mmHg)	Uncertainty (mmHg)	Absolute Difference (mmHg)	Tolerance (mmHg)	Conformity
0.00	-0.00	0.12	0.00	± 1.0	Passed
-10.00	-10.00	0.16	0.00	± 1.1	Passed
20.00	20.00	0.21	0.00	± 1.2	Passed
0.00	-0.00	0.12	0.00	± 0.1	Passed
50.00	49.90	0.39	0.10	± 1.5	Passed
100.00	99.80	0.78	0.20	± 2.0	Passed
200.0	199.6	1.6	0.4	± 3.0	Passed
300.0	299.0	1.8	1.0	± 5.1	Passed
0.00	0.00	0.12	0.00	± 1.0	Passed

Table 24. IBP 1st Channel, 40 µV/(V/mmHg) Measurement Results

Supply: 10 V DC

Reference Value (mmHg)	Measured Value (mmHg)	Uncertainty (mmHg)	Absolute Difference (mmHg)	Tolerance (mmHg)	Conformity
0.00	0.00	0.12	0.00	± 1.0	Passed
-10.00	-10.00	0.12	0.00	± 1.1	Passed
20.00	20.00	0.21	0.00	± 1.2	Passed
0.00	0.00	0.12	0.00	± 1.0	Passed
50.00	50.00	0.26	0.00	± 1.5	Passed
100.00	99.90	0.42	0.10	± 2.0	Passed
200.00	199.90	0.76	0.10	± 3.0	Passed
300.0	299.8	1.3	0.2	± 4.0	Passed
0.00	0.00	0.12	0.00	± 1.0	Passed

Table 25. IBP 2nd Channel, 5 µV/(V/mmHg) Measurement Results

Supply: 10 V DC

Reference Value (mmHg)	Measured Value (mmHg)	Uncertainty (mmHg)	Absolute Difference (mmHg)	Tolerance (mmHg)	Conformity
0.00	-0.00	0.12	0.00	± 1.0	Passed
-10.00	-10.00	0.12	0.00	± 1.1	Passed
20.00	19.90	0.21	0.10	± 1.2	Passed
0.00	0.00	0.12	0.00	± 1.0	Passed
50.00	49.80	0.42	0.20	± 1.5	Passed
100.00	99.70	0.21	0.30	± 2.0	Passed
200.00	199.30	0.48	0.70	± 3.0	Passed
300.00	298.90	0.67	1.10	± 4.5	Passed
0.00	-0.00	0.12	0.00	± 1.0	Passed

Table 26. IBP 2nd Channel, 40 µV/(V/mmHg) Measurement Results

Supply: 10 V DC

Reference Value (mmHg)	Measured Value (mmHg)	Uncertainty (mmHg)	Absolute Difference (mmHg)	Tolerance (mmHg)	Conformity
0.00	-0.00	0.12	0.00	± 1.0	Passed
-10.00	-10.00	0.13	0.00	± 1.1	Passed
20.00	20.00	0.13	0.00	± 1.2	Passed
0.00	0.00	0.12	0.00	± 1.0	Passed
50.00	50.00	0.13	0.00	± 1.5	Passed
100.00	99.90	0.31	0.10	± 2.0	Passed
200.00	199.80	0.59	0.20	± 3.0	Passed
300.00	299.70	0.82	0.30	± 4.0	Passed
0.00	0.00	0.12	0.00	± 1.0	Passed

Table 27. YSI Series 400 Verification Measurement Results

Heat (°C)	Reference Value (Ω)	Measured Value (Ω)	Uncertainty (Ω)	Absolute Difference (Ω)	Tolerance (Ω)	Conformity
30.0	1815.0	1815.0	0.4	0.0	± 31	Passed
35.0	1471.0	1470.0	0.4	1.0	± 24	Passed
40.0	1200.0	1200.0	0.3	0.0	± 20	Passed
42.0	1107.0	1107.0	0.3	0.0	± 18	Passed

Table 28. YSI Series 700 T1 Verification Measurement Results

Heat (°C)	Reference Value (Ω)	Measured Value (Ω)	Uncertainty (Ω)	Absolute Difference (Ω)	Tolerance (Ω)	Conformity
30.0	4834.0	4834.0	0.7	0.0	± 82	Passed
35.0	3918.0	3914.0	0.6	4.0	± 65	Passed
40.0	3196.0	3189.0	0.6	7.0	± 52	Passed
42.0	2950.0	2949.0	0.5	1.0	± 47	Passed

Table 29. YSI Series 700 T2 Verification Measurement Results

Heat (°C)	Reference Value (Ω)	Measured Value (Ω)	Uncertainty (Ω)	Absolute Difference (Ω)	Tolerance (Ω)	Conformity
30.0	24270.0	24266.0	4.0	4.0	± 406	Passed
35.0	19740.0	19719.0	3.5	21.0	± 322	Passed
40.0	16150.0	16109.0	3.1	41.0	± 256	Passed
42.0	14920.0	14909.0	2.9	11.0	± 234	Passed

Table 30. Cardiac Output Verification Measurement Results

Heat (°C)	Reference Value (Ω)	Measured Value (Ω)	Uncertainty (Ω)	Absolute Difference (Ω)	Tolerance (Ω)	Conformity
34.0	15584.0	15576.0	3.0	8.0	± 105	Passed
35.0	15057.0	15043.0	3.0	14.0	± 101	Passed
36.0	14530.0	14519.0	2.9	11.0	± 105	Passed
37.0	14004.0	13997.0	2.8	7.0	± 109	Passed
38.0	13477.0	13472.0	2.8	5.0	± 105	Passed

Table 31. Pressure Test Measurement Results

Parameter	Reference Value (mmHg)	Measured Value (mmHg)	Uncertainty (mmHg)	Absolute Difference (mmHg)	Tolerance (mmHg)	Conformity
50.0 mmHg accuracy test	51.29	51.00	0.29	0.29	± 0.8	Passed
100.0 mmHg accuracy test	101.53	101.20	0.21	0.33	± 1.0	Passed
200.0 mmHg accuracy test	201.49	200.90	0.21	0.59	± 1.5	Passed
300.0 mmHg accuracy test	301.70	300.70	0.18	1.00	± 2.0	Passed
350.0 mmHg accuracy test	351.92	350.80	0.13	1.12	± 2.3	Passed
400.0 mmHg accuracy test	402.10	400.90	0.23	1.20	± 2.5	Passed
300.0 mmHg accuracy test	302.52	301.60	0.13	0.92	± 2.0	Passed
100.0 mmHg accuracy test	102.83	102.60	0.58	0.23	± 1.0	Passed

Table 32. SpO2 Measurement Results Using Nellcor

Reference Value (% SpO_2)	Measured Value (% SpO_2)	Uncertainty (% SpO_2)	Absolute Difference (% SpO_2)	Tolerance (% SpO_2)	Conformity
85.0	85.0	2.0	0.0	± 3	Passed
88.0	88.0	2.0	0.0		Passed
94.0	94.0	2.1	0.0		Passed
95.0	96.0	2.2	1.0		Passed
97.0	97.0	2.2	0.0		Passed

Table 33. Pulse Measurement Results Using Nellcor

Reference Value (bpm)	Measured Value (bpm)	Uncertainty (bpm)	Absolute Difference (bpm)	Tolerance (bpm)	Conformity
30.0	30.0	1.1	0.0	± 1	Passed
40.0	40.0	1.4	0.0		Passed
60.0	60.0	2.1	0.0		Passed
130.0	130.0	4.4	0.0		Passed
180.0	180.0	6.0	0.0		Passed

Table 34. SpO2 Measurement Results Using Massimo Radical 7

Reference Value (% SpO_2)	Measured Value (% SpO_2)	Uncertainty (% SpO_2)	Absolute Difference (% SpO_2)	Tolerance (% SpO_2)	Conformity
85.0	85.0	2.6	0.0	± 3	Passed
88.0	88.0	2.7	0.0		Passed
94.0	94.0	2.9	0.0		Passed
95.0	95.0	2.9	0.0		Passed
97.0	97.0	3.0	0.0		Passed

Table 35. Pulse Measurement Results Using Massimo Radical 7

Reference Value (bpm)	Measured Value (bpm)	Uncertainty (bpm)	Absolute Difference (bpm)	Tolerance (bpm)	Conformity
30.0	30.0	3.1	0.0	± 1	Passed
40.0	40.0		0.0		Passed
60.0	60.0		0.0		Passed
130.0	130.0		0.0		Passed
180.0	179.0		1.0		Passed

Defibrillator Analyzer

Defibrillators are critical resuscitation devices designed to deliver a controlled electric charge or current to the heart. Their primary function is to restore a normal sinus rhythm following sudden cardiac arrest (SCA). Furthermore, certain implantable or wearable defibrillator models are capable of correcting specific dangerous arrhythmias—abnormalities in heart rate or rhythm.

It is imperative for hospitals and medical centers to ensure these vital medical devices are safe, accurate, dependable, and fully operational at their specified performance levels. The deployment of reliable defibrillators has been instrumental in enhancing treatment efficacy and improving patient safety by enabling better control and management of complications during Cardiopulmonary Resuscitation (CPR).

Figure 7. Types of Defibrillator's and calibration process

Calibrated measurement functions:

Energy measurement

ECG arrhythmia simulator

Performance waveforms

Table 36. Energy Measurement Results

LifePak Defibrillator Energy Produced (J)	With Gold Standard Measured Energy (J)	With the device Measured Energy (J)	Uncertainty Value Calculated for the Device (J)	Deviation (%)	Tolerance	Conformity
2.0	2.0	1.9	0.1	-5.0	± (1 ± 2 LSD)	Passed
3.0	3.0	2.9	0.1	-3.3		Passed
4.0	4.0	3.9	0.1	-2.5		Passed
5.0	5.0	4.9	0.1	-2.0		Passed
6.0	6.0	5.9	0.1	-1.7		Passed
7.0	7.1	6.9	0.2	-2.8		Passed
8.0	8.0	7.9	0.2	-1.3		Passed
9.0	9.1	8.9	0.2	-2.2		Passed
10.0	10.0	9.9	0.2	-1.0		Passed
15.0	15.0	14.8	0.3	-1.3		Passed
20.0	20.2	19.9	0.4	-1.5		Passed
30.0	30.3	29.9	0.6	-1.3		Passed
50.0	50.6	49.9	1.0	-1.4		Passed
70.0	70.5	69.7	1.4	-1.1		Passed
100.0	100.9	99.9	2.0	-1.0		Passed
125.0	126.5	125.2	2.5	-1.0		Passed
150.0	151.9	150.4	3.0	-1.0		Passed
175.0	177.2	175.5	3.5	-1.0		Passed
200.0	201.8	199.9	4.0	-0.9		Passed
225.0	227.3	225.7	4.5	-0.7		Passed
250.0	252.5	250.3	5.0	-0.9		Passed
275.0	277.8	275.4	5.5	-0.9		Passed
300.0	303.5	300.9	6.0	-0.9		Passed
325.0	328.3	325.4	6.5	-0.9		Passed
360.0	363.7	360.1	7.2	-1.0		Passed

Table 37. ECG Waveform Verification Measurement Results (with LEAD)

Connection	Reference Value (bpm)	Measured Value (bpm)	Uncertainty Value (bpm)	Deviation (%)	Tolerance (%)	Conformity
3-Way Connection RA-LL-LA	30.0	30.0	1.0	0.0	± 0.2	Passed
	60.0	60.0		0.0		Passed
	90.0	90.0		0.0		Passed
	120.0	120.0		0.0		Passed
	150.0	150.0		0.0		Passed
	180.0	180.0		0.0		Passed
	240.0	240.0		0.0		Passed
	300.0	300.0		0.0		Passed

Table 38. Pacer Rate Verification Measurement Results

Measurement Point	Reference Value (ppm)	Measured Value (ppm)	Uncertainty (ppm)	Deviation (%)	Tolerance	Conformity
at 10 mA	30.0	29.9	1.1	-0.3	± (1% ±1 LSD)	Passed
	60.0	60.0	1.9	-0.1		Passed
	90.0	89.6	2.8	-0.5		Passed
at 20 mA	30.0	29.9	1.1	-0.3		Passed
	60.0	60.0	1.9	-0.1		Passed
	90.0	89.6	2.8	-0.5		Passed

Table 39. Pacer Current Value Verification Measurement Results

Reference Value (mA)	Measured Value (mA)	Uncertainty (mA)	Deviation (%)	Tolerance	Conformity
10.0	10.0	0.5	-0.3	± (1% ±1 LSD)	Passed
20.0	19.9		-0.3		Passed

Table 40. Loading Time Verification Measurement Results

Reference Energy Value (J)	Measured Energy Value (J)	Measured by the Device Charge Time (s)	Measured by the Reference Device Charge Time (s)	Difference (s)	Uncertainty (s)	Tolerance (s)	Conformity
201.8	199.9	10.3	9.4	0.9	0.5	2.0	Passed
252.5	249.7	12.7	11.7	1.1	0.6		Passed
303.5	300.9	15.6	14.3	1.3	0.8		Passed
363.7	360.1	19.0	17.6	1.5	1.0		Passed

correlation between the Reference Energy and the Load Times of the calibrated device . Furthermore, there is a 100% positive correlation between the synchronization times of both the reference and calibrated devices.

Table 41. Synchronization Time Verification Measurement Results

Reference Energy Value (J)	Measured Energy Value (J)	Measured by the Device Synchronization Time (Sync. Time) (ms)	Measured by the Reference Device Synchronization Time (Sync. Time) (ms)	Difference (ms)	Uncertainty (ms)	Tolerance	Conformity
201.8	199.9	24.7	25.7	-1.0	3.8	Reference < 60 ms	Passed
252.5	249.7	27.0	26.3	0.7	2.7		Passed
303.5	300.9	25.3	23.3	2.0	3.6		Passed
363.7	360.1	27.3	26.3	1.0	2.3		Passed

Note: According to the Lifepak 20/20e Defibrillator/Monitor Performance Inspection procedure (PIP-Instructions, Therapy-Delivered Energy and Sync Test, 5-25), defibrillator analyzers must measure a sync R-wave duration of 60 ms or less. This ensures that the calibrated device measures synchronization times accurately.

Electrosurgical Unit (ESU) and Electrosurgical Analyzer (ESA)

Electrosurgical Unit (ESU)

An ESU is a surgical device that employs high-frequency electrical energy to dissect biological tissue and achieve hemostasis through coagulation. This process relies on the generation of heat from the electrical current, enabling accurate cutting and the sealing of blood vessels during operations.

The system generally consists of a generator, an applicator (active electrode), and often a return electrode (dispersive pad or grounding pad). The generator's primary function is to elevate standard electrical frequency to a much higher range, thereby avoiding unwanted stimulation of nerves and muscles.

Figure 8. Electrosurgical Unit

Electrosurgical Analyzer (ESA)

This is a testing device designed to evaluate the operational performance of high-frequency electrosurgical units. The principle of electrosurgery involves converting a high-frequency electrical current into thermal energy. This heat produces the intended clinical outcomes, which include cutting, coagulating, dehydrating (desiccating), or sparking (fulgurating) tissue at the application site.

In essence, electrosurgery utilizes a high-frequency, alternating electric current to induce thermal effects in tissue. The degree of heating can be controlled to accomplish various tissue interactions such as cutting, ablation, desiccation, or blended effects. ESUs are widely utilized across numerous medical specialties, including Gastroenterology, General Surgery, Obstetrics and Gynecology, Ear-Nose-Throat, Pulmonary Medicine, and Dermatology. The application of electrosurgery in endoscopic procedures dates back to the 1970s. In gastrointestinal endoscopy, it is instrumental for procedures like polyp removal (polypectomy), tissue resection, controlling bleeding (hemostasis), ablation, and certain biliary and pancreatic endoscopic interventions.

The mechanism of action involves the use of a high-frequency current, produced by the ESU, to cut or coagulate tissue. This current is delivered via a handheld instrument (the active electrode), generating focused heat that allows for precise surgical incisions or vessel sealing, thereby minimizing blood loss. Clinicians can tailor the device's effect by modifying the technique, operational mode, and power level (wattage) to suit different surgical needs.

Common Performance Tests for ESUs

The typical validation tests conducted on ESUs are as follows:

High-Frequency (HF) Power Output Tests

These measurements assess the fundamental energy output of the unit.
Current (I)
Voltage (V)
Power (W)
Impedance (Ω)

Crest Factor (a frequency-related measurement of waveform amplitude) determined using a series of variable loads.

High-Frequency Leakage Current Tests

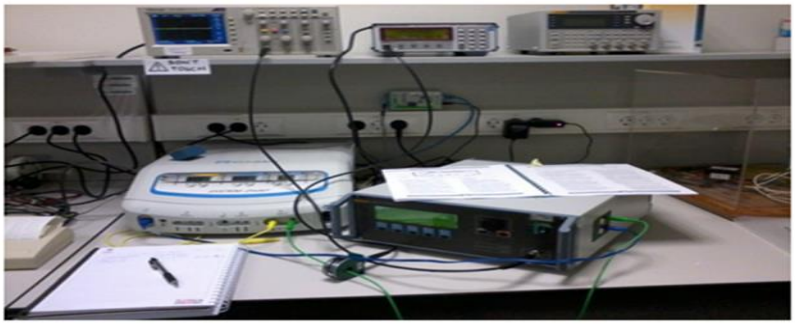
These tests verify the absence of dangerous stray currents and limit capacitive leakage. They ensure that in the event of an electrode fault, any leakage is effectively contained and isolated from the patient. According to the IEC 60601 standard, the leakage current to earth ground through a 200 Ω load must not exceed 150mA.

Return Electrode Monitoring Tests

These tests confirm that the system's alarms are activated and the ESU is shut down if the impedance of the patient return electrode (grounding pad) goes beyond predefined limits. The specific resistance thresholds are provided by the manufacturer's performance specifications. Generally, there are two limits: a low-resistance alarm (approximately 10 Ω) and a high-resistance alarm (approximately 250 Ω).

Note: For all tests listed above, a CONSTANT POWER setting is maintained on the ESU, and the results are documented as described below.

Resistance Measurement



Fixed and Variable Resistance Measurement Results

The data for these measurements were obtained using the setup illustrated in Figure 9 and are presented in the accompanying table.

Figure 9. Monopolar Cut current and Power Measurement Connection

Monopolar Cut Mode: Current and Power Results

Coagulation (Electrosurgical Context)

In electrosurgery, coagulation is a technique where high-frequency electrical current is applied to tissue, generating heat. This heat causes proteins to denature, forming a seal that closes off blood vessels and minimizes bleeding.

Coagulation (Physiological Context)

Commonly known as clotting, this is the natural process where blood transitions from a liquid to a gel state, forming a clot. This mechanism, called hemostasis, stops blood loss from an injured vessel and initiates the healing process. It involves the activation, adhesion, and clumping of platelets, along with the formation and strengthening of fibrin strands.

Denature

This term describes the alteration or destruction of the original three-dimensional structure of a biological molecule, such as a protein or DNA, leading to a loss of its normal function.

Cutting

This mode employs higher power settings, causing instant vaporization of tissue cells rather than simple heating. This effect allows surgeons to make precise incisions while concurrently controlling hemorrhage. Both cutting and coagulation techniques are managed by an electrosurgical generator, which delivers the current with precision for effective surgical outcomes.

Monopolar Coagulation

This is a method where electrical current is delivered to the surgical site through a single active electrode. The current generates heat within the tissue, causing it to coagulate and solidify. This approach is frequently used to manage bleeding during operations, effectively sealing tissues to reduce blood loss. Its applications are widespread in fields like gynecology and laparoscopic surgery.

Note: The Reference Standard Current value is calculated by taking a measurement in millivolts (mV) and dividing it by the current conversion factor (0.1) of the coil meter on the yellow cable. This correlates to the output volts per Amp, as demonstrated in the image below.

Monopolar Coagulation Mode: Current and Power Results

(The definitions for Coagulation, Denature, and Cutting, as provided in the sections above, are applicable here and are not repeated.)

Bipolar Coagulation

This technique utilizes a pair of electrodes (e.g., forceps) to apply electrical current directly to the tissue held between them. The current passes through the tissue, generating heat that promotes coagulation and controls bleeding. A key advantage of this method is the confinement of current between the two electrodes, which reduces thermal damage to adjacent tissues compared to monopolar methods. It is widely used in laparoscopic and other minimally invasive surgeries.

Core Performance Tests for Electrosurgical Units (ESUs)

The validation of ESUs depends on three fundamental tests:

I. High-Frequency (HF) Power Tests

These tests evaluate the unit's output by measuring current, voltage, power (wattage), and crest factor across

a range of simulated tissue loads (resistances). Testing is performed on all operational modes at their maximum power setting. The manufacturer's performance schedule specifies the required test loads and any additional power levels that must be verified. The output power is typically required to be within a tolerance of +/- 10% of the set value.

Modern ESU analyzers incorporate automated testing routines and built-in variable resistors. A comprehensive maintenance schedule for the ESU can often be programmed into these analyzers to ensure consistent and straightforward testing.

II. High-Frequency Leakage Current Tests

These tests verify that the ESU effectively limits stray capacitive currents, which could pose a risk to the patient. Measurements are taken under all operational modes and simulated fault conditions. In monopolar mode, leakage is tested from both the active and return electrodes. In bipolar mode, tests are conducted from both electrodes.

Distinction Between an Electrosurgical Analyzer and an Electrical Safety Tester

These two instruments are designed for distinct aspects of medical equipment verification:

4.1 Electrosurgical Analyzer

Purpose: This instrument is specialized for testing and calibrating Electrosurgical Units (ESUs), which generate high-frequency currents for cutting tissue and achieving hemostasis.

Functions: It measures specific high-frequency output parameters such as power, current, voltage, and crest factor to confirm the ESU operates correctly and safely according to its performance specifications.

Usage: It is indispensable for performance verification and quality assurance of ESUs, ensuring they comply with manufacturer guidelines and regulatory requirements.

4.2 Electrical Safety Tester

Purpose: This is a general-purpose device used to conduct electrical safety checks on a wide variety of medical equipment.

Functions: It evaluates safety parameters like ground wire integrity, enclosure (chassis) leakage current, and insulation resistance to ensure a device does not present an electrical shock or fire hazard.

Usage: It is critical for routine safety inspections and preventive maintenance across numerous medical devices to protect both patients and operators.

Summary: An Electrosurgical Analyzer is a specialized tool for performance testing of ESUs, whereas an Electrical Safety Tester is a general tool for verifying the basic electrical safety of many types of medical equipment. Both are vital for ensuring the safe and effective operation of medical devices.

Table 42. Fixed and Variable Resistance Measurement Results

Exit	Reference Resistance (Ω)	Measured Resistance (Ω)	Mistake (%)	Tolerance (%)	Conformity
Fixed Resistance	200.00	199.88	-0.06	± 2.5	Passed
Variable Resistor	20.00	20.35	1.75		Passed
	50.00	50.34	0.68		Passed
	100.00	100.34	0.34		Passed
	150.00	150.25	0.17		Passed
	200.00	200.38	0.19		Passed
	300.00	300.29	0.10		Passed
	500.00	500.04	0.01		Passed
	750.00	749.92	-0.01		Passed
	1000.00	1004.70	0.47		Passed
	1500.00	1504.41	0.29		Passed
	2000.00	2001.20	0.06		Passed

Table 43. Monopolar Cut Current and Power Measurement Results

Load Resistance (Ω)	Nominal Power (W)	Reference Current (mA)	Calculated Power (W)	Measured Current (mA)	Measured Power (W)	Current Error (%)	Tolerance (Current)	Conformity
20.4	120.0	1000.8	20.4	1007.0	20.3	0.6	± (2.5% of reading + 1 mA)	Passed
50.3	120.0	995.4	49.8	995.0	49.5	0.0		Passed
100.3	120.0	975.3	95.4	985.0	97.1	1.0		Passed
150.3	120.0	891.7	119.5	901.0	122.0	1.0		Passed
200.4	120.0	770.4	118.9	777.0	121.0	0.9		Passed
300.3	120.0	632.8	120.3	637.0	122.0	0.7		Passed
500.0	120.0	492.5	121.3	492.0	121.0	-0.1		Passed
749.9	120.0	410.8	126.6	409.0	125.0	-0.4		Passed
1004.7	120.0	350.4	123.4	349.0	122.0	-0.4		Passed
1504.4	120.0	242.4	88.4	239.0	86.2	-1.4		Passed
2001.2	120.0	180.9	65.5	176.0	62.1	-2.7		Passed

Table 44. Monopolar Cut Power Measurement Uncertainty

Load Resistance (Ω)	Reference Current (mA)	Calculated Reference Power (W)	Measured Power (W)	Uncertainty (W)
20.4	1000.8	20.4	20.3	1.2
50.3	995.4	49.8	49.5	1.2
100.3	975.3	95.4	97.1	1.1
150.3	891.7	119.5	122.0	1.0
200.4	770.4	118.9	121.0	0.8
300.3	632.8	120.3	122.0	0.6
500.0	492.5	121.3	121.0	0.4
749.9	410.8	126.6	125.0	0.4
1004.7	350.4	123.4	122.0	0.3
1504.4	242.4	88.4	86.2	0.3
2001.2	180.9	65.5	62.1	0.3

Table 45. Monopolar Coagulation Power Measurement Uncertainty

Load Resistance (Ω)	Reference Current (mA)	Calculated Reference Power (W)	Measured Power (W)	Uncertainty (W)
20.4	649.6	8.6	8.4	0.6
50.3	642.8	20.8	20.6	0.6
100.3	631.5	40.0	39.8	0.5
150.3	619.9	57.8	57.5	0.5
200.4	609.1	74.3	74.0	0.5
300.3	587.3	103.6	104.0	0.5
500.0	489.4	119.8	119.0	0.4
749.9	409.9	126.0	124.0	0.4
1004.7	352.7	125.0	119.0	0.4
1504.4	293.6	129.7	122.0	0.4
2001.2	251.7	126.8	122.0	0.4

Table 46. Bipolar Coagulation Current and Power Measurement Results

Load Resistance (Ω)	Nominal Power (W)	Reference Current (mA)	Measured Current (mA)	Measured Power (W)	Current Error (%)	Tolerance (Current)	Conformity
20.4	50.0	1077.0	1079.0	23.3	0.2	± (2.5% of reading + 1 mA)	Passed
50.3	50.0	993.7	1004.0	50.4	1.0		Passed
100.3	50.0	709.2	716.0	51.2	1.0		Passed
150.3	50.0	492.6	494.0	36.5	0.3		Passed
200.4	50.0	374.7	375.0	25.2	0.1		Passed
300.3	50.0	253.6	254.0	19.3	0.2		Passed
500.0	50.0	153.2	152.0	11.5	-0.8		Passed
749.9	50.0	103.9	104.0	8.1	0.1		Passed
1004.7	50.0	76.5	76.0	5.8	-0.7		Passed
1504.4	50.0	52.5	52.0	4.0	-1.0		Passed
2001.2	50.0	39.6	39.0	3.0	-1.6		Passed

Table 47. Bipolar Coagulation Power Measurement Uncertainty

Load Resistance (Ω)	Reference Current (mA)	Calculated Reference Power (W)	Measured Power (W)	Uncertainty (W)
20.4	1077.0	23.7	23.3	1.4
50.3	993.7	49.7	50.4	1.2
100.3	709.2	50.4	51.2	0.7
150.3	492.6	36.5	36.5	0.4
200.4	374.7	28.1	25.2	0.3
300.3	253.6	19.3	19.3	0.2
500.0	153.2	11.7	11.5	0.2
749.9	103.9	8.1	8.1	0.1
1004.7	76.5	5.9	5.8	0.1
1504.4	52.5	4.1	4.0	0.1
2001.2	39.6	3.1	3.0	0.1

Calibration of Ultrasound and Ultrasonic Power at TUBITAK UME

The Medical Metrology Laboratory of the Turkish National Metrology Institute (TUBITAK UME) performs high-precision calibrations of ultrasonic output power for medical diagnostic ultrasound systems. This process is critical for ensuring patient safety (by preventing excessive tissue heating) and diagnostic efficacy.

Primary Principle: Radiation Force Balance

TUBITAK UME, like other national metrology institutes, uses the radiation force balance method as its primary standard. This method is absolute and based on the direct measurement of the force exerted by an ultrasonic beam.

Principle of Operation: An ultrasonic wave emitted by a transducer carries both energy and momentum. When this beam is incident upon a special target, it creates a radiation pressure, which is equivalent to a force. By measuring this force, the acoustic power can be calculated.

Simplified formula for an absorbing target:

$$P = F * c$$

where:

P is the Acoustic power (W)

F is the Measured force (N)

c is the Speed of sound in the medium (water), (m/s)

Detailed Calibration Process

Preparation and Environmental Conditions:

Measurements are conducted in a thermostatically controlled water tank filled with degassed and deionized water to minimize errors caused by bubbles and impurities.

The water temperature is strictly controlled because the speed of sound c is temperature-dependent.

Production and Characterization of the Phantom (Device Under Test):

However, for research and method development purposes, the laboratory can create calibration phantoms. These phantoms are complex devices:

Casing: A container designed to mimic the acoustic properties of human tissue (often using hydrogels or polymers with specific acoustic impedance and attenuation coefficients).

Target: At the core of the phantom is a highly absorbing target (often made of rubber or special plastic with high attenuation) which is connected to ultra-sensitive balances.

Purpose: Such a phantom allows for the direct measurement of the force exerted by the ultrasound beam under conditions that simulate clinical use.

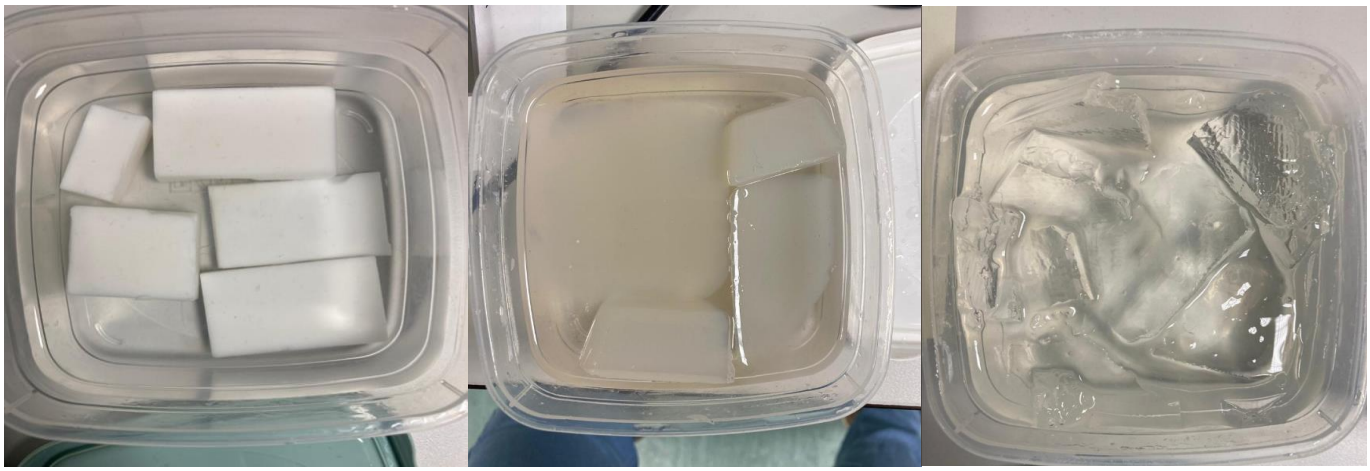


Figure 10. Types of phantom (Agar, muscle and zerdine)

Measurement Procedure:

The ultrasound transducer under test is immersed in the water and precisely aligned relative to the absorbing target of the radiation force balance.

The transducer is driven at a specific frequency and power level.

The ultrasonic beam is fully absorbed by the target, and the resulting force is measured by the balance.

The force generated by radiation pressure is very small (on the order of micronewtons for diagnostic power levels), requiring highly precise balances and effective isolation from vibrations and convective currents in the water.

Measurements are repeated multiple times for different operational modes of the device (continuous wave, pulsed) and different set power levels.

Traceability

The traceability chain at TUBITAK UME is established to the base units of the International System of Units (SI):

Force (Newton): Traceable through the calibration of the balance against the national standard for mass (kilogram) and the local acceleration due to gravity g.
Speed of Sound (m/s): Traceable through precise measurements of the water temperature, which are, in turn, traceable to the national standard for temperature.
Time (s): Traceable through frequency and time standards used for signal generation and pulse duration measurements.
Thus, the power calibration result from TUBITAK UME has an unbroken metrological link to the SI units through a chain of confirmed comparisons.
Uncertainty Evaluation
The uncertainty budget for ultrasonic power measurement is comprehensive and includes the following main components:
Uncertainty of Force Measurement (Major Contribution):
Resolution and repeatability of the balance.
Zero drift of the balance.
Influence of vibrations and convection.
Uncertainty in Determining the Speed of Sound:
Accuracy of controlling and measuring the water temperature.
Purity and composition of the water (which affects the speed of sound).
Uncertainty Related to Positioning and Geometry:
Accuracy of positioning the transducer relative to the target. Misalignment between the acoustic axis and the axis of the balance leads to significant error.
Non-ideal absorption of the target (a portion of energy may be reflected or scattered).
Divergence of the ultrasonic beam (the calculation assumes a plane wave, which is not always the case).
Uncertainty Related to Electronics:
Stability of the signal generator driving the transducer.
Accuracy of measuring the electrical power delivered to the transducer.
A typical level of uncertainty achieved by leading metrology institutes like TUBITAK UME for calibrating ultrasonic power in the diagnostic range is approximately 5% (with a coverage factor k=2, corresponding to a confidence level of approximately 95%).

Ultrasound

Ultrasound refers to sound waves with frequencies exceeding 20 kHz, often extending into the gigahertz (GHz) range. In medical diagnostics, the typical frequency band used is 1 to 20 MHz. This imaging modality employs these high-frequency sound waves to generate visual representations of internal organs, tissues, and anatomical structures. Clinicians utilize it for prenatal care, cardiac assessment, and as a guide for interventional procedures. A significant advantage of ultrasound over techniques like X-rays is the absence of ionizing radiation, enhancing its safety profile for all patients, including expectant mothers.

Sound Speed Measurements

The following apparatus was used in this experiment:
An Oscilloscope (with a 70 MHz bandwidth)
An Ultrasonic Probe (1 MHz operating frequency)
A Signal Generator
Various Phantoms (Agar, Muscle, and Zerdine)
The speed of sound within the different phantoms (figures 39, 40, and 41) was determined using the pulse-echo technique. A 1 MHz immersion ultrasonic transducer was used for this purpose. The velocity was calculated using Equation:

$$V = x / t \ (ms^{-1})$$
$$x = 2d$$

Where:
d is the distance from the probe to the base of the phantom.
x is the total path length for one complete echo cycle.

Attenuation Coefficient Measurements and Calculations

This measurement involved positioning two ultrasonic transducers of the same frequency parallel to each other on opposite sides of the phantom sample. An exponential decrease in the signal amplitude received by the second transducer was observed. The attenuation coefficient was derived using Equations:

$$I = I_0\, e\text{^}(-\mu x)$$
$$\mu = -(1/x)\, ln(I / I_0)$$
$$x = 2d$$

Where:
I is the final amplitude (received signal)
I_0 is the initial amplitude (transmitted signal)
μ is the attenuation coefficient

Acoustic Impedance Calculations

The acoustic impedance was computed using Equation:

$z = \rho c$

Where:
z is the Acoustic Impedance ($kg/m^2 \cdot s$)
ρ is the Density of the phantom (kg/m^3)
c is the Speed of sound in the phantom (m/s)

Density Measurements

Density is defined as the mass of an object per its unit volume. The volume of each cubic sample was determined using Archimedes' principle. This principle states that the buoyant force on a submerged object is equivalent to the weight of the fluid it displaces.

The mass of the phantom was measured, and the volume was determined by the amount of distilled water it displaced. Density was then calculated using Equation:

$$\rho = M / V$$

Where:
ρ is the Density of the phantom (kg/m^3)
M is the Mass of the phantom (kg)
V is the Volume of the phantom (m^3)

Ultrasonic Power

Ultrasonic power quantifies the energy delivered by ultrasonic waves per unit time, with the standard unit of measurement being the watt (W). These are acoustic waves whose frequency lies above the human auditory range (typically >20 kHz), and they are utilized in applications requiring precise energy delivery.

Applications:

Medical and Therapeutic Uses: In diagnostic imaging, ultrasonic power is used to emit waves whose reflections create detailed images. Therapeutic ultrasound applies controlled power to promote blood flow and generate tissue heat for treating injuries.

Ultrasonic Cleaning: In cleaners, ultrasonic power induces cavitation in a liquid, forming microscopic bubbles. The implosion of these bubbles generates shockwaves that effectively remove contaminants from objects such as jewelry and delicate instruments.

Material Processing and Sonochemistry: Ultrasonic power is applied in plastic welding, nanoparticle dispersion, and sonochemistry to accelerate reactions. The high-frequency vibrations facilitate the breakdown of materials and enhance mixing.

Note: The magnitude of the ultrasonic power directly influences the effect's intensity. Higher power results in more potent ultrasonic effects but also increases thermal output and the potential for material degradation.

Key Parameters in Ultrasonic Power Measurement

When quantifying ultrasonic power, several parameters are critical to ensure accuracy, efficacy, and safety across different applications:

Frequency (kHz or MHz): This determines the energy and penetration depth. Lower frequencies (20-100 kHz) are common in industrial cleaning and welding, while higher frequencies (1-15 MHz) are used for medical imaging.

Power Output (Wattage): The total energy output of the device, measured in watts (W). It governs the intensity of the ultrasonic effects.

Intensity (W/cm^2): The power delivered per unit area. Higher intensity leads to more powerful interactions, such as deeper tissue heating or more effective cleaning.

Duty Cycle: In pulsed operation, this is the percentage of time the ultrasound is active. It is a crucial control parameter for managing thermal buildup, especially in therapeutic settings.

Amplitude (microns or dB): The magnitude of the wave's particle displacement or pressure variation. Greater amplitude enhances effects like cavitation but also raises the risk of damaging materials.
Waveform Type: Ultrasound can be continuous (steady output) or pulsed (intermittent output). Pulsed waves are often used to mitigate heat accumulation.
Temperature: The temperature of the medium affects efficiency, as it can influence cavitation dynamics and reaction rates in processes like sonochemistry.
Cavitation Threshold: The minimum intensity required to generate cavitation bubbles in a specific medium. This threshold depends on frequency, medium properties, and temperature.
Impedance Matching: Optimizing the transfer of power from the transducer to the medium by minimizing energy loss due to reflection.
Beam Profile: The spatial distribution of the ultrasonic energy (e.g., focused or unfocused). A focused beam concentrates power for high-intensity local effects, while an unfocused beam distributes it over a wider area.

Table 48. Acoustic Attenuation Coefficient Measurement Results

Reference Value ($dB \cdot cm^{-1} \cdot MHz^{-1}$)	Measured Value ($dB \cdot cm^{-1} \cdot MHz^{-1}$)	Uncertainty ($dB \cdot cm^{-1} \cdot MHz^{-1}$)
0.50 ± 0.05	0.51	0.17

Table 49. Sound Speed Measurement Results

Reference Value (m/s)	Measured Value (m/s)	Uncertainty (m/s)
1540.0 ± 10.0	1536.9	16.0

Table 50. Calibration Results

Reference Mass in Water (g)	Measured Mass in Water (g)	Measured Ultrasonic Power (Watt)	Calculated Ultrasonic Power (Watt)	Mistake (%)	Tolerance* (%)	Conformity
0.09	0.1	1.28	1.27	1.1	± 3.0	Passed
0.17	0.2	2.53	2.53	-0.1		Passed
0.43	0.4	6.48	6.33	2.4		Passed
0.87	0.9	12.82	12.66	1.3		Passed
1.73	1.8	25.64	25.31	1.3		Passed

Conclusions and Future Work

Conclusions

This internship at TUBITAK UME has provided invaluable, hands-on experience in the fundamental principles and practical applications of medical metrology across a range of critical devices. The primary objectives of understanding and performing key measurement and calibration techniques were successfully achieved.

The key learnings from this work are summarized as follows:

Patient Safety Monitoring: Proficiency was gained in verifying the accuracy of **patient monitors**, specifically performing electrical safety tests and calibrating parameters such as electrocardiogram (ECG) amplitude, heart rate, blood pressure (non-invasive and invasive), and oxygen saturation (SpO_2). This underscored the direct link between measurement traceability and reliable patient diagnosis.

Anesthesia and Respiratory Care: Practical experience was acquired in calibrating **medical gas analyzers** for oxygen (O_2), carbon dioxide (CO_2), and anesthetic agents. Understanding the principles of side-stream and main-stream sampling and ensuring the accuracy of these devices is critical for patient safety during surgical procedures.

Precision Drug Delivery: The internship covered the metrological control of **infusion pumps** and syringe pumps. This involved testing for flow rate accuracy, occlusion pressure, and bolus delivery, ensuring these devices deliver medications as prescribed, which is vital for patient treatment, especially in critical care.

Diagnostic Imaging Safety and Performance: A comprehensive understanding was developed in characterizing **ultrasound** systems. This included measuring key acoustic parameters—sound speed, attenuation coefficient, and acoustic output power—using tissue-mimicking phantoms. This work is essential for ensuring both image quality and patient safety by controlling thermal and mechanical effects.

Surgical Energy: Competence was developed in conducting essential performance and safety tests on **Electrosurgical Units (ESUs)**, including high-frequency power output, leakage current, and return electrode monitoring, highlighting their role in preventing electrosurgical burns.

In summary, this work has solidified the understanding that robust, traceable, and well-characterized measurements are the foundational pillar for the safety, efficacy, and performance of all medical devices, from diagnostic to therapeutic.

Future Work

The outcomes and competencies gained during this internship will be directly applied to enhance the capabilities of our National Metrology Institute (UzNIM). The following steps are planned:

Service Expansion: We intend to establish and offer new calibration services based on the methodologies learned. Priority will be given to **infusion device testing**, **medical gas analyzer calibration**, and **ultrasonic power measurement**, addressing critical needs in our national healthcare system.

Development of Local Test Platforms: A key project will be to develop in-house test setups, such as tissue-mimicking **ultrasound phantoms** and flow resistor arrays for **infusion pump** testing. This will increase our self-reliance and allow for customized testing protocols.

Knowledge Transfer: The acquired knowledge on the metrology of **patient monitors**, **gas analyzers**, and **ESUs** will be disseminated within our NMI through internal workshops and training sessions, aiming to build a core team of experts in medical metrology.

Proficiency Testing: We plan to initiate participation in inter-laboratory comparisons for the newly learned fields, particularly for **ultrasound power** and **infusion device** calibration, to validate our measurement capabilities and ensure international equivalence.

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This training program has been a cornerstone in deepening my expertise in Medical Metrology. I will forever treasure my time in Türkiye and the invaluable expertise I gained, which will benefit not only my professional growth but also contribute to this field development in my country. My sincere thanks go to the exceptional team at the TÜBİTAK UME Medical Metrology Laboratories, under the leadership of **Assoc. Prof. Dr. Baki Karaböce,** and including **Dr. Hüseyin Okan Durmuş, Mr. Gökhan Güler, Elif Başaran and Feyzanur Ak**. This remarkable team dedicated immense time and effort to mentor me through every concept, ensuring the success of my research project. Their hospitality was extraordinary and deeply touching. I am truly thankful to each one of you.

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This training allowed me to not only meet my technical objectives but also to cultivate essential soft skills that will propel my career forward. The dedication and professional ethos of the TÜBİTAK UME team have made a lasting impact on my mindset and approach to work.

During my stay, I observed a team deeply committed to research, consistently exceeding expectations to develop innovative solutions for complex challenges. Their ability to create custom-made approaches perfectly suited to their applications is an insight I fully intend to integrate into my work at my home institute, UzNIM. Thank you from the bottom of my heart — teşekkür ederim, my dear friends!