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Vital Reference Handbook for Biomedical Equipment Testing and Calibration

Essential Parameters, Procedures and Formulas for Fluke Analyzers

Incorporating ISO/IEC 17025 Quality Management Requirements

A Comprehensive Textbook Reference for Medical Device Quality Assurance

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Disclaimer: This handbook is intended as a technical reference for biomedical engineers, clinical engineers, and healthcare professionals involved in medical equipment testing and calibration. Information is derived from manufacturer technical manuals, peer-reviewed journals, international standards publications, and authoritative textbooks. While every effort has been made to ensure accuracy, the author and institution assume no responsibility for errors, omissions, or misuse. All specifications are subject to change. Users must consult original manufacturer documentation and comply with applicable international standards (IEC 60601 series, ANSI/AAMI, NFPA-99, ISO/IEC 17025) before conducting equipment testing.

Primary Standards and References:

- ISO/IEC 17025:2017 — General requirements for testing and calibration laboratories
- IEC 60601-1:2005 + A1:2011 — Medical electrical equipment safety
- IEC 60601-2-4:2010 — Cardiac defibrillators
- IEC 60601-2-27:2011 — Electrocardiographs
- IEC 62353:2014 — In-service safety and performance testing
- ANSI/AAMI ES-1:2014 — Electrical safety for medical devices
- NFPA-99:2015 — Healthcare facilities code
- JCGM 100:2008 — Evaluation of measurement data and uncertainty

Contents

Chapter 1

Introduction to ISO/IEC 17025

1.1 Overview of ISO/IEC 17025

ISO/IEC 17025:2017 specifies general requirements for the competence, impartiality, and consistent operation of testing and calibration laboratories. This international standard ensures that biomedical equipment testing laboratories produce accurate, reliable results traceable to national and international standards.

The eight core management components are:

1. **Organization** — Laboratory structure, responsibilities, and management oversight
2. **Management System** — Documented procedures, control mechanisms, and continuous monitoring
3. **Resource Management** — Personnel qualification, facilities, equipment, and calibration
4. **Process Requirements** — Test methods validation, uncertainty budgets, and quality records
5. **Evaluation of Measurement Uncertainty** — Quantifying and documenting result reliability
6. **Ensuring Quality of Results** — Internal quality control and external proficiency testing
7. **Reporting of Results** — Clear, complete, and traceable documentation
8. **Impartiality, Confidentiality, and Complaints** — Professional conduct and nonconformance management

Each section of this handbook integrates these requirements into practical testing workflows for biomedical equipment. The theoretical foundation relies on established references including Webster's *Medical Instrumentation*, Bronzino's *Biomedical Engineering Handbook*, and Khandpur's *Handbook of Biomedical Instrumentation*.

Chapter 2

Fluke ESA612 Electrical Safety Analyzer

2.1 Introduction and Purpose

The Fluke ESA612 is a portable electrical safety analyzer combining protective earth continuity, insulation resistance, leakage current, mains voltage and frequency measurement with basic ECG simulation capabilities. According to the ESA612 Technical Manual, the instrument incorporates an internal IEC 60601-1 compliant measuring network (MOPP/MOOP leakage network) and multiple test configurations for Class I and Class II medical equipment, with support for both Type BF and Type CF applied parts. Internally, the leakage current measurement path uses precision burden resistors and a wide-band current-to-voltage converter so that both low-frequency and high-frequency leakage components can be captured over the DC–1 MHz band.

The analyzer integrates automatic test sequences with programmable DUT receptacle polarity switching (normal, reverse, open neutral) and multiple fault conditions (open protective earth, open neutral, mains reversed) for systematic execution of the IEC 60601-1 leakage test matrix. Line synchronization circuitry allows accurate leakage current measurement at the mains fundamental and harmonics, which is crucial for interpreting devices with switched-mode power supplies and complex input filters.

ISO/IEC 17025 — Organization and Management System

Establish written procedures for ESA612 operation, maintenance, and calibration per ISO/IEC 17025 Clause 4.2. Designate qualified personnel with minimum 2-year formal training. Document test schedules, equipment ownership, and traceability records. Maintain training records showing competency in electrical safety testing per IEC 60601-1.

2.2 Electrical Safety Specifications

2.2.1 Mains Voltage Measurement

The ESA612 measures alternating voltage at the mains inlet according to IEC 60601-1 requirements. Table 2.1 presents essential mains voltage specifications.

Voltage Measurement Accuracy Formula:

$$V_{\text{accuracy}} = \pm(0.02 \times V_{\text{reading}}) + \pm 0.2 \text{ V} \tag{2.1}$$

Table 2.1: ESA612 Mains Voltage Measurement Specifications

Parameter	Specification
Mains voltage range (lower)	90–132 V_{ac} rms
Mains voltage range (upper)	180–264 V_{ac} rms
Accessible voltage range	0–300 V_{ac} rms
Measurement accuracy	±(2% of reading +0.2 V)
Resolution	0.1 V
Frequency response	DC to 1 MHz

Example: For 230 V_{ac}:

$$V_{\text{accuracy}} = \pm(0.02 \times 230) + \pm 0.2 = \pm 4.8 \text{ V } (\pm 2.09\%). \tag{2.2}$$

ISO/IEC 17025 — Process Requirements and Measurement Uncertainty

Calculate combined uncertainty using accuracy specifications and JCGM 100:2008 standards. Document uncertainty contributions from analyzer accuracy (±2%) and resolution (±0.2 V). Include environmental effects. Ensure reported voltage includes expanded uncertainty (multiply by $k = 2$ for 95% confidence). Maintain uncertainty calculation worksheets in laboratory quality files.

CAUTION

Always verify mains supply voltage matches device nameplate rating per IEC 60601-1 Clause 8.2. Energized circuits present electrical shock hazard. Use proper PPE (insulated gloves per IEC 60903, safety glasses) and follow facility lockout/tagout procedures.

2.2.2 Leakage Current Measurement

Leakage current testing is critical for patient safety verification. The ESA612 measures leakage currents across a wide frequency spectrum per IEC 60601-1 Clauses 8.3 and 8.4.

Table 2.2: ESA612 Leakage Current Accuracy by Frequency Band

Frequency Band	Accuracy	Test Type
DC to 50 Hz	$\pm(2\% + 2.5\ \mu A)$	Ground wire, chassis
50 Hz to 1 kHz	$\pm(2\% + 1\ \mu A)$	Ground and isolation
1 kHz to 100 kHz	$\pm(2\% + 1\ \mu A)$	High-frequency
100 kHz to 1 MHz	$\pm(5\% + 1\ \mu A)$	RF susceptibility

Leakage Current Accuracy Formula:

$$I_{\text{leak\_acc}} = \pm(0.02 \times I_{\text{reading}}) + \pm 2.5\ \mu A \tag{2.3}$$

ISO/IEC 17025 — Resource Management — Calibration

ESA612 must be calibrated annually to NIST-traceable standards. Maintain calibration certificate with measurement points at 100 V, 150 V, 230 V, and 300 V_{ac} per manufacturer procedure. Document calibration uncertainty. Establish control chart to track analyzer drift. If drift exceeds 1/3 of tolerance, remove from service.

CAUTION

Patient leakage currents exceeding 5 mA (Type BF) or 10 mA (Type CF) pose electrocution risk per IEC 60601-1 Table 3. Immediately remove device from service if limits exceeded. Document failure with manufacturer, model, and serial number.

2.2.3 Insulation Resistance Testing

Insulation resistance verification ensures electrical isolation between patient-accessible parts and mains per IEC 60601-1 Clause 8.4.

Table 2.3: ESA612 Insulation Resistance Test Configurations

Configuration	Test Voltage	Acceptance Criterion
Mains to PE	500 V or 1000 V DC	> 0.5 MΩ
Applied Part to PE	500 V or 1000 V DC	> 0.5 MΩ
Mains to Non-Earthed	500 V or 1000 V DC	Per IEC 60601-1 8.4.2

Insulation Resistance Calculation:

$$R_{\text{insulation}} = \frac{V_{\text{test}}}{I_{\text{measured}}} \tag{2.4}$$

ISO/IEC 17025 — Reporting of Results and Quality Records

Per ISO/IEC 17025 Clause 7, every test must include: device identification (serial, model, asset tag); test method reference (IEC 60601-1 clause); measured values with expanded uncertainty per JCGM 100:2008; pass/fail determination with acceptance limits; date, time, technician name, and analyzer calibration status; environmental conditions (temperature, humidity); any deviations noted. Store reports for minimum 6 years.

2.3 ECG Simulation Specifications

The ESA612 ECG simulator generates clinically realistic waveforms for patient monitor testing per IEC 60601-2-27.

Table 2.4: ESA612 ECG Simulation Parameters

Parameter	Specification
Lead configuration	12-lead ECG per IEC 60601-2-27 Clause 5.7
Heart rate range	30, 60, 120, 180, 240 BPM
ECG amplitude (Lead II)	0.5 to 5 mV
Amplitude accuracy	±2% for normal waveforms
Output impedance	1000 Ω nominal ±10%
Pacemaker pulse	63 ms width at 30–60 BPM

ECG Amplitude Accuracy Formula:

$$A_{\text{accuracy}} = \pm 0.02 \times A_{\text{setting}} \tag{2.5}$$

ISO/IEC 17025 — Ensuring Quality of Results — QC

Test ESA612 ECG output monthly with reference patient monitor (calibrated per ISO/IEC 17025 Clause 6.6). Verify displayed heart rate, amplitude, and waveform morphology remain within ±2% accuracy. Maintain ECG quality control chart. If QC results drift $>$ 1 SD beyond control limits, investigate and recalibrate before resuming testing.

CAUTION

When testing monitors with defibrillators, ensure defibrillator is disabled or isolated from ESA612 output per IEC 60601-2-4 Section 10. Always verify monitor is in DEMO or TEST mode.

2.4 Test Procedure

1. Pre-Test: Verify ESA612 calibration is current (within 12 months)
2. Visual Inspection: Check for physical damage and proper grounding
3. Earth Bond Test: Verify ground wire resistance $<$ 0.1 Ω
4. Leakage Current: Measure at 100% mains voltage in required configurations
5. Insulation Resistance: Apply 500 V or 1000 V DC; record minimum
6. ECG Verification: Simulate NSR at 60 BPM and 1 mV

7. Documentation: Complete test report with parameters and uncertainty

ISO/IEC 17025 — Impartiality and Confidentiality

Maintain impartial, unbiased testing regardless of device origin per ISO/IEC 17025 Clause 2.2. Do not release results to unauthorized parties per ISO/IEC 17025 Clause 8.8.2. Maintain confidentiality. If conflict of interest exists, declare immediately and delegate testing to an independent technician.

2.4.1 Typical Devices Under Test (DUTs) for ESA612

The ESA612 can be used to perform electrical safety and basic functional checks on a wide range of mains-powered and patient-connected medical devices, including but not limited to:

- Patient monitors (bedside multi-parameter and transport monitors)
- Ventilators and anesthesia workstations with integrated power supplies
- Infusion and syringe pumps with mains power or external power adapters
- Defibrillators and monitor-defibrillators (for mains leakage and chassis tests)
- Electrosurgical units (ESUs) basic safety leakage and earth continuity
- Ultrasound scanners (cart-based) and imaging peripherals
- Dialysis machines and blood warmers
- Operating theatre tables, lights and ceiling pendants with mains power
- Infant incubators, radiant warmers and phototherapy units
- Laboratory analyzers (auto-analyzers, centrifuges) located in clinical areas

For battery-powered devices with external chargers, the ESA612 is typically applied to the charger or docking station (mains-connected portion), while applied-part leakage is evaluated in representative operating modes as defined in the manufacturers technical documentation.

Chapter 3

Fluke IDA-1S Infusion Device Analyzer

3.1 Introduction and Purpose

The Fluke IDA-1S is a one-channel infusion device analyzer designed for portable, battery-operated testing of infusion pump performance. Internally, the analyzer uses a precision volumetric measurement cell in combination with a high-resolution time base to compute average flow rate as the ratio of delivered volume to elapsed time. The fluid path and sensing geometry are optimized to reduce the influence of surface tension and meniscus effects, which is especially important at very low flow rates (below 5 mL/h) and for viscous or non-Newtonian test fluids.

The IDA-1S firmware includes algorithms for auto-start (triggering on flow), stabilization time, and auto-stop conditions. These features allow standardized measurement windows to be applied across different pump technologies (piston, peristaltic, rotary, and syringe mechanisms) while minimizing operator variability. The system can also log long-duration infusions, enabling trending of flow drift over several hours, which is critical in oncology and neonatal infusion applications.

ISO/IEC 17025 — Resource Management — Personnel Competence

Technicians must demonstrate competency per ISO/IEC 17025 Clause 6.2 in: infusion pump classification and types; flow measurement principles; units conversion (mL/h, mL/min); pressure concepts; data recording and uncertainty documentation per JCGM 100:2008. Maintain training records and competency assessments; update annually.

3.2 Flow Rate Measurement

3.2.1 Specifications

Table 3.1: IDA-1S Flow Rate Measurement Specifications

Parameter	Specification
Measurement principle	Volumetric method
Flow rate range	0.5 to 1000 mL/h
Accuracy (16–200 mL/h)	±1% reading ±1 LSD
Accuracy (V > 10 mL)	±2% reading ±1 LSD
Maximum test duration	10 hours continuous
Resolution	0.01 mL/h

Flow Rate Accuracy Formula:

$$F_{\text{accuracy}} = \pm(0.01 \times F_{\text{reading}}) + \pm 1 \text{ LSD} \tag{3.1}$$

Example: For 100 mL/h: $F_{\text{accuracy}} = \pm 1.0$ mL/h (acceptance range: 99–101 mL/h).

ISO/IEC 17025 — Process Requirements — Method Validation

Establish written procedure per ISO/IEC 17025 Clause 7.2 specifying: pump types, volume window (minimum 20 mL), acceptable ranges, uncertainty calculation per JCGM 100:2008, pass/fail criteria. Validate by comparing against reference pump at minimum 5 flow rates. Document validation report.

CAUTION

Air bubbles in the measurement chamber cause erratic readings. Prime chamber thoroughly per ISO 8835 Annex C. Allow gravity to fill naturally. Inspect tubing for kinks or obstructions.

3.3 Volume and Pressure

Table 3.2: IDA-1S Volume and Pressure Specifications

Parameter	Specification
Volume range	0.06 to 999 mL
Volume accuracy (V > 20 mL)	±1% reading ±1 LSD
Pressure range	0 to 45 psi (0 to 310 kPa)
Pressure accuracy	±1% Full Scale ±1 LSD

ISO/IEC 17025 — Evaluation of Measurement Uncertainty

Combine uncertainty components: (1) IDA-1S spec (±1% to ±2%); (2) reference standard (∼ ±0.5%); (3) repeatability (∼ ±0.5%); (4) environment (±0.3%). Use root-sum-square: $u_c = \sqrt{u_1^2 + u_2^2 + u_3^2 + u_4^2}$. Multiply by $k = 2$ for 95% confidence per JCGM 100:2008.

3.3.1 Dynamic Response and Low-Flow Behaviour

At very low flow rates (for example 0.5–5 mL/h), the dominant contributors to uncertainty are startup transients, pump pulsatility and evaporation effects. To minimize these influences, the IDA-1S test method should use:

- A minimum test window of 30–60 minutes for low-flow verification
- Closed fluid reservoirs to reduce evaporative loss
- Stable ambient temperature, since viscosity changes with temperature
- Consistent vertical positioning of the pump relative to the analyzer inlet to avoid hydrostatic head differences

For occlusion testing, the step response of pressure versus time can be used to differentiate between a slowly occluding line (kinking, partial obstruction) and an abrupt mechanical blockage. Recording the time-to-alarm at a given programmed flow provides additional diagnostic information about the pumps internal alarm logic.

3.3.2 Typical Devices Under Test (DUTs) for IDA-1S

The IDA-1S is suitable for performance testing of most volumetric and syringe-type infusion systems, including:

- Volumetric infusion pumps (general ward, ICU, oncology)
- Syringe pumps (neonatal, anesthesia, critical care)
- Ambulatory infusion pumps (when adapted to bench-test configurations)
- Enteral feeding pumps (for volume and flow-rate verification)
- PCA (patient-controlled analgesia) pumps basal rate and bolus volume tests
- Integrated infusion modules on multi-parameter patient care systems
- Gravity infusion sets with flow regulators (for educational and research checks)

While occlusion pressure testing can be performed on most modern pumps, the acceptance limits and alarm logic are strongly manufacturer-specific; therefore, each DUT must be evaluated against its own technical manual and clinical application (adult vs neonatal).

Chapter 4

Fluke VT650 Gas Flow Analyzer

4.1 Introduction and Purpose

The Fluke VT650 is a portable gas flow analyzer intended for verification of respiratory and anesthesia equipment, including ventilators, flowmeters and oxygen delivery systems. The instrument uses a differential-pressure based thermal mass flow sensor with integrated temperature and barometric compensation, allowing accurate measurement of bidirectional flow, pressure and volumetric parameters over a wide dynamic range. The analyzer supports both adult and neonatal ranges and can apply ventilator-style test profiles such as volume-controlled, pressure-controlled and high-flow nasal cannula conditions.

In addition to instantaneous flow, the VT650 can calculate derived parameters including tidal volume, minute volume, peak inspiratory and expiratory flows, I:E ratio, and leak fraction when used with the appropriate test setup. Internally, numerical integration of flow over time is used to compute delivered volume for each simulated breath, making synchronization with ventilator trigger timings important when performing high-accuracy volume verification.

ISO/IEC 17025 — Organization — Scope of Testing

Laboratory scope per ISO/IEC 17025 Clause 4.3 includes testing of ventilators (ICU, neonatal), CPAP/BiPAP systems, oxygen delivery devices. Tests include flow (±300 L/min), pressure measurement, temperature/humidity compensation per JCGM 100:2008, oxygen concentration. Accreditation limited to 15–30°C, 30–80% RH.

4.2 Flow Measurement

Table 4.1: VT650 Bidirectional Flow Measurement

Parameter	Specification
Measurement technique	Thermal mass flow meter
Flow range	±300 L/min
Directional capability	Bidirectional
Resolution	≈ 0.1 L/min
Response time	< 100 ms

Thermal Flow Principle:

$$Q \propto \frac{T_{\text{hot}} - T_{\text{ambient}}}{R_{\text{thermal}}} \tag{4.1}$$

ISO/IEC 17025 — Resource Management — Environmental Controls

Testing requires per ISO/IEC 17025 Clause 6.3: Temperature 15–30°C (preferably 20–25°C); Humidity 30–80% RH; Barometric pressure within range. Monitor continuously. If outside limits, pause until stabilization or apply validated correction factors per JCGM 100:2008. Document environmental conditions on all reports.

CAUTION

Never block flow sensor inlet or outlet. Inspect airway adapter for debris or moisture per IEC 60601-2-30 Clause 9.2.1. Clean per facility protocols per ISO 11135.

4.2.1 Typical Devices Under Test (DUTs) for VT650

The VT650 can be used to verify performance of a wide range of respiratory care and anesthesia devices, for example:

- ICU ventilators (adult, pediatric and neonatal modes)
- Transport ventilators used in ambulances and intra-hospital transfer
- Anesthesia workstations with integrated ventilator modules
- High-flow nasal cannula (HFNC) therapy devices
- CPAP and BiPAP systems (sleep therapy and acute care)
- Mechanical resuscitators and emergency ventilatory devices
- Oxygen flowmeters and blenders (for flow and FiO_2 verification when used with compatible O_2 sensors)
- Respiratory therapy devices such as nebulizer compressors and peak-flow/FEV_1 simulators (for bench comparison)

When testing ventilators that use active exhalation valves or dual-limb circuits, care must be taken to connect the analyzer in the correct limb (inspiratory or expiratory) and to configure the VT650 for the appropriate circuit type (single-limb with leak, dual-limb, or mask-based circuits).

Chapter 5

Fluke Impulse 6000D Defibrillator Analyzer

5.1 Introduction and Purpose

The Impulse 6000D is a defibrillator analyzer used for testing external manual, semi-automatic (AED) and advisory defibrillators, as well as devices combining defibrillation and ECG monitoring. The analyzer incorporates an internal precision, non-inductive 50 Ω load and high-speed sampling circuitry to capture the complete defibrillation waveform, including leading edge voltage, current, and energy delivered. For biphasic defibrillators, separate measurements of first- and second-phase amplitudes and durations can be made, enabling detailed waveform characterization against manufacturer specifications.

In addition to energy measurement, the Impulse 6000D can perform synchronized cardioversion timing checks, charge-time tests, and output verification for external transcutaneous pacemakers. Pacemaker output is characterized by pulse amplitude, pulse width and rate; the analyzer internally uses a low-capacitance measuring circuit to avoid distorting the very short-duration pacer pulses.

ISO/IEC 17025 — Management System — Safety Assessment

Impulse testing involves high-voltage hazards (up to 5000 V) per IEC 60601-2-4 Clause 12. Establish Laboratory Safety Protocol per ISO/IEC 17025 Clause 4.5: only trained personnel operate; annual competency training; PPE requirements (gloves per IEC 60903, safety glasses); two-person rule; emergency procedures; first-aid kit. Post warning signs.

5.2 Energy Measurement

Table 5.1: Impulse 6000D Energy Measurement Specifications

Parameter	Specification
Energy range	0.1 to 600 J
Accuracy (0.1–360 J)	±1% reading +0.1 J
Accuracy (360–600 J)	±1% reading +0.1 J
Test load	50 Ω non-inductive
Maximum pulses	10 shocks per 5 minutes

Energy Accuracy:

$$E_{\text{accuracy}} = \pm(0.01 \times E_{\text{measured}}) + \pm 0.1 \text{ J} \tag{5.1}$$

Example: For 200 J: $E_{\text{accuracy}} = \pm 2.1$ J ($\pm 1.05\%$).

ISO/IEC 17025 — Resource Management — Test Load Calibration

50 Ω resistor critical for traceability per ISO/IEC 17025 Clause 6.6: Verify resistance quarterly with calibrated multimeter traceable to NIST per ISO Guide 35; ensure non-inductive construction (< 2 ţH); replace if drifts $> 1\%$; maintain calibration certificate.

CAUTION

High-voltage shock hazard present per IEC 60601-2-4 Clause 12. Never work alone. Maintain 1 meter minimum clearance per IEC 60903. Always connect test load before charge sequence. Wear proper PPE.

5.2.1 Typical Devices Under Test (DUTs) for Impulse 6000D

The Impulse 6000D supports verification of the following categories of equipment:

- Manual external defibrillators (monophasic and biphasic)
- Monitor-defibrillators with integrated ECG monitoring and pacing
- Automated external defibrillators (AEDs) and public-access defibrillators
- Transport and pre-hospital defibrillators used in ambulances and air medical services
- External transcutaneous pacemakers (for pacing output checks)
- Training defibrillators (for verifying trainer output and scenario fidelity)

When testing AEDs, special AED-specific cables or paddle adapters are used to connect between the AED pads and the analyzer input. Some AED models require simulation of patient impedance or particular pad placement patterns; in these cases, the test setup must strictly follow the AED manufacturers technical manual to ensure that the device enters the intended energy delivery mode.

Chapter 6

Fluke ProSim 8 Vital Signs Simulator

6.1 Introduction and Purpose

The ProSim 8 is a multifunction vital signs simulator designed to serve as a consolidated source of physiological signals for testing multi-parameter patient monitors, including ECG, respiration, invasive and non-invasive blood pressure, temperature, cardiac output and pulse oximetry. Internally, the simulator uses high-resolution DACs and carefully shaped digital waveforms to reproduce physiologically realistic morphology, timing and amplitude relationships between signals (for example, synchronizing respiration and ECG artefacts, or coupling NIBP cuff inflation profiles with SpO_2 and heart-rate changes).

For NIBP simulation, ProSim 8 generates a dynamic pressure waveform that mimics the brachial artery pressure during cuff inflation and deflation, with superimposed oscillometric pulses. By adjusting pulse amplitude and envelope, the simulator can emulate different vascular compliances and heart rates, allowing verification of monitor algorithms under a variety of clinical scenarios. For SpO_2, a dedicated optical suspension and encoded R-curve library are used to approximate manufacturer-specific sensor calibration curves.

ISO/IEC 17025 — Organization — Scope and Authority

Laboratory scope per ISO/IEC 17025 Clause 4.3 includes: ECG verification per IEC 60601-2-27; multiparameter monitor tests; NIBP calibration (up to 300 mmHg); temperature simulation per IEC 60601-2-29; SpO_2 probe testing per IEC 60601-2-61. Limitations: SpO_2 module not for primary oximeter calibration (requires reference systems); advanced wavelengths require validation per JCGM 100:2008.

6.2 ECG Simulation

Table 6.1: ProSim 8 ECG Simulation Parameters

Parameter	Specification
Lead configuration	12-lead
Heart rate range	30 to 240 BPM
ECG amplitude (Lead II)	0.5 to 5 mV
Amplitude accuracy	±2%
ST elevation	−0.8 to +0.8 mV

ISO/IEC 17025 — Process Requirements — Method Validation

Connect ProSim output to reference monitor (calibrated per ISO Guide 35); program NSR at 60 BPM, 1 mV per IEC 60601-2-27 Clause 7; verify display matches expectations within uncertainty per JCGM 100:2008; document validation; establish acceptance criteria (HR display ±1 BPM, amplitude ±0.1 mV); repeat at 6-month intervals.

6.3 Blood Pressure Parameters

Table 6.2: ProSim 8 Blood Pressure Specifications

Type	Range	Accuracy
IBP	−10 to +300 mmHg	±(1% + 1 mmHg)
NIBP	0 to 300 mmHg	±(1% + 1 mmHg)
Temperature	32–42 °C	±0.5°C

ISO/IEC 17025 — Evaluation of Measurement Uncertainty

NIBP uncertainty components per JCGM 100:2008: ProSim spec (±1% + 1 mmHg); repeatability (∼ ±0.5 mmHg); transducer drift (ś1–2 mmHg); environment. Combine via root-sum-square. Multiply by $k = 2$ for 95% confidence. Report with expanded uncertainty per ISO/IEC 17025 Clause 7.

CAUTION

SpO_2 probe contact quality affects reading per IEC 60601-2-61 Clause 7.2.101. Ensure proper probe seating. High ambient light causes erratic readings per Annex B. Verify correct manufacturer R-curve.

6.3.1 Typical Devices Under Test (DUTs) for ProSim 8

The ProSim 8 can be used as a primary functional simulator for a wide spectrum of monitoring devices, such as:

- Bedside multi-parameter patient monitors (adult, pediatric, neonatal)
- Operating theatre and recovery room monitors
- Transport and ambulance monitors with SpO_2 and NIBP
- Anesthesia monitors incorporating ECG, NIBP, IBP, temperature and respiration
- Central monitoring stations (via networked acquisition from multiple bedside monitors)

- Stand-alone NIBP monitors used in wards and outpatient clinics
- Stand-alone SpO_2 pulse oximeters and handheld spot-check devices
- Cardiac output-enabled monitors (for thermodilution or simulated CO inputs)

For high-acuity applications, it is good practice to exercise a monitor using multiple combinations of parametersfor example, low amplitude ECG with tachycardia, hypotension on NIBP and desaturation on $SpO_2$to confirm that alarm priorities and annunciation follow the hospitals alarm management policies.

Field Notes and Observations

Use the following 5 pages to record observations, calibration results, test deviations, maintenance issues, or additional notes during biomedical equipment testing and calibration procedures.

TEST RECORD 1

Test Date: _____ **Time:** _____

Equipment ID: _____

Analyzer Used: _____

Technician Name: _____

Supervisor: _____

Observations and Findings:

Results and Recommendations:

Corrective Actions (if any):

Technician Signature: _____ Supervisor Signature: _____

TEST RECORD 2

Test Date: _____ **Time:** _____

Equipment ID: _____

Analyzer Used: _____

Technician Name: _____

Supervisor: _____

Observations and Findings:

Results and Recommendations:

Corrective Actions (if any):

Technician Signature: _____ Supervisor Signature: _____

TEST RECORD 3

Test Date: _____ **Time:** _____

Equipment ID: _____

Analyzer Used: _____

Technician Name: _____

Supervisor: _____

Observations and Findings:

Results and Recommendations:

Corrective Actions (if any):

Technician Signature: _____ Supervisor Signature: _____

TEST RECORD 4

Test Date: _____ **Time:** _____

Equipment ID: _____

Analyzer Used: _____

Technician Name: _____

Supervisor: _____

Observations and Findings:

Results and Recommendations:

Corrective Actions (if any):

Technician Signature: _____ Supervisor Signature: _____

TEST RECORD 5_____

Test Date: _____ **Time:** _____

Equipment ID: _____

Analyzer Used: _____

Technician Name: _____

Supervisor: _____

Observations and Findings:

Results and Recommendations:

Corrective Actions (if any):

Technician Signature: _____ Supervisor Signature: _____

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