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Polysomnography (PSG) Sleep Study System

Technical Specification

1. Equipment Details

1. The system shall be a comprehensive digital Polysomnography (PSG) system capable of performing diagnostic sleep studies and CPAP/BiPAP titration studies in accordance with current sleep medicine standards.
2. The system shall support simultaneous multi-channel physiological signal acquisition, storage, and analysis.
3. The system shall be suitable for attended sleep laboratory studies and unattended monitoring where applicable.
4. The equipment shall be connected/disconnected to/from the patient via an easy connector.

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2. Physiological Signal Acquisition

The system shall support recording and analysis of the following signals:

Neurological Monitoring

1. EEG channels including:
    - F3

- F4
- C3
- C4
- O1
- O2

2. Electrooculogram (EOG)
    - Minimum **2 channels**
3. Electromyography (EMG)
    - Chin EMG (minimum **2 channels**)
    - Leg movement EMG
4. Electrocardiogram (ECG)
    - Minimum **1 channel**
5. Arterial Blood Pressure (AB

Respiratory Monitoring

1. Airflow monitoring via:
    - Nasal pressure cannula and/or thermistor
    - Thermistor airflow sensor
    - Simulated airflow channel support
2. Snoring detection via:
    - Snoring sensor and/or microphone
3. Respiratory Effort Monitoring
    - Thoracic Respiratory Inductive Plethysmography (RIP) belt
    - Abdominal RIP belt
    - Respiratory effort detection and analysis
4. Simulated airflow channel support
5. Thoracic and abdominal movement monitoring

Oxygenation and Cardiovascular Monitoring

1. Pulse oximetry with:
    - SpO_2 monitoring
    - Pulse rate monitoring
2. Heart rate monitoring
3. Cardiopulmonary coupling (CPC) analysis capability
4. Non-invasive blood pressure monitoring including:
    - Systolic BP (SBP)
    - Diastolic BP (DBP)
    - Mean arterial pressure (MAP)

Movement and Position Monitoring

1. Body position sensor
2. Body movement monitoring
3. Limb movement detection (periodic limb movement analysis)

Audio and Video Monitoring

1. Snoring microphone recording
2. Voice recording capability
3. Integrated **audio recording system**
4. Video recording capability synchronized with physiological signals

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3) PAP Therapy Integration

1. The system shall support **CPAP/BiPAP titration studies**.

2. Capability to monitor:
    - CPAP pressure
    - Leak detection
    - Respiratory airflow during PAP therapy.

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4. Data Acquisition and Channel Capacity

1. The system shall support **minimum 32 physiological channels** or more.
2. All signals shall be **digitally recorded with high-resolution sampling**.
3. Adjustable sampling rates suitable for EEG and respiratory signals.
4. Real-time signal display and monitoring.

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5. Software and Analysis Features

1. Automatic and manual **sleep stage scoring** capability.
2. Detection and analysis of:
    - Apnea events
    - Hypopnea events
    - Respiratory effort related arousals (RERA)
    - Limb movement events
    - Snoring
3. Event marking and annotation tools.
4. Automated report generation.
5. Database for patient study storage and retrieval.
6. Compatibility with **standard sleep scoring guidelines**.

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6. User Interface and Workstation

1. Dedicated acquisition workstation with high-resolution display.
2. User-friendly graphical interface for signal monitoring and analysis.
3. Real-time waveform display.
4. Multi-screen display capability.

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7. Data Storage and Connectivity

1. Internal storage for **long-duration sleep recordings**.
2. Network connectivity for data transfer and backup.
3. Export capability in **standard data formats** for clinical review.
4. Hospital Information System (HIS) integration

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8. Safety and Regulatory Compliance

The system shall comply with the following standards:

- **Quality Management:** ISO 13485
- **Electrical Safety:** IEC 60601-1
- **Electromagnetic Compatibility:** IEC 60601-1-2
- **Medical Device Certification:** CE and/or FDA approval

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9. Accessories and Consumables

The system shall be supplied with:

1. EEG electrodes and leads

2. EOG electrodes and leads
3. EMG electrodes and leads (chin and leg)
4. ECG electrodes and leads
5. BP connector and cuffs (adult and paediatric sizes)
6. Nasal airflow cannulas
7. Snoring sensors / microphones
8. Thoracic RIP belt
9. Abdominal RIP belt
10. Pulse oximeter sensor
11. Body position sensor
12. Connection cables and patient interface modules

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10. Training and Warranty

1. On-site installation and commissioning shall be provided.
2. User training for clinical and technical staff shall be included.
3. Technical training to be provided for Biomedical staff.
4. Minimum **1 year manufacturer warranty**.
5. Availability of buffer consumable item stock, spare parts, and service support.
6. Regular/ required software updates to be provided.
7. User/Technical manuals provided in English
