HR-FMS Online Monitoring System Solution for Hospitals & Laboratories

Compliant with ISO 14644 / ASHRAE 170 / EU GMP Annex 1 Standards

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1. SOLUTION OVERVIEW

The **HR-FMS Online Monitoring System** by Honri Purification is specifically designed for high-risk areas such as operating rooms, ICUs, negative pressure isolation wards, PCR laboratories, biosafety labs, and sterility testing rooms. The system provides 7×24H automated online monitoring of suspended particles, viable organisms, temperature, humidity, differential pressure, air velocity, illuminance, and chemical pollutants (TVOC).

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2. CORE DESIGN PRINCIPLES

2.1 Risk-Based Classification & Sampling Design (ISO 14644-1)

- **Zoned Monitoring Strategy**: Differentiated monitoring plans are implemented for areas with different risk levels, such as Operating Rooms (ISO Class 5), PCR Lab Amplification Zones (ISO Class 7), and ICUs (ISO Class 6).
- **Sampling Location Calculation**: For high-risk areas, the minimum number of sampling locations (NL) is calculated strictly using the standard formula:

NL = √A

> **Parameters:**
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> - **NL**: Minimum number of sampling locations (rounded up to the next whole number).
> - **A**: Cleanroom area (Unit: m^2).

- **Priority for Critical Workstations**: At least one monitoring point is placed at core exposure areas such as directly above the operating table, sample processing benches, and aseptic filling stations.
- **Standardized Positioning**: Sampling probes are set at a uniform height of 0.8–1.2 m; locations must be ≥ 30 cm from walls and ≥ 1 m from HEPA filters to ensure representative data.

2.2 Airflow & Microbial Control (ISO 14644-4 / ASHRAE 170)

- **Isokinetic Sampling**: Probes in unidirectional flow areas (e.g., laminar flow ORs) must be equipped with isokinetic sampling heads to match the air velocity of **0.36–0.54 m/s**.
- **Pressure Gradient Specifications**: Ensures a differential pressure of ≥ 15 Pa between clean and non-clean zones, and ≥ 5 Pa between zones of the same grade to effectively prevent cross-contamination.

2.3 Data Compliance & Traceability (21 CFR Part 11)

- **Audit Trail**: The system logs all parameter modifications, alarm acknowledgments, and data exports, ensuring the data is authentic, tamper-proof, and traceable throughout its lifecycle.

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3. CORE HARDWARE CONFIGURATION

Parameters	Recommended Model	Key Specifications	Compliance Standards
Airborne Particles	**CLJ-R210**	2.83 LPM flow rate; monitors 0.3/0.5/5.0 μm	ISO 14644 / EU GMP
Viable Particles	**FSC-R10**	Flow rate up to 100 LPM; efficiency ≥ 98%	ISO 14698 / Grade A < 1 cfu
Temp & Humidity	**TH-30R / 25**	Temp Accuracy: ± 0.3°C; Humidity: ± 3% RH	ASHRAE 170 Medical Standard
Pressure Diff.	**DP-30R / 25**	Ranges from 0–± 125 Pa to 0–5000 Pa	ASHRAE 170 / ISO 14644
Air Velocity	**WS-30R / 25**	Precise monitoring of 0.36–0.54 m/s flow	ISO 14644-4
Chemicals	**MIC600 PID**	Monitors TVOC with ppb-level detection limits	ISO 14644-8
Illuminance	**LD-20R**	Measurement range: 0–200,000 lx	Int'l Hospital/Lab Standards

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4. SOFTWARE SYSTEM CAPABILITIES

- **Multi-Zone & Multi-Standard Monitoring**: Displays data grouped by department or lab type; interfaces can be customized for facility management or research oversight.
- **Hierarchical User Rights**: Configurable access for Administrators, Department Heads, and Operators with electronic signature support.
- **Intelligent Alerts**: Thresholds can be customized per international standards; alerts are sent via local sirens, SMS, and mobile APP notifications.
- **Compliance Reporting**: Data is categorized and stored to generate encrypted PDF reports, meeting long-term archival requirements for hospital accreditation.
- **Seamless Integration**: Supports RS485, WiFi, and TCP/IP for direct connection to Hospital Information Systems (HIS) or Laboratory Information Management Systems (LIMS).

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5. STRATEGIC VALUE

1. **International Compliance**: Assists hospitals in achieving **JCI Accreditation** and labs in securing **CNAS/ILAC** recognition.
2. **Precision Risk Control**: Real-time monitoring of high-risk parameters reduces post-operative infection rates and sample cross-contamination.
3. **Research Quality Assurance**: Provides continuous, accurate, and tamper-proof environmental data to support the reliability of scientific results.
4. **Energy Efficiency**: Aligns with ISO 14644-16 to optimize ventilation system operation based on data analysis, reducing energy costs.

Solution Provider:
Suzhou Honri Purification Technology Co., Ltd. (Suzhou Honri Purification)