



QSG GROUP

REAL TIME MONITORING INNOVATORS



IVAS PORTABLE MICROBIAL — AIR SAMPLER

TECHNICAL DATA SHEET

iVAS ROAM

PORTABLE MICROBIAL AIR SAMPLER

A002538



The iVAS Roam is a state-of-the-art portable microbial air sampler designed to ensure EN 17141:2020-compliant environmental monitoring in cleanrooms of all grades. With an intuitive graphical interface and advanced features such as the Tour Configurator, it enables optimized microbiological sampling, ensuring traceability and data integrity. Its ergonomic and lightweight design, combined with the ability to integrate with environmental management software, makes it the ideal solution for precise and efficient microbiological monitoring.

PORTABLE AIR SAMPLING WITH NEXT-GENERATION DATA INTEGRITY

Expanding on our existing viable air sampling technology, the iVAS Roam delivers assured sampling performance that is EN 17141:2020 compliant. With an innovative design and user-friendly graphical interface, the iVAS Roam is a feature rich, intuitive portable air sampler.

Designed for use in cleanroom environments of all grades, the iVAS Roam offers the user a range of features and benefits that support a compliant environmental monitoring strategy.



Traceability



- Two incorporated RFID readers capture operator ID and unit location in the sample record.
- Integral barcode scanner enables plate identification without user input. Creating important end-to-end data integrity.



User Friendly



- A lightweight, ergonomic design with an integrated handle.
- Features a retaining mechanism for the sieve head, enabling easy movement of the unit between sampling locations.
- Intuitive graphics are displayed on an angled 4.3-inch touch screen. Clearly displaying sample progress and completion.
- Adjustable plate height and size.

TECHNICAL SPECIFICATIONS

Sampling Flow Rate	50 or 100lpm	Program Features	20 Programmable Sample Recipes. 50 Programmable Users Programmable Start Delay. Stores at least 2500 Records.
Exhaust Air	HEPA filtered (>99.999% efficiency)		
Compatible Plate Size	90mm plates, adjustable for fill depth	Sampling Modes	Continuous, Intermittent
Physical Efficiency (D50 Value)	1.13 µm @ 100lpm 1.62 µm @ 50lpm	Dimensions	Sieve head diameter: 10.4 cm Whole unit: 26x20x14 cm
Unit Weight	2.6 kg	Environmental	Operating temperature 0 to 45°C. Storage temperature -20 to 60°C. Relative humidity: 5 – 95% (non-condensing). Altitude – below 5000m.
Battery Specification/Life	Internal 14.4V, 96 Wh Li-ion battery >8.5 hours sampling @ 100 lpm. Charge time 4 hrs from 0% to 100%.		
User Tracking	PIN or RFID Tag (RFID Tracking model only)	Connection Type	USB-C for communication and charging. Supplied with power supply for either EU, UK, US or CA plug as standard.
Location Tracking	Manual Entry or RFID Tag (RFID Tracking model only)		
Plate Tracking	Barcode Scanner	Cleaning Agent Compatibility	IPA, QUATS, 3% H ₂ O ₂
User Interface	4.3" angled colour touchscreen	Materials of Construction	Body – ABS. Sieve Head – 316L Stainless Steel



Sample Tour Functionality



- Innovative Tour Configurator feature that enables users to predefine sample locations in a tour pattern.
- Simplifies the setup of complex sampling routes, whilst guaranteeing that every critical area is monitored systematically.
- Enhances the thoroughness and reliability of environmental data collection.



Compliance



- Directly supports compliance with industry regulations.
- The 316 stainless steel sieve head maximises physical and biological efficiency. Giving a d50 value of 1.13µm @ 100 litres per minute, meeting with all relevant regulatory requirements including EU-GMP Annex 1.
- iVAS Roam Manager App offers a range of features that support compliance – see overleaf.

QUALITY AND COMPLIANCE - ANNEX 1

iVAS is fully compliant to EU GMP ANNEX 1:



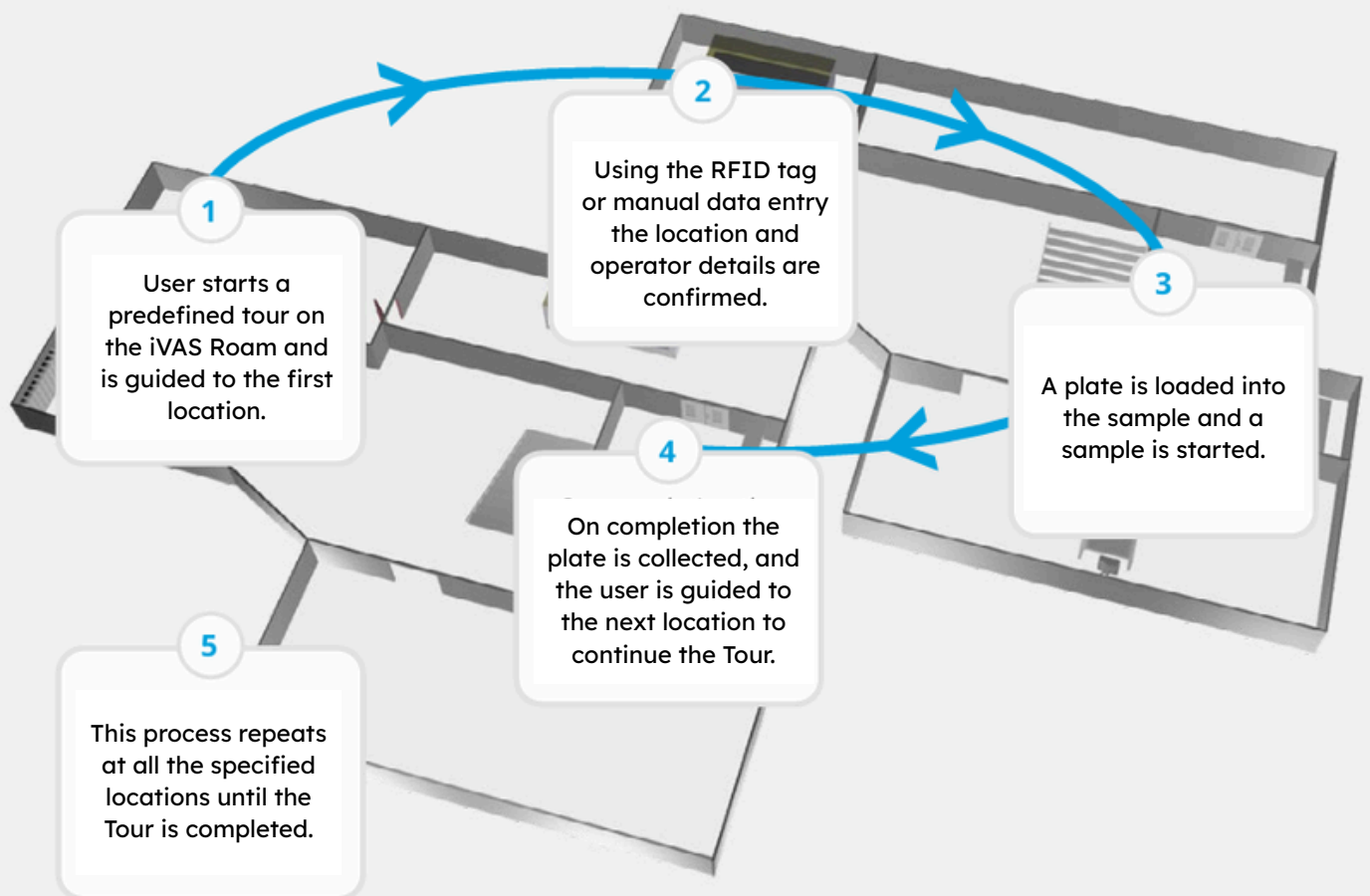
ANNEX 1		iVAS
3.1 - PQS requirements	Monitoring systems must support contamination control strategy (CCS)	Key component of Environmental Monitoring Strategy
3.2 - Data integrity	Data must be reliable, attributable, and traceable	Integration with compliant EMS platforms (audit trail, electronic records)
4.12 - Cleanroom classification	Environmental monitoring must confirm compliance with classification	Suitable for Grades A-D, especially critical zones
4.16 - Monitoring of cleanrooms	Ongoing monitoring required to demonstrate environmental control	Continuous viable monitoring capability
5.2 - Equipment design	Equipment must minimize contamination risk and be cleanable	Hygienic design, stainless steel head, minimal footprint
5.3 - Cleanability and decontamination	Compatibility with disinfection/decontamination processes	Compatible with VHP/HPV environments
5.35 - Calibration	Monitoring devices must be calibrated and controlled	Integrated flow control and calibration management
8.10 - Environmental monitoring in aseptic processes	Monitoring must demonstrate control during critical processing	Suitable for filling lines, isolators, RABS
8.11 - Monitoring during interventions	Monitoring must detect contamination risks during operations	Real-time / near real-time viable air sampling
9.22 - Active air sampling	Requires validated active air sampling methods for viable monitoring	Controlled airflow, defined sample volume, validated performance
9.24 - Monitoring in Grade A	Continuous monitoring expected during critical aseptic operations	Continuous or intermittent sampling modes suitable for Grade A
9.26 - Monitoring locations and methods	Sampling must be representative and justified within the EM program	Flexible installation (isolators, RABS, cleanrooms)
9.33 - Data evaluation and trending	Monitoring data must be trended and reviewed	Integration with EMS for trending and analysis
9.34 - Alert and action limits	Defined limits and response to excursions required	Real-time data acquisition supporting alert/alarm systems

TOUR CONFIGURATOR EXPLAINED

The iVAS Roam introduces an innovative Tour Configurator feature designed to enhance the precision and efficiency of environmental monitoring. This allows users to create and save a defined route around a facility – namely a Tour.

A Tour is created by specifying the sampling locations and order in which they will be sampled, this information is saved to the iVAS Roam with a unique identifier.

This then guides the user to each location in sequence as follows:



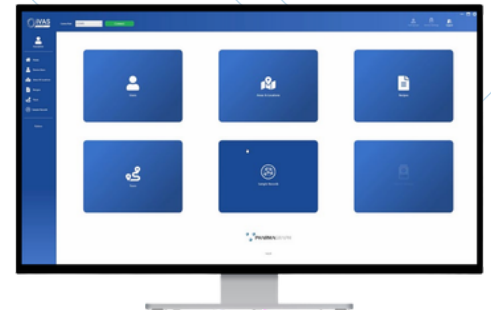
Each Tour is easily configured via the Manager App using an intuitive user interface, which supports the ordering and dragging of locations to craft the exact sequence desired for the sampling process. Tours are then saved directly to the unit, ensuring a seamless transition from planning to execution. Multiple Tours can be configured and saved to the same iVAS Roam; these can also be duplicated to other units.

This capability not only simplifies the setup of complex sampling routes but also guarantees that every critical area is monitored systematically, enhancing the thoroughness and reliability of environmental data collection.

IVAS ROAM MANAGER APP

The iVAS Roam can either integrate directly with Pharmagraph's enVigil FMS software or operate as a standalone unit, managing set up and sampling records with the companion iVAS Roam Manager App.

- Ability to deploy a single site configuration to multiple units.
- Comprehensive audit trail offers a detailed record of all changes made within the application, providing traceability that is essential for compliance with regulatory standards, including 21 CFR Part 11.
- Real-time data synchronization maintains an up-to-date database, vital for real-time compliance monitoring and reporting.
- Advanced reporting and visualisation generate detailed reports in multiple formats that are easy to interpret and analyse.



The iVAS Roam Manager App is designed for a wide range of users in cleanroom and laboratory settings, from technical experts to personnel with minimal technical background. It provides an intuitive, user-friendly platform that not only streamlines environmental monitoring tasks but also ensures that operations remain in strict compliance with regulatory standards.

QUALITY AND COMPLIANCE

iVAS meets with all relevant regulatory requirements:

- EU GMP Annex 1
- 21 CFR Part 11
- EN17141:2020
- USP 797



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