

GMP

Annex 1



Clean Air Monitoring Solutions

Continuous Viable Air Monitoring Using 9cm Agar Plates



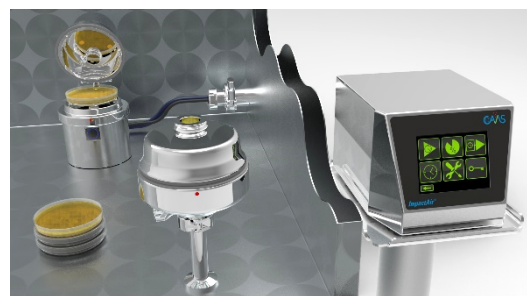
Introduction

The **Clean Air Monitoring Solutions (CAMS)** portable and isolator range of microbial air monitors have been designed to meet the demanding requirements of the pharmaceutical and healthcare. They are used for **continuous monitoring** in high-grade areas, where in-process monitoring of viable particles can be critical and where ISO-14698, CEN-17141 and GMP Annex 1 compliance must be satisfied.

Most users are already familiar with using agar based methods for environmental monitoring - using settle plates for up to 4 hours and air samplers to sample a cubic metre of air in just 10 minutes. Along with these methods, users will have many years of valuable experience of handling plates, interpreting the results and a wealth of historic data as a reference.

Early air samplers typically used larger agar plates and were capable of sampling for longer periods, but with legislation allowing the use of 'rapid m³ samplers', the need to monitor disappeared and agar became a forgotten monitoring method. The introduction of Annex 1 has left many in the industry searching for a suitable monitoring technology. Real time fluorescence based systems are pitched as the 'latest and greatest' solution but they are complex, results interpretation is not as clearly defined as agar based methods and crucially, they do not allow easy identification to species level.

The most effective way to achieve Annex 1 compliance could be to stay with your existing proven, trusted and validated agar based methods. In most cases there is no need to change to a different method at all. Agar is easy to use and easy to understand. It works perfectly well, why change?



By simply changing from an air *sampler* to an air *monitor*, **4+ hours continuous monitoring** is possible using a single 9cm agar plate and **Clean Air Monitoring Solutions** has developed a range of monitors to achieve just that.

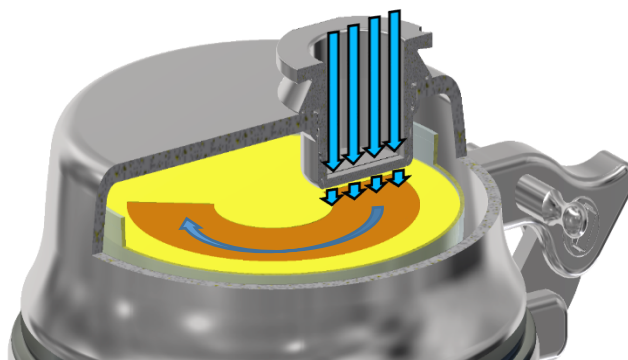
CAMS air monitors are based on the slit-to-agar method which has very low d50 values of around 0.5 μ with exceptional biological efficiency and the ability to easily count **real viable microbial events** in CFU while being able to **identify to species** level using existing methods and existing historic data as a reference.

CAMS has listened to the voice of many end users and created a **monitoring platform** that meets the requirements of the regulations while offering a range of flexible solutions to meet the end users specific requirements. The platform uses common components and user interface throughout to create a suite of solutions based on the same core technology that can be deployed across all areas. Using a common platform reduces the operator training requirement, reduces risk, simplifies regulator audits, simplifies product support and calibration, and allows data from different areas to be compared on the same baseline.

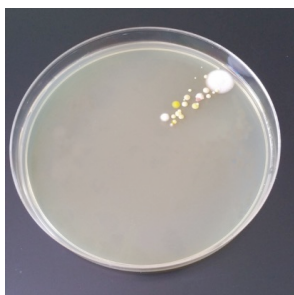
At the heart of this platform is the monitoring head which contains all of the necessary controls required to rotate the agar plate and control the air flow, and is connected to a separate vacuum pump source. CAMS also supply a range of vacuum pump solutions but it also has the flexibility to allow isolator manufacturers to connect the head into an existing vacuum system and perform their own control. CAMS also has a manifold system for a multi-point monitoring turnkey solution.

Technology

Air is drawn at high speed through a very narrow inlet slit, whereupon particles, including microbes in the air, impact and stick onto an agar surface in a petri dish. The petri dish is slowly rotated under the inlet, thus ensuring the air is always 'impacted' onto an area of fresh agar. This dramatically reduces the desiccation of the microbes resulting in a very high biological and physical efficiency unmatched by other types of sampler or real-time systems.



Most air samplers on the market have hundreds of inlet holes and a static agar plate which limit the sampling time to typically 10 minutes. The slit-to-agar method is the only method that allows a single plate to sample for many hours (continuously monitor), dramatically reducing the number of plates used, the cost and the amount of human intervention.



Another advantage of the rotating agar plate is that the results are time correlated. Whilst not timed to the second, localised growth on the plate can be time estimated based by its position on the plate.

Specification (Default Settings)

Air flow	15 lpm	Communication	USB, Ethernet
d50	0.53 μ	Certification	CE
Plate size	9cm	Interface	MODBUS/SCADA
Sampling time	10 min to 4 hours	Weight	Model dependent
Plate usage	1% to 100%	Head \varnothing	122mm
User interface	Touch screen LCD	VHP	Head VHP compatible
Exhaust	HEPA H14	Noise level	65dB Max
Construction	316L Stainless	Validation	Physical & Biological
Inlet	F22 Fitting		
Power	Universal PSU		

ISO-90-UMH - Universal Monitoring Head

The **Universal Monitoring Head** contains all controls and mechanisms necessary to rotate the agar plate throughout the monitoring period. The head does not contain a pump but internal flow sensors can enable the head to send signals to a vacuum source to control the air flow very accurately.

The head is compact with a diameter of only 122mm and a height of 110mm from the clamp flange to the top of the inlet.

There are a number of different approaches using active air samplers to meet Annex 1 compliance. The pharmaceutical industry use isolators, RABS, and others manufacture in open cleanrooms. Some processes are highly automated and some more manual. Users also require flexibility to monitor for shorter periods at higher efficiency, whilst others want to monitor for the longest period possible with minimal human intervention.

These different requirements would normally necessitate different instruments but the **ISO-90-UMH** inlet can be configured to optimise the sampling parameters. There is a default and fully validated configuration that allows **4 hours monitoring onto a single agar plate** with a flow rate of 15 litres per minute at a d50 of 0.53 μ .

A button located on the head unit is available so the operator can simply load a plate and press the button to start, pause or stop a run.

The head can be supplied in a number of deployment formats to suit the application and with an increase in the use of **robots** within isolators, the chamber can also be supplied with robot compatible manipulation features.



Desk-top



Tri-Clover



Hinged



Lift Off (+Robot)



ISO-90-UMH - Universal Monitoring Head

Key features

- 9cm Agar Plate
- Up to 4 hours continuous monitoring per agar plate
- Default 15 LPM Flowrate
- Default D50 = 0.53 μ
- Small size – 122mm diameter
- PoE (Power over Ethernet) option
- Compatible with
 - **ISO-CON** flow controller – single point turnkey solution
 - **ISO-90-V** – Isolator manufacturers who use own pump and flow control
 - **ISO-CON-IFC** – Integrated Flow Controller
 - **ISO-90-MH – Multi-head manifold system for multi-point monitoring**
 - External pump unit for special flow rates
- VHP compatible
- ‘RunRelays’ – to control external pump and/or in-line VHP block valve
- Ethernet communication
- Full MODBUS control and data monitoring
- Built-in flow sensor option
- Configurable Flowrate & D50 options
- Connect to Wi-Fi module

ImpactAir-MSK – Monitoring System Controller

Key features

- Ethernet based controller
- PoE
- Control multiple CAMS heads
- Control multiple ISO-CON/ICO-CON-IFC

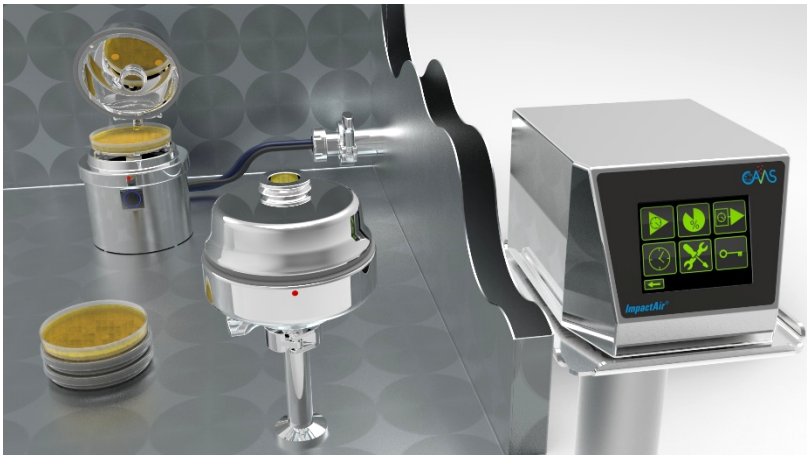
Benefits

- Easy upgrade of isolator to Annex 1 Monitoring
- Can switch off old system and use MSC
- Can sit alongside existing system



ISO-CON-90 – Complete Monitoring System

Single Monitoring Head Solution for RABS/Isolators



The **ISO-CON** system is a complete turnkey monitoring solution for isolators. The system comprises an **ISO-90** monitoring head plus an ISO-CON flow control unit. The head occupies minimal space within the isolator by keeping the pump and control unit separate and away from the head. The ISO-CON has a touchscreen display with the familiar **CAMS** intuitive user interface.

A powerful built-in vacuum pump ensures smooth running of the head at distances of up to 10+ metres away making it possible to locate the ISO-CON away from the head in a more convenient location. The exhaust is via the base of the ISO-CON passing through a H14 HEPA filter.

The ISO-CON is used to set up the run parameters (sampling time, % plate rotation, delayed start, username and location) and also store run results for upload to a LIMS/FMS system. Communication is by means of USB or Ethernet, with the Ethernet enabling the ISO-CON to communicate via MODBUS into a software system such as SCADA.

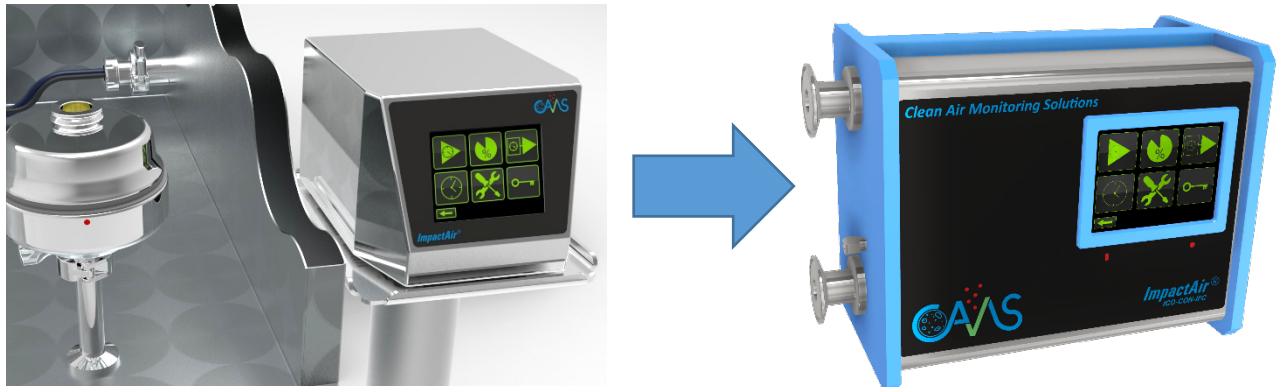
A secondary remote screen is available for mounting on or close to the isolator whilst allowing the ISO-CON to be located away from the process environment. A control cable and hose connects the ISO-90 head to the ISO-CON and special cable & hose ports are available from CAMS designed to fit onto a standard



1½" Tri-Clover fitting. This facilitates very easy installation of a monitoring system.

ISO-CON-IFC – Integrated Flow Controller

Single Monitoring Head Solution for RABS/Isolators with VHP integrated VHP Loop



The **ISO-CON-IFC** system is a complete turnkey monitoring solution for isolators. The system comprises an **ISO-90** monitoring head plus an **ISO-CON-IFC** integrated flow control unit which includes a VHP decontamination loop. The head occupies minimal space within the isolator by keeping the pump and control unit separate and away from the head. The ISO-CON-IFC is designed to mount into the technical area of an Isolator and be fully controlled via Ethernet/MODBUS.

The design allows for an easy upgrade from popular isolator viable samplers to continuous viable monitoring for full Annex 1 compliance.

ImpactAir 90 - Portable Monitor

With the head mounted directly onto a reduced size format and introducing low power electronics has made it possible to produce the first Annex 1 compliant monitor.

It has the now familiar CAMS user interface which can communicate with systems via Ethernet using MODBUS.

With a footprint of only 150mm x 200mm, the ImpactAir-90 is an ideal option for general monitoring in pharma, hospitals and food producers.

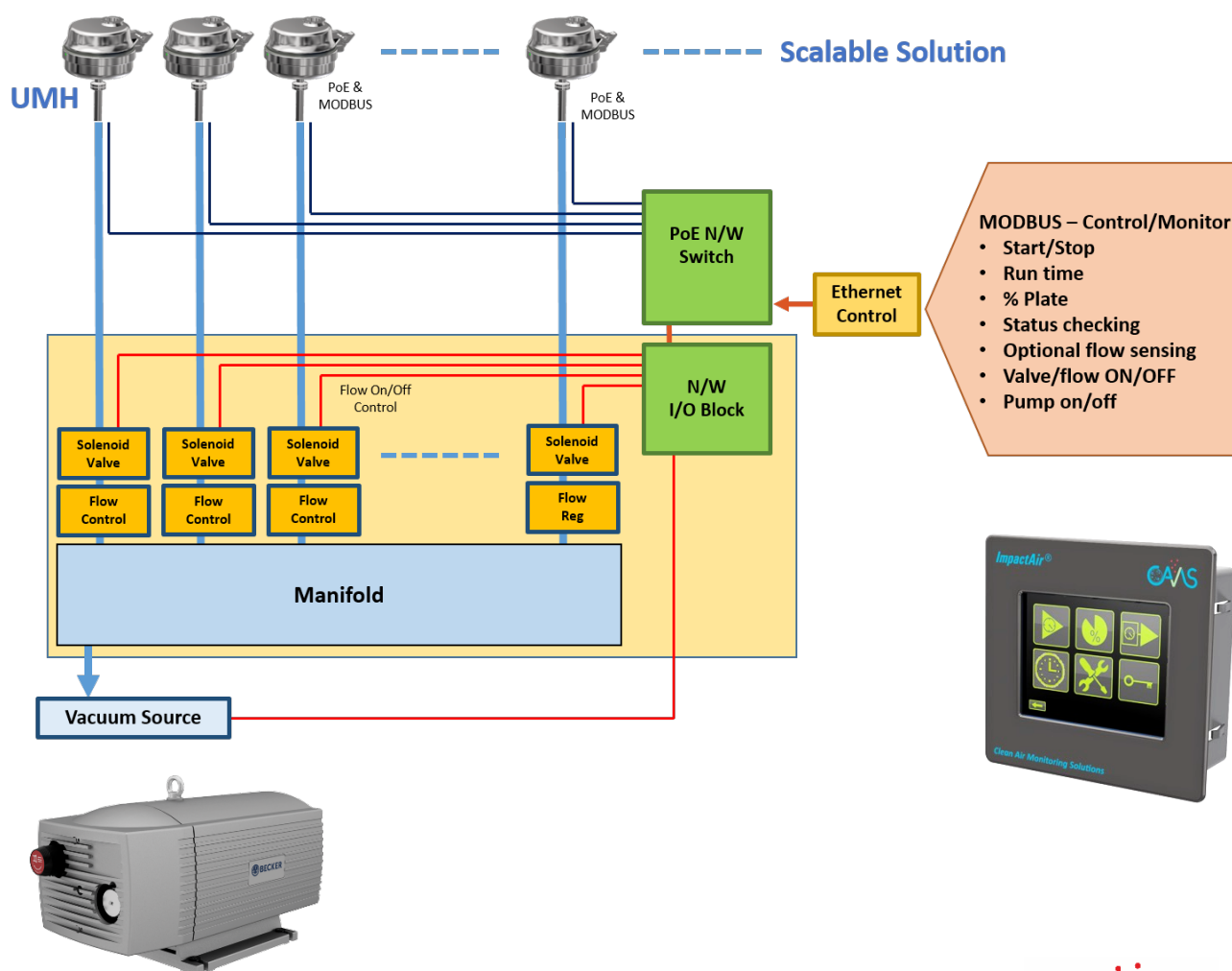


Multi-point Monitoring - Manifold System

Most isolator projects require a number of monitoring points which can significantly increase the complexity of the monitoring system required. The CAMS system has been designed to minimise the engineering effort required to install a new multi-point monitor system or to upgrade an existing isolator from sampling heads to monitoring heads in order to achieve GMP Annex 1 compliance. Multiple ISO-90-UMH monitoring heads can be connected to a manifold and controlled independently using standard networking and pneumatic components to create an easily scalable solution.

The ISO-90-UMH heads can be powered from a standard 24V D.C. source or a PoE (Power over Ethernet) option will be available.

As with all CAMS monitoring solutions, the airflow and D50 configuration can be adapted to suit the customer requirements so ensure adequate air is samples throughout the run or to ensure the longest possible run times per agar plate to minimise human interventions.



ISO-90-N – PoE Monitoring Head with Built-in Pump

We have successfully reduced the size and power consumption of the vacuum pump such that the pump can fit into the 122mm diameter monitoring head and does not require any external vacuum source or pipework. This makes it ideal for bio-safety cabinets or isolators where the exhaust must be fed back into the same environment through an optional built-in HEPA filter.

The reduced power consumption has made it possible to be **PoE** (Power-over-Ethernet) driven.

It is designed to connect directly into an isolator control system requiring no other hardware other than a PoE network switch.

This could be an ideal sampler to monitor upgrade option for existing isolators.



Clean Air Monitoring Solutions – Your solution, cost effectively

Our modular design approach gives YOU the ability to design an Environmental Monitoring solution that meets YOUR application.

COST

- ✓ Fewer agar plates
- ✓ Reduces operator time
- ✓ Less incubation
- ✓ Less analysis
- ✓ Reduced waste & disposal
- ✓ Short return on investment
- ✓ Reduced life costs

COMPLIANCE

- ✓ Fully validated
- ✓ Annex 1
- ✓ ISO 14698
- ✓ CEN 17141
- ✓ GMP
- ✓ Confidence



TECHNOLOGY

- ✓ Slit-to-Agar
- ✓ Established method
- ✓ Trusted results
- ✓ True viable monitoring
- ✓ Species identification
- ✓ No False positives

APPLICATION

- ✓ Open cleanrooms
- ✓ Isolators / RABS
- ✓ Portable / Fixed
- ✓ New builds
- ✓ Upgrade
- ✓ Scalable

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Clean Air Monitoring Solutions

To find out more, please visit:

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