

Annex 1
Ready



Continuous Viable Air Monitoring Solutions using 9cm Agar Plates



ImpactAir-90
ISO-CON-90
ISO-90

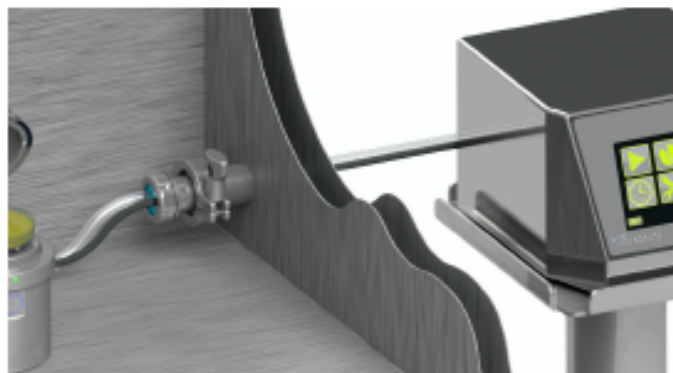
Introduction

The ImpactAir-90 and ISO-90 range of microbial air monitors have been designed to meet the demanding requirements of the pharmaceutical, healthcare and specialist food industries. 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 technology 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 Pinpoint Scientific has developed a range of monitors to achieve just that.

Pinpoint Scientific 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.

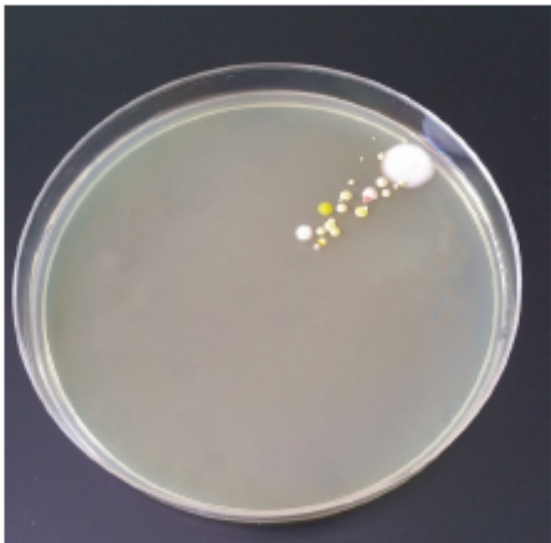
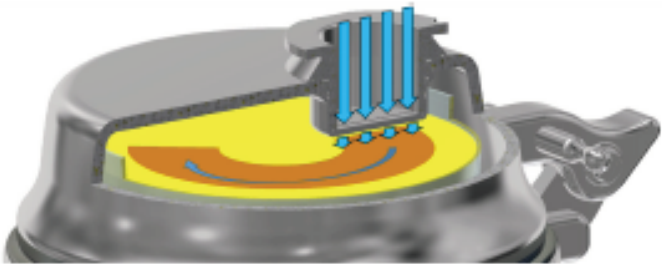
Pinpoint Scientific has listened to the voice of many end users and created a *monitoring platform* that meets the requirements of the regulations whilst offering a range of flexible solutions to meet the end users specific requirements. The platform uses common components and user interface throughout 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 new platform is the new *ISO-90 monitoring head*. The head 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. Pinpoint also supply a vacuum pump solution (ISO-CON) but it also has the flexibility to allow isolator manufacturers to connect the ISO-90 head into an existing vacuum system and perform their own control.

All Pinpoint Scientific monitors are built using 316L stainless steel.

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.



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	0.53µ	Certification	CE
Plate size	9cm	Interface	MODBUS/SCADA
Sampling time	10 min to 4 hours	Weight	Model dependent
Plate usage	1% to 100%	Head Ø	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 - Monitoring Head

At the heart of this flexible new platform is the new [ISO-90 monitoring head](#). The 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 are used to enable the head to send signals to a vacuum source to control the air flow very accurately.

The head is 122mm diameter and 107mm 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, R.A.B.S., and others manufacture in 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 head inlet can be configured to optimise the sampling parameters. There is a default configuration that allows 4 hours monitoring onto a single agar plate with a flow rate of 15 litres per minute at a d50 of 0.53μ .

Alternative inlet sizes are available – please ask our representative for more details.

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



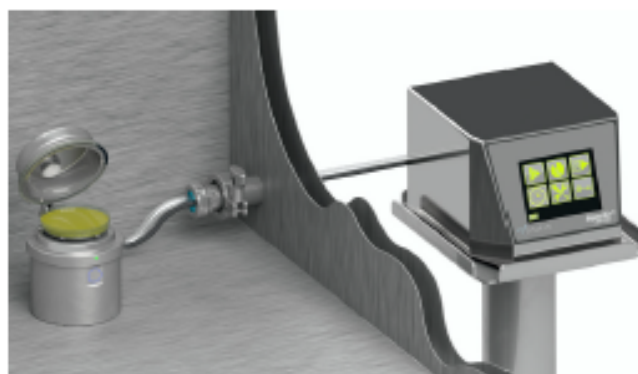
Lift Off (+ Robot)



ISO-CON-90 – Complete Monitoring System

The ISO-CON-90 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 ISO-90 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 Pinpoint Scientific intuitive user interface.

A powerful built-in vacuum pump ensures smooth running of the ISO-90 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 (time, % plate, delayed start, username and location) and also store run results for upload to a LIMS 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 glands/ports are available from Pinpoint designed to fit onto a standard 1½" Tri-Clover fitting as shown in the image above.

ImpactAir-90-B/M - Portable Monitor

Using the ISO-90 head mounted directly onto a reduced size ISO-CON and introducing low power electronics has made it possible to produce the first battery powered Annex 1 compliant monitor and/or compact desk top portable mains monitor

This self-contained monitor is available in two versions:

- **ImpactAir-90-B** – Battery powered with external PSU charger.
- **ImpactAir-90-M** - Mains only version with internal power supply.

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

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



ImpactAir-90-HF – High Flow Portable Monitor (Built to order)

Using the ISO-90 head mounted directly onto a full size ISO-CON with our most powerful pump is the **High Flow** option. This is aimed at existing ImpactAir-140 users who wish to maintain the previous flow parameters.

This solution is also suitable for those wishing to sample the air in a much shorter time period or where large volume air samples are required

This model is only available as mains powered due to its high power pump.



ISO-90-V - Monitoring Head

This model is designed specifically for isolator manufacturers who wish to perform their own flow control using their own vacuum source.

The head is configured during install with a default run time and % plate rotation.

The head can be configured to run immediately after receiving power, or run after an adjustable time-delay, or to run after receiving a command via Ethernet.



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

(Built to order)

This is our latest and probably most remarkable innovation. 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.



Recent Case Studies

94% Reduction in Plate Usage!

A new customer to Pinpoint Scientific had been MAS100 users for many years. Having made the decision to start performing continuous monitoring in their Grade A areas, they found themselves changing agar plates every 10 minutes and generating 36 plates per shift for each of their sample locations. They decided to install ISO-CON-90 systems and are now running 4 hours per plate with only 2 plates per location per shift. Very happy customer.

Surprising 25% Increase in Sampling Efficiency.

An existing ImpactAir-140 user performed an extensive trial of the ISO-CON-90 system. The -90 was configured with a d50 of 0.53 which, compared to the 0.42 d50 of the older -140 meant we were expecting to see maybe a 20% reduction in sampling performance. The results were not as we expected as we actually saw a 25-30% increase in performance. Subsequent research has shown this is due to the unique design of the inlet in the ISO-90 head which leads to improved physical and biological efficiency.

New lease of life for agar based EM.

A new customer to Pinpoint Scientific has been actively seeking a continuous monitoring solution to meet the requirements of Annex 1. Like many others, they thoroughly explored the real time fluorescence based systems but have concluded that *monitoring onto agar is the most practical and reliable option*. "With agar, we are dealing with real CFU and not 'events', and colonies are very easy to grow, count and identify to species level". Pharma companies already have all of the infrastructure and knowhow to handle agar plates and interpret the results with many years of historic data as a baseline. The ISO-90 has an impressive 0.53μ d50 whereas the particle concentrator inside a real-time system has around a 2μ d50 which is not great when one organism is highly significant. The real-time system is also big, expensive and complex and makes it a high risk option.



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