



myfog[®]

A high-quality
dense smoke

Fog generator for the visual
monitoring of airflows
in classified environments



MADE IN ITALY

aminstruments[®] 

CLEAN SMOKE

SMOKE GENERATOR FOR VISUAL MONITORING OF AIRFLOWS

MYFOG IS A UNIQUE AND INNOVATIVE TOOL!

- WORKS WITH PROCESS WATER
- A SINGLE OPERATOR
- REMOTE CONTROL
- HIGH-QUALITY DENSE SMOKE

THE ADVANTAGES OF MYFOG

A single operator, thanks to the standard remote control option, is able to manage the start/stop of the unit, as well as the intensity and speed of smoke regulation.

MyFog has an intuitive interface with a 2.8" touch screen, which immediately gives the operator a diagnosis and overview of the main operating parameters.

ACCESSORIES ALL-INCLUSIVE

MYFOG SHIPS WITH SMART ACCESSORIES

- additional fittings for hose extension
- multi-hole lance for fog curtains
- telescopic boom
- cart
- casing with wheels for transport
- "follow me" tube
- support



APPLICATIONS FOR EVERY NEED

MYFOG IS THE TOOL YOU HAVE BEEN WAITING FOR

- display of airflow speed and direction in all classified environments
- pressure balance between premises through visual indication
- help in identifying areas of stagnant air



ADVANCED TECHNOLOGY

- remote control with radio commands (fan speed, fog density and pause mode)
- 2.8" TfT touch screen display
- water level indication and diagnostics with colour-coded status reading
- temperature monitoring and diagnostics with graphic display
- automatic optimisation of transducer life-cycle with selective switch-on based on operating hours
- fog density regulation
- adjustment of the fan rotation speed (fog diffusion speed)
- rapid Start/Stop function
- monitoring of switch-on hours, emissions and use of each individual piezoelectric transducer
- piezoelectric transducer malfunction diagnostics
- explicit indication of diagnostic alarm
- diagnostic menu in operator mode (read-only) password-protected
- diagnostic menu in supervisor mode (changes allowed) password-protected
- pause function with storage of current generation settings
- reset of the cycle to the stored settings when you exit the pause or power interruption
- alarm variable by function
- transducer life-cycle alarm



SMOKE STUDY

NOT JUST THE DISPLAY OF AIRFLOWS

NOT JUST THE DISPLAY OF AIRFLOWS THE AMTECH SMOKE STUDY IS NOT LIMITED TO AIRFLOW CONTROL, BUT, IN RESPONSE TO THE INCREASINGLY PRESSING NEEDS OF REGULATORY AGENCIES, IDENTIFIES AREAS OF POTENTIAL PROCESS RISK AND SUPPORTS THE IDENTIFICATION OF CORRECTIVE ACTIONS.

A RELIABLE ALLY FOR QUALITY

THE TEAM

The AM Instruments validation team has been offering its smoke study service for years. Competence, combined with experience, has led to an operating mode that can be summarised in a fundamental concept: as the AM Instruments Validation Manager says , a smoke study cannot and must not be a mere control of airflows, but a careful analysis of all the elements that contribute to the control of contamination. It is no coincidence that in recent years regulatory agencies have used smoke studies as a test of verification covering not just airflows, but also and in particular operational dynamics. This means that the In Operation situation takes precedence over the At Rest situation.

DOMINO EFFECT

The smoke study initiates a sort of domino effect, in which the monitoring of airflows becomes the engine of the subsequent controls and checks.

The behaviour of cleanroom operators, their strict adherence to SOPs, their training and the quality of the processes become verifiable through the smoke study. Indeed, regulatory agencies often challenge evidence that are not necessarily related to airflows, such as the transfer of materials from different areas.



APPLICATIONS FOR EVERY NEED

REGULATORY REQUIREMENTS, RISKS, SUCCESS

The purpose of airflow visualisation studies is to demonstrate on the one hand the visual evidence of unidirectional airflows within an aseptic structure and on the other the ability of the system as a whole to protect the product and critical areas through a constant movement of primary air from absolute filters.

The flow visualisation study must be performed under conditions when the process to be analysed is both operating and at rest. Particularly suitable for highlighting possible sources of risk of potential physical or biological contamination within a production process or the surrounding environment, the visualisation study or more usually the smoke study takes into account the sources of risk that may be caused by:

- inappropriate design of critical production areas
- problematic flow management by the ventilation system, whether centralised or built ad hoc through LAF (Laminar Air Flow) in the most critical process areas
- intervention of personnel interrupting the unidirectionality of airflows during aseptic operations

The performance of a good flow visualisation study makes it possible to identify areas of potential risk for the process, supports the identification of corrective actions and thus enables the assessment of their effectiveness following their implementation.



DURING INSPECTIONS

From a regulatory perspective, regulatory agencies have repeatedly acted through comments and warning letters, complaining about the absence of adequate tests documenting satisfactory airflow under both At Rest and In Operation conditions.

Particular mention should be made of the following comments and warning letters: "CFR 21 part 113 (b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, should be established and followed. Such procedures should include validation of all aseptic and sterilisation processes..." when the operator interrupts the unidirectionality of the flow by creating a turbulent movement, or when, during testing, the camera angle does not allow correct display of the flow, or the tracer source is not positioned effectively.

Other comments report that:

- smoke studies in GMP Class A/ISO5 hoods were not conducted under operating conditions
- no airflow assessment study has been performed during aseptic operations
- smoke studies have not been adequately documented
- the airflow video does not present data to adequately evaluate the potential impact of the airflow on the product by observing the vortices in the centre of the GMP Class A/ISO5 hoods during operation.



SMOKE STUDY

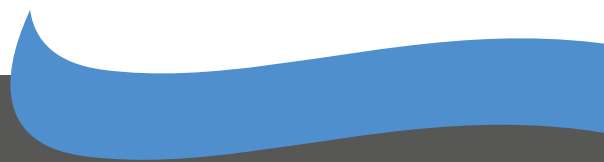
SUCCESS FACTORS OF A SMOKE STUDY

In order for a flow visualisation analysis to give a real benefit to the process for which it was designed, it is also essential that its performance and the technical and qualification documentation are clearly and objectively organised. All stages of the test must be clear, in particular with regard to the test conditions and the process steps investigated. The evidence produced must be organised with particular attention to the integrity aspect of the raw data collected during the study and on which the final conclusions are based.

As can be seen from the FDA's comments, there are some fundamental elements in the performance of a proper visualisation study:

- in the preliminary phase, it is essential to carefully study the layout of the environment and the equipment it contains. Not only that, it is very important to have a precise picture of the operations that are performed In Operation by the personnel present during the process
- determine in advance the movements of the video operator according to the specifications described above: it is, in fact, essential that, taking into account any obstacles, or whether or not to keep the camera at the right distance from the flow, the footage is studied in advance and, if necessary, designed from different angles according to the needs
- type of smoke generator and tracer type





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COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV GL
= ISO 9001:2015 =