

### STEMP MIS CONTAMINATION FREE AIRFLOW VISUALISATION IN CLEAN ROOMS ACC. TO GMP & ISO 14644-3





#### BACKGROUND OF APPLICATION

CLEANROOMS ARE DYNAMIC SYSTEMS. PEOPLE AND GOODS ARE CONSTANTLY IN MOTION. INSTALLATIONS, PRODUCTION LINES AND MACHINES DO REQUIRE PERIODICAL ADJUSTMENT TO THE PRODUCTION OF DIFFERENT PRODUCTS. ACC. TO THE RELEVANT STANDARD ISO 14644-3 THE OPERATORS OF CLEANROOMS ARE OBLIGED TO GIVE PERIODICALLY EVIDENCE OF THE IN SITUE AIR FLOW SITUATION BY AN AIR FLOW MAPPING SUPPORTED BY HIGH PURITY CLEAN ROOM FOGGERS.



THE AFM35-NEO CLEANROOM FOGGER USES A HIGH PERFORMANCE TRASONIC MODULE OF 35 PIEZOELECTRIC CERAMICS TO GENERATE IN ITS CLASS UNMATCHED 1,25 CUBIC METERS OF PURE FOG PER MINUTE WITH 170 ML OF FOG DENSITY PER MINUTE TO PROVIDE 5 TO 7 M OF VISIBLE AIR FLOWS FOR SMOKE STUDIES IN CLEAN ROOMS, MEDICAL ROOMS, ISO SUITES, BARRIER ISOLATORS, FUME HOODS AND SIMILAR APPLICATIONS IN CLEAN ROOMS. THE AFM35-NEO IS THE ONLY ULTRASONIC BASED AIR FLOW MAPPER / CLEAN ROOM FOGGER THAT COMPETES IN FOG VOLUME AND FOG DENSITY (PURE WHITE) WITH ANY AVAILABLE LN2 BASED CLEAN ROOM FOGGER (THIS AT THE ONLY EXCEPTION OF SISTEMA'S LN2 FOG MACHINE AP35). YET ITS UNIQUE CRITERION IN THIS COMPETITION IS THAT THE AFM35-NEO (ONLY NEEDS DI WATER OR WFI WATER TO PRODUCE THIS HIGHER VOLUME OF WHITE DENSE PURE FOG AND NOT A MEDIA OF TWO COMPONENTS LIKE LN2 AND DI WATER AS WITH THE LN2 FOGGERS.

### FOG OUTPUT CHARACTERISTICS



DENSE PAPER WHITE PURE FOG

CYCLE TIME OF 80 MIN OF WHICH 50 MIN WITH PURE WHITE FOG

SUFFICIENT IN VOLUME FOR A VOLUME SPLIT INTO TWO HOSES BOTH PROVIDING PURE WHITE FOG SIMULTANEOUSLY ATOMIZING UP TO UNMATCHED 170 ML OF DI-WATER PER MINUTE INTO 1,25 CUBIC METERS OF WHITE FOG PER MIN. 5 TO 7 M OF VISIBLE AIR FLOWS

HIGHEST FOG OUPUT RATE OF ALL ULTRASONIC PIEZOELECTRIC BASED CLEAN ROOM FOGGERS IN MARKET

#### TYPICAL APPLICATIONS



AIRFLOW RECOVERY TESTS GUIDED BY ISO 14644-3 ANNEX B12

AIRFLOW VISUALIZATION TESTS GUIDED BY ISO 14644-3 ANNEX B7

USP 797 IN-SITU AIRFLOW ANALYSIS

USP 800 COMPOUND PHARMACY AIRFLOW TESTS

AIRFLOW TESTS FOR NSF 49 AND BIO-SAFETY CABINETS

AIRFLOW REQUIREMENTS USING SEMICONDUCTOR CLEAN ROOM GUIDELINES, FEDERAL STANDARD 209E

CONTAINMENT TRANSPORT STUDIES ON PROCESS TOOLS

OPTIMIZATION OF EQUIPMENT LOCATIONS

TRACKING ROUTES OF AIR INFILTRATION INTO CLEANROOMS

PRESSURE BALANCING (ROOMS AND SPACES)

**OPERATORS TRAININGS** 

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STEUERNUMMER / TAX #: 59350/34402



# SISTEMA-MIX CONTAMINATION FREE AIRFLOW VISUALISATION Engineering. Products. Services. IN CLEAN ROOMS ACC. TO GMP & ISO 14644-3



#### SPECS AND FEATURES

CASING AND TANK IN ELECTROPOLISHED STAINLESS STEEL

DIMENSIONS OF (L X H X W) 571 X 293 X 325 MM

**NET WEIGHT OF 20 KGS** 

TANK CAPACITY OF 10 L

MAX. CYCLE TIME OF 80 MIN OF WHICH 50 MIN ARE WITH PURE WHITE FOG.

ULTRASONIC MODULE OF 35 PIEZOELECTRIC CERAMIC DISCS

0 - 100 % ADJUSTMENT OF FOG INTENSITY AND DENSITY

MICRO FAN, 24 V, IP 68

FOG OUTLET Ø OF 80 MM)

DOTMATRIX DISPLAY FOR INDICATION OF OPERATING STATE AND ALL OPERATING FUNCTIONS

ELECTRONICAL WATER FILL LEVEL SURVEY VIA 3 CAPACITIVE SENSORS

TEMPERATURE SURVEY FUNCTION

**ELAPSED TIME METER** 

REDUNDANCY FUNCTION ENABLING THE SYSTEM FUNCTIONALITY EITHER WITH 3 OR 2 OR 1 ULTRASONIC BLOCS IN CASE OF SINGLE BLOC FAILURE SOFT START ELECTRONIC

SELF MONITORING FUNCTIONALITY

COMING WITH STANDARD ACCESSORIES INCLUDING

90 – 264 VAC WIDE RANGE POWER SUPPLY COVERING 90 . . . 264 VAC, 47 . . . 63 HZ, 5 A @ 230 VAC, 3 A @ 115 VAC

BUFFER FUNCTIONALITY IN CASE OF UNSTABLE POWER SUPPLY GRIDS

650 MM STRAIGHT PATTERN TRANSAPRENT FOG RAKE OF 80 MM IN Ø

Y-PATTERN SPLITTER ENABLING SPLITTING OF ONE TUBE INTO TWO TUBES BOTH PROVIDING PURE WHITE FOG SIMULTANEOUSLY AND ENABLING WORKING SAME TIME ON TWO SEPARATE SPOTS

2 SETS OF FLEXIBLE TUBE (L X Ø) OF 3.000 X 80 MM PLUS FITTINGS

TUBE - TUBE CONNECTOR COUPLING TWO SINGLE TUBINGS

**POWER CABLE** 

24 MONTHS WARRANTY

**CE-COMPLIANCE CERTIFICATE** 

USER MANUAL

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### SYSTEM OVERLOOK AND ACCESSORIES

<u> </u>	STSTEIN OVERLOOK AND ACCESSORIES					
LINE	ITEM #	PICTURE	ITEM DESCRIPTION			
	AFM35-NEO GEN.2019 SERIES - 230 OR 115 VAC VERSIONS W/STRD. ACCESSORIES (POWER CABLE + 5 M TUBING)					
1	AFM35-NEO (GEN.2019)		AFM35-NEO GEN.2019 ATOMIZING FROM MINIMUM 3,46 LITER (WITH A 25 % FAN OUTPUT) TO MAXIMUM 10,20 LITER (WITH A 100 % FAN OUTPUT) OF WFI-WATER IN 45 min. MAXIMUM CYCLE TIME AT 90 min. POWER CABLE + 3 M TUBING INCLUDED.			
	OPTIONAL ACCESSORIES					
2	FL.650.80-STR		Ø 80 x 650 mm FOG RAKE STRAIGHT VERSION, TRANSPARENT			
3	FL.1300.80-STR		Ø 80 x 1.350 mm FOG RAKE STRAIGHT VERS., TRANSPARENT			
4	FL.1800.80-STR		Ø 80 x 1.800 mm FOG RAKE STRAIGHT VERS., TRANSPARENT			
5	FL.650.60-STR		Ø 60 x 650 mm FOG RAKE STRAIGHT VERSION, TRANSPARENT			
6	FL.1300.60-STR		Ø 60 x 1.300 mm FOG RAKE STRAIGHT VERS., TRANSPARENT			
7	FL.1300.80-T		Ø 80 mm x 1.300 FOG RAKE T-PATTERN VERSION, TRANSPARENT, COMING WITH 80 TO 60 MM REDUCTION			
8	OUTLET.45°	3111	<b>45° FLEXIBLE HOSE</b> TO BE CONNECTED TO APXX FOG OUTLET PROVIDING A STABLE OUTPUT RIGHT ON SPOT. COMING WITH SOFT TIPS BOTH SIDES.			
9	TUBE.3000.80-BS		3 m FLEXIBLE TUBE WITH END TIPS (Ø 80 mm)			
10	TUBE.5000.80-BS		5 m FLEXIBLE TUBE WITH END TIPS (Ø 80 mm)			
11	TUBE.10000.80-BS		10 m FLEXIBLE TUBE WITH END TIPS (Ø 80 mm)			
12	TUBE.3000.60-BS		3 m FLEXIBLE TUBE WITH END TIPS (Ø 60 mm)			
13	TUBE.5000.60-BS		5 m FLEXIBLE TUBE WITH END TIPS (Ø 60 mm)			
14	TUBE.CON		TUBE CONNECTOR COUPLING TWO HOSES MAKING IT A XL-HOSE			
15	NOZ.350		350 mm BROAD FLAT OUTPUT NOZZLE			
16	NOZ.500	4 14 1	500 mm BROAD FLAT OUTPUT NOZZLE WITH INSIDE BLADE STRUCTURE FOR A HOMOGENEOUS FOG OUTPUT			
17	Y-SPLITTER	<b>-</b>	Y-PATTERN SPLITTER FOR SPLITTING ONE TO TWO HOSES ENABELOING WORKING SAME TIME AT TWO VISUALIZATION SPOTS. COMING WITH ADDITIONAL SHORT HOSE CONNECTING APXX WITH Y-SPLITTER.			

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LINE	ITEM #	PICTURE	ITEM DESCRIPTION
18	LED.BOOST		LED LUMINAIRE W/ADJUSTABLE SPOT SIZE INCL. SPECIAL
			MULTI LENSE ARRAY (LINE PATTERNS) & HIGHER CONTRAST
19	FLEX.KIT-80/60/50		FLEXIBILITY KIT ENABLING A SPLITTING OF THE STANDARD Ø 80 mm INTO TWO Ø 50 mm HOSES. INCLUDING ONE Y- SPLITTER CONNECTING DIRECTLY TO THE AFM-NEO'S FOG OUTLET + TWO Ø 80 TO Ø 50 mm REDUCTIONS (WITH INSIDE THROTTLE VALVE FOR A FROM 0 TO 100 % OUTPUT ADJUSTMENT IN EACH OF THE Y-ADAPTER OUTLETS) PLUS 2 UNITS OF THE 3 m Ø 50 mm HOSE. AS MAJOR PROS THIS FLEXIBILITY KIT ENABLES WORKING ON TWO SPOTS PARALLELY WITH POSSIBILITY OF INDIVIDUALLY ADJUSTMENT OF THE FOG OUTPUT FROM 0 TO 100 % IN EACH OF THE TWO Ø 50 mm HOSES AND GOING INTO NARROW OR CORNER SPACES NOT REACHABLE WITH A
20	RC.AFM.BASIC		STANDARD Ø 80 mm HOSE.  BASIC REMOTE CONTROL FOR ALL SYSTEM FUNCTIONS
20	RC.AFIVI.BASIC		ON/OFF, SWITCH MODE AND FLASH MODE
21	RC.AFM.AD		ADVANCED REMOTE CONTROL FOR SYSTEM FUNCTIONS ON/OFF, SWITCH & FLASH MODE, FAN UP/DOWN, 4-3-2-1 BLOCK RUN.
22	WR.PS	WORLDWIDE USE	BUILT IN WIDE RANGE POWER SUPPLY ENABLING A WORLDWIDE SYSTEM USE
23	LF.AFM		CARRIAGE WITH STEERING HOLM FOR A EASY HANDLING W/O LIFTING ON THE JOB
24	80/60 RED.THR	7	THROTTLE VALVE FOR A 0 TO 100 % OUTPUT ADJUSTMENT AT HOSE TIP & REDUCTION FROM 80 TO 60 mm DIAMTER
25	BOX.GEN.2019		HEAVY DUTY TRANSPORT BOX WITH TELESCOPIC HANDLE FITTED WITH HANDLES AND HEAVY DUTY FOAM, COLOUR SILVER

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#### REFREFERENCE EXTRACT



























### **FURTHER REFERENCES 2018/2019**

**SANDOZ** CANADA AND AUSTRIA

**LAM RESEARCH USA** 

**REGENERON** USA AND IRELAND

**ALLERGAN USA AND BRAZIL** 

MESA3 USA

**MSD** ANIMAL HEALTH UK

**OPTIMA PHARMA GERMANY** 

**NOVO NORDISK FRANCE** 

**LIFECORE USA** 

**BC TECHNOLOGY** GERMANY

**ESPRIT VALIDATION FRANCE** 

**NOVARTIS** USA AND SINGAPORE

**PFIZER ITALY AND USA** 

**GSK** UK AND CANADA

**ADVANCED AUTOMATICS USA** 

**SANOFI** USA

**TECHNOLOG PHARMA UKRAINE** 

**HEMOPHARM** SERBIA

**OCTAPHARMA FRANCE** 

**IGIENAIR** (QUALIFIER) FRANCE

**PHARMASERV** GERMANY

**HYGENIKS** USA

**TEVA PHARMA USA** 

**AMGEN** USA

**ALCON BELGIUM AND USA** 

**PERFORMANCE VALIDATION USA** 

**BOEHRINGER I. GERMANY & CHINA & USA** 

FRESENIUS KABI SOUTH AFRICA AND USA

**ROMPHARMA** ROMANIA

**PJSC TECHNOLOG UKRAINE** 

**HEX GROUP** (QUALIFIER) BELGIUM / FRANCE

LDMI (QUALIFIER) FRANCE

CAS (QUALIFIER) SWITZERLAND

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