Südtiroler Sanitätsbetrieb
Health Authority of Alto Adige
Health Authority of Sudtirol

VIA LORENZ BÖHLER, 5
BOLZANO

‘TOUL LAMINAR FLOW’ PARTICULATE DEVICE VALIDATION

The text is translated from the original document:

CONVALIDA PARTICELLARE DISPOSITIVO “TOUL FLUSSO LAMINARE”

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Attachment 1: Calibration certificates of the tools used

1 INTRODUCTION

On 18 December 2019, the company Veram S.r.l. performed environmental monitoring in a room of the Hospital of Bolzano at the via Lorenz Böhler, 5 site.
The purpose of the monitoring was to validate the actual efficacy of a device called 'Toul Laminar Flow'. This portable device can ensure the particulate levels necessary to achieve ISO Class 5 values in parts of rooms with higher particulate classes.
The particulate contamination inside the effective area of the device will be validated. Below is a description of how it was carried out.
The relative regulation is UNI EN ISO 14644 - 'Cleanrooms and Associated Controlled Environments'.

2 PARTICULATE CONTAMINATION

Particulate contamination controls are performed to assess the capacity of the air conditioning system to maintain suitable conditions for the proper conduct of activities in hospital premises, considering that airborne particulates can spread any microorganisms present. The control must be done periodically as part of a quality assurance programme.
A particle counter tool was used for samplings, pursuant to UNI EN technical standards 13205:2002[1] (light-diffusion device) that can:

- visualise or record the count and size of the particles in the air;
- distinguish the size of the particles to measure the total concentration of the particles within the size range being checked.

The sensor of the particle count sampling tool is turned into the air flow. If the direction of the air flow cannot be determined (turbulent flow) the sensor must be turned upward.
The assessment of the particle concentration in air must be performed in operating room-ready conditions (at rest - with operating room set up and without staff). The minimum number of sampling points is tabulated (UNI EN ISO 14644-1 and EU GCMP Annex 1 standards), depending on the area of the room to be classified: if the flow is unidirectional/mixed, the transversal section to the perpendicular movement of the flow must be considered. In all other cases the area must be checked horizontally.

If the flow is unidirectional/mixed, the sampling points are distributed homogeneously under the vent. If the flow is turbulent, the sampling points are distributed homogenously inside the room but in any case near the vents.
The results regarding the measurement of each sample are recorded as the concentration of the particulates for each size considered. The data are then processed and compared with Table 3.1 should classification be done pursuant to EU GCMO Annex 1 standards and to Table 3.2 should classification be done pursuant to UNI EN ISO 14644-1 standards.

[1] UNI EN 13205:2002: Atmosphere in the work room - Performance assessment of airborne particle concentration measurement tools

Table 3.1 – cleanroom maximum concentration limits (GMP)

Class	At rest (particulates per m^3)		Operational (particulates per m^3)	
	≥ 0.5 µm	≥ 5 µm	≥ 0.5 µm	≥ 5 µm
A	3,520	20	3,520	29
B	3,520	29	352,000	2,900
C	352,000	2,900	3,520,000	29,000
D	3,520,000	29,000	N/A	N/A

Table 3.2 – particulate maximum concentration limits pursuant to UNI EN ISO 14644-1 standards

ISO classification number	Maximum concentration limits (air particulates/m^3) for particulates greater or equal in size to those checked indicated below					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO Class 1	10[b]	d	d	d	d	e
ISO Class 2	100	24[b]	10[b]	d	d	e
ISO Class 3	1,000	237	102	35[b]	d	e
ISO Class 4	10,000	2,370	1,020	352	83[b]	e
ISO Class 5	100,000	23,700	10,200	3,520	832	d, e, f
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO Class 7	c	c	c	352,000	83,200	2,930
ISO Class 8	c	c	c	3,520,000	832,000	29,300
ISO Class 9	c	c	c	35,200,000	8,320,000	293,000

a) All concentrations in the table are cumulative, i.e., for ISO Class 5, the 10,200 assigned to size 0.3 µm include all particulates equal to and greater than this size;
b) Too large of an air volume may need to be sampled for classification at these concentrations;
c) Concentration limits in this area of the table are not applicable as they are too high;
d) The statistical limitations of low-concentration particle sampling make classification inappropriate;
e) Both low-concentration particle sampling and sampling over 1 µm make classification inappropriate due to potential loss of particles in the sampling system;
f) Factor M must be used to specify this particle size in association with ISO Class 5 (section C.7. 14644-1:2016) along with another size;
g) This class is applicable only for in-operation validations.

3 INVESTIGATION STRATEGIES

3.1 Particulate contamination

A particle counter was used for measuring the particulate count (see Figure 2). The tool can visualise and record the count and size of the particles in the air, distinguishing the size of the particles to measure the total concentration of those falling under the size range being checked.

Fig. 2 – Aerotrack

As previously stated, the device tested must meet ISO Class 5 standards inside the effective area in unstructured rooms to guarantee that degree of cleanliness.
Therefore the particle counter was positioned with the sensor turned into the air flow and following the following steps:

- Particle count with the device off. This measurement was to test the starting conditions of the effective area.
- Continuous measurement for 30 seconds of the particle concentration in two measurement points: the first a few centimetres from the device filter, the second at the end of the effective area. This measurement was to figure out how long it would take the space under the effective area of the 'Toul Laminar Flow' device to go from an ISO Class 5 noncompliant particle concentration to a potentially compliant concentration. For this measurement, the device was switched on simultaneously with the start of measurement.
- Particulate count with the device on. That measurement was to figure out if the space confined by the effective area was actually ISO Class 5 compliant.

The results of said measurement are indicated in the below paragraph.

4 MONITORING OUTCOME SUMMARY

PARTICULATE COUNT WITH DEVICE OFF

Sampling Data for Particles ≥ 0.3 µm		
Mean Concentration (particle/m^3)	ISO Class 5 Limit (particle/m^3)	Outcome
98,638,870	10,200	Noncompliant
Sampling Data for Particles ≥ 0.5 µm		
Mean Concentration (particle/m^3)	ISO Class 5 Limit (particle/m^3)	Outcome
9,240,283	3,520	Noncompliant

The table shows that the starting data inside the effective area of the device was ISO Class 5 noncompliant

CONTINUOUS MEASUREMENT WITH DEVICE ON

Position 1

Sampling Data for Particles ≥ 0.3 µm		
Time	Mean Concentration (particle/m^3)	ISO Class 5 Limit (particle/m^3)
30''	14,134	10,200
1'	707	10,200
1' 30''	0	10,200

Sampling Data for Particles ≥ 0.5 µm		
Time	Mean Concentration (particle/m^3)	ISO Class 5 Limit (particle/m^3)
30”	12,721	3,250
1’	0	3,250
1’ 30’’	0	3,250

As the table shows, once the device was switched on, the 0.3 µm particle concentration at Position 1 went from an ISO Class 5 noncompliant value to 0 particles/ m^3 after about 1 min and 30 sec. The data is even better for 0.5 µm particles, which went from an ISO Class 5 noncompliant value to 0 particles/m^3 after 1 min.

Position 2

Sampling Data for Particles ≥ 0.3 µm		
Time	Mean Concentration (particle/m^3)	ISO Class 5 Limit (particle/m^3)
30”	384,452	10,200
1’	459,364	10,200
1’ 30’’	91,873	10,200
2’	0	10,200

Sampling Data for Particles ≥ 0.5 µm		
Time	Mean Concentration (particle/m^3)	ISO Class 5 Limit (particle/m^3)
30”	31,095	3,250
1’	38,163	3,250
1’ 30’’	6,360	3,250
2’	0	3,250

For Position 2, the table shows that both 0.3 and 0.5 µm particles go from ISO Class 5 noncompliant concentrations to 0 particles/m^3 after two minutes of switching on the device.

PARTICULATE COUNT WITH THE DEVICE ON

Sampling Data for Particles ≥ 0.3 µm		
Mean Concentration (particle/m^3)	ISO Class 5 Limit (particle/m^3)	Outcome
208	10,200	Compliant
0	10,200	Compliant
Sampling Data for Particles ≥ 0.5 µm		
Mean Concentration (particle/m^3)	ISO Class 5 Limit (particle/m^3)	Outcome
42	3,520	Compliant
0	3,520	Compliant

The table shows that the particle count inside the effective area with the device on is ISO Class 5 compliant

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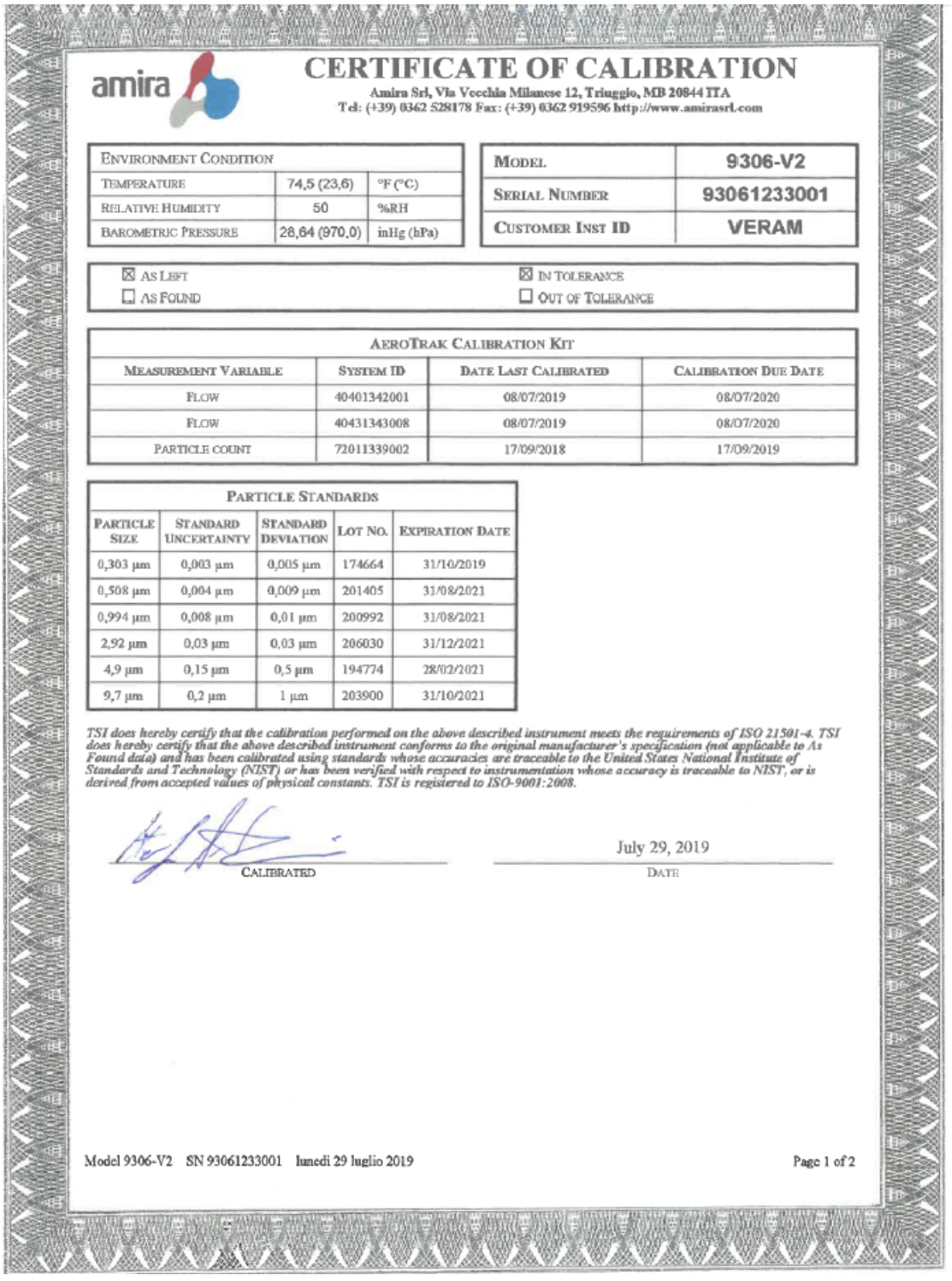
PARTICULATE DEVICE VALIDATION

ATTACHMENT 1

Calibration certificates of the tools used

Calibration certificates of the particle counter



CERTIFICATE OF CALIBRATION

Amira Srl, Via Vecchia Milanese 12, Triuggio, MB 20844 ITA
Tel: (+39) 0362 528178 Fax: (+39) 0362 919596 http://www.amirasrl.com

Environment Condition		
Temperature	74,5 (23,6)	°F (°C)
Relative Humidity	50	%RH
Barometric Pressure	28,64 (970,0)	inHg (hPa)

Model	9306-V2
Serial Number	93061233001
Customer Inst ID	VERAM

☒ As Left ☐ As Found
☒ In Tolerance ☐ Out of Tolerance

AeroTrak Calibration Kit			
Measurement Variable	System ID	Date Last Calibrated	Calibration Due Date
Flow	40401342001	08/07/2019	08/07/2020
Flow	40431343008	08/07/2019	08/07/2020
Particle Count	72011339002	17/09/2018	17/09/2019

Particle Standards				
Particle Size	Standard Uncertainty	Standard Deviation	Lot No.	Expiration Date
0,303 µm	0,003 µm	0,005 µm	174664	31/10/2019
0,508 µm	0,004 µm	0,009 µm	201405	31/08/2021
0,994 µm	0,008 µm	0,01 µm	200992	31/08/2021
2,92 µm	0,03 µm	0,03 µm	206030	31/12/2021
4,9 µm	0,15 µm	0,5 µm	194774	28/02/2021
9,7 µm	0,2 µm	1 µm	203900	31/10/2021

TSI does hereby certify that the calibration performed on the above described instrument meets the requirements of ISO 21501-4. TSI does hereby certify that the above described instrument conforms to the original manufacturer's specification (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the United States National Institute of Standards and Technology (NIST) or has been verified with respect to instrumentation whose accuracy is traceable to NIST, or is derived from accepted values of physical constants. TSI is registered to ISO-9001:2008.

Calibrated

July 29, 2019
Date

Model 9306-V2 SN 93061233001 lunedì 29 luglio 2019 Page 1 of 2