

VALIDATION REPORT no. 874/2023

All measurements were performed in accordance with EN ISO 14644-1 standard.

System:	ČISTI PROSTOR
Date:	04.12.2023
Customer:	MedicalPlast MD d.o.o.
	Zalog 28
	8000 Novo mesto
User:	MedicalPlast MD d.o.o.
	Zalog 28
	8000 Novo mesto

MEASUREMENTS TAKEN	RESULTS COMPLY
AIRFLOW VOLUME AND AIR CHANGE RATE	No requirements given
DIFFERENTIAL PRESSURE BETWEEN ROOMS	YES
PARTICLE COUNTING AND ROOM CLASSIFICATIONS	YES
VISUAL SMOKE TEST	YES
TEMPERATURE AND HUMIDITY TEST	No requirements given

Place:
Šentjernej,

Date: 04.12.2023
Valid until: 04.12.2025

Testing performed by:
Peter Barbič, univ.dipl.biokem.

gbc

Stamp:



Iskra PIO d.o.o.
Trubarjeva cesta 5
SI - 8310 Šentjernej

Report issued by :
Iskra PIO d.o.o.

Direktor

Andraž Rumpret, univ.dipl.inž.

[Signature]

VALIDACIJSKO POROČILO št. 874/2023

Izvajanje meritev: V skladu z zahtevami v standardu EN ISO 14644-1

Objekt testiranja:	ČISTI PROSTOR
Datum:	04.12.2023
Naročnik:	MedicalPlast MD d.o.o.
	Zalog 28
	8000 Novo mesto
Uporabnik:	MedicalPlast MD d.o.o.
	Zalog 28
	8000 Novo mesto

OPRAVLJENI TESTI IN MERITVE	USTREZA KRITERIJU
MERITVE DOVODNIH KOLIČIN ZRAKA IN IZRAČUN ŠTEVILA IZMENJAV ZRAKA V PROSTORU	Ni podanih zahtev
MERITVE RAZLIKE TLAKOV MED PROSTORI	DA
MERITVE ŠTEVILA DELCEV IN KLASIFIKACIJA PROSTORA	DA
DIMNI TEST	DA
MERITVE TEMPERATURE IN VLAŽNOSTI ZRAKA V PROSTORU	Ni podanih zahtev

Kraj:
Šentjernej,

Datum: 04.12.2023
Veljavnost do: 04.12.2025

Testiranje izvedel:
Peter Barbič, univ.dipl.biokem.

glie



Žig:

Iskra PIO d.o.o.
Trubarjeva cesta 5
SI - 8310 Šentjernej

Dokument izdal:
Iskra PIO d.o.o.

Direktor

Andraž Rumpret, univ.dipl.inž.

VALIDACIJSKO POROČILO

IZVRŠENA TESTIRANJA IN UPORABLJENI MERILNI INŠTRUMENTI

1. Meritve dovodnih količin zraka pod difuzorji in izračun števila izmenjav zraka v prostoru

MERILNI INŠTRUMENT: AccuBalance 8380 - TSI

2. Meritve razlike tlakov med prostori

MERILNI INŠTRUMENT: TESTO 480

3. Meritve temperature in vlažnosti zraka

MERILNI INŠTRUMENT: TESTO 480

4. Štetje delcev v prostoru

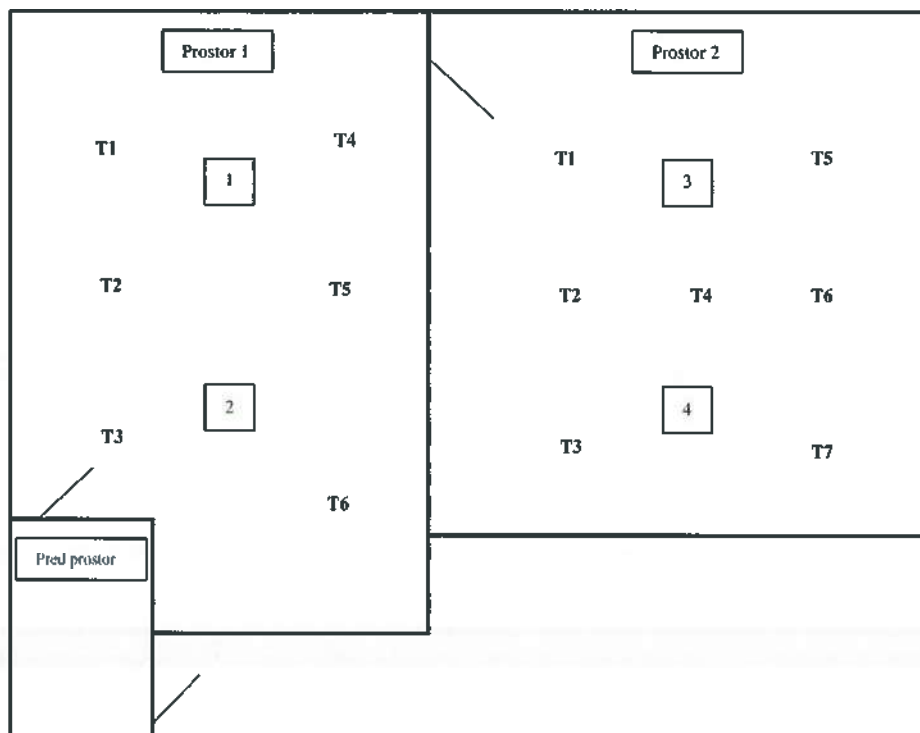
MERILNI INŠTRUMENT: Laserski števec delcev Lighthouse Solair 3100

5. Dimni test

MERILNI INŠTRUMENT: Safex Flow Marker B7009578

6. Priloge

SKICA PROSTORA



REZULTATI TESTIRANJA

1. MERITVE DOVODNIH KOLIČINE ZRAKA POD DIFUZORJI, ŠT. IZMENJAV ZRAKA V PROSTORU

1.1 Namen

- Namen testa je ugotoviti količino dovedenega zraka v prostoru in števila izmenjav zraka v prostoru.

1.2 Uporabljen merilni inštrumenti

- Merilnik hitrosti pretoka zraka – AccuBalance 8380 - TSI

1.3 Kriterij sprejemljivosti

- Zahteve niso podane

1.4 Rezultati meritev dovodnih količin zraka pod filtri in št. izmenjav zraka

ČISTI PROSTOR 1	FILTER	Pretok zraka m ³ /h	Skupni pretok (m ³ /h)	Koristni volumen Vk (m ³)	Število izmenjav/h Izmerjeno
	1	500	983	66,47	15
	2	483			

Število izmenjav zraka v prostoru ⇒ 15 / h

ČISTI PROSTOR 2	FILTER	Pretok zraka m ³ /h	Skupni pretok (m ³ /h)	Koristni volumen Vk (m ³)	Število izmenjav/h Izmerjeno
	3	397	959	69,00	14
	4	562			

Število izmenjav zraka v prostoru ⇒ 14 / h

Datum meritev: 04.12.2023

Meritve opravil: Peter Barbič




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2. MERITVE RAZLIKE TLAKOV MED PROSTORI

2.1 Namen

- Namen testa je preveriti razlike tlakov med prostori, ki zagotavljajo pravilno smer gibanja zraka.

2.2 Uporabljen merilni inštrumenti

- Testo 480.

2.3 Kriterij sprejemljivosti

- Čisti prostor 1 $\Rightarrow$ Okolica + 15 Pa $\pm$ 5

2.4 Rezultati meritev

- Čisti prostor 1 – Okolica
 $\Delta p = 16,2 \text{ Pa}$
- Tlak na prikazovalniku:
 $\Delta p = 16 \text{ Pa}$

Datum meritev: 04.12.2023

Meritve opravil: Peter Barbič



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3. MERITVE TEMPERATURE IN VLAŽNOSTI ZRAKA V PROSTORU

3.1 Namen

- Namen testa je preveriti temperaturo in vlažnost zraka v prostoru.

3.2 Uporabljen merilni inštrumenti

- Testo 480 + sonda za merjenje temperature in vlažnosti zraka.

3.2 Kriterij sprejemljivosti

- Zahteve niso podane.

3.4 Rezultati meritev

Prostor	Merilne točke	°C	% RH
Čisti prostor 1	T1	21,6	48,8
	T2	21,7	48,3
	T3	21,8	48,1
	T4	21,8	47,3
	T5	21,7	47,4
	T6	21,9	47,6
Čisti prostor 2	T1	21,9	46,8
	T2	22,0	47,0
	T3	22,0	46,6
	T4	22,1	46,8
	T5	22,1	46,2
	T6	22,1	47,1
	T7	22,2	46,9

Temperatura in vlaga na prikazovalniku:

T = 21,6 °C; Rh = 48,7 %

Datum meritev: 04.12.2023

Meritve opravil: Peter Barbič



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4. ŠTETJE DELCEV IN KLASIFIKACIJA PROSTORA

4.1 Namen

Ugotoviti količino prisotnih delcev v čistem prostoru ter ugotoviti razred čistosti prostora – v skladu z EN ISO 14644-1 standardom.

4.2 Merilni inštrument

Laserski števec delcev tip Solair 3100 - Lighthouse, ki ima naslednje lastnosti:

- a) prikazuje in izpiše število in velikost delcev prisotnih v zraku.
- b) zmožnost ločevanja delcev glede na velikost
- c) vzorčni volumen zraka 1 ft³/min.

4.3 Kriterij sprejemljivosti

Čisti prostor ustreza kriteriju v kolikor izmerjene koncentracije v posameznih merilnih točkah ne presegajo dovoljene koncentracije delcev zahtevanega razreda čistosti.

Tabela 1 – Razredi čistosti ter dopustne koncentracije delcev

ISO Class number (N)	Maximum allowable concentrations (particles/m ³) for particles equal to and greater than the considered sizes, shown below ^a					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
1	10 ^b	d	d	d	d	e
2	100	24 ^b	10 ^b	d	d	e
3	1000	237	102	35 ^b	d	e
4	10000	2370	1020	352	83 ^b	e
5	100000	23700	10200	3520	832	d,e,f
6	1000000	237000	102000	35200	8320	293
7	c	c	c	352000	83200	2930
8	c	c	c	3520000	832000	29300
9g	c	c	c	35200000	8320000	293000

^a All concentrations in the table are cumulative, e.g. for ISO Class 5, the 10 200 particles shown at 0,3 µm include all particles equal to and greater than this size.

^b These concentrations will lead to large air sample volumes for classification. Sequential sampling procedure may be applied; see Annex D.

^c Concentration limits are not applicable in this region of the table due to very high particle concentration.

^d Sampling and statistical limitations for particles in low concentrations make classification inappropriate.

^e Sample collection limitations for both particles in low concentrations and sizes greater than 1 µm make classification at this particle size inappropriate, due to potential particle losses in the sampling system.

^f In order to specify this particle size in association with ISO Class 5, the macroparticle descriptor M may be adapted and used in conjunction with at least one other particle size. (See C.7.)

^g This class is only applicable for the in-operation state.

4.5 Izvajanje meritev:

V skladu z zahtevami v standardu EN ISO 14644-1.

Pri izvedbi meritve se postavi izokinetična sonda števca delcev na prej določena merilna mesta in izmeri predpisani volumen zraka.

Merilna mesta morajo biti enakomerno porazdeljena po površini čistega prostora (glej str. 3).

Sondo števca delcev na vsakem merilnem mestu postaviti tako, da je odprtina usmerjena proti zračnemu toku (proti hepa filtru). V kolikor smer zračnega toka ni definirana (turbulentni zračni tok) postaviti sondo števca delcev tako, da je usmerjena vertikalno navzgor.

Kadar na določenem merilnem mestu testiramo dva ali več vzorcev je potrebno izračunati srednjo vrednost za vsako opazovano velikost delcev.

Na vsakem merilnem mestu je potrebno testirati zadosten volumen zraka, da zaznamo minimalno 20 delcev, če je koncentracija največjih opazovanih delcev znotraj zahtev predpisanega razreda čistosti - enačba A2; standard ISO 14644-1; dodatek A.

V primeru, ko je čas testiranja zelo velik ga lahko zmanjšamo z uporabo »sekvenčne« metode ⇒ ISO 14466-1; dodatek D.

4.4 Štetje delcev in klasifikacija prostora – REZULTATI

Prostor 1 – Čisti prostor

- Projektiran razred prostora: **ISO razred 8**
- Površina čistega prostora: **A = 23,74 m²**
- Stanje prostora pri izvajanju meritev : **mirovanje** (ISO 14644-1)
- Število merilnih točk v prostoru: **N_{L min} = 6** (Tabela A1; ISO 14644-1; dodatek A)
- Delci katere bomo opazovali: **0, 5μm in 5 μm**
- Zahtevani čas merjenja v posamezni točki = **1 min** (A2; ISO 14644-1; dodatek A).

Meritve smo izvajali na delovni višini (cca. 0.8 – 1 m).

Delci ≥ 0,5 μm

Merilno mesto	Število delcev (≥ 0,5μm) / m ³	Zahteva kriterija ISO razred 8	Ustreza kriteriju
T1	192889	< 3 520 000 del./m³	DA
T2	187238		DA
T3	169652		DA
T4	161741		DA
T5	149875		DA
T6	161988		DA

Iz rezultatov je razvidno, da koncentracija delcev v posameznih točkah ne presega dopustno koncentracijo delcev (ISO razred 8).

- Zahteva kriterija ISO razred 8(≥ 0,5μm): **< 3 520 000 del./m³**
- Ustreza kriteriju: **DA**

Delci $\geq 5 \mu\text{m}$

Merilno mesto	Število delcev ($\geq 5 \mu\text{m}$) / m^3	Zahteva kriterija ISO razred 8	Ustreza kriteriju
T1	1660	< 29 300 del./ m^3	DA
T2	1483		DA
T3	1377		DA
T4	1625		DA
T5	954		DA
T6	848		DA

Iz rezultatov je razvidno, da koncentracija delcev v posameznih točkah ne presega dopustno koncentracijo delcev (ISO razred 8).

- Zahteva kriterija ISO razred 8 ($\geq 5 \mu\text{m}$): < 29 300 del./ m^3
- Ustreza kriteriju: **DA**

Datum meritev: 04.12.2023

Meritve opravil: Peter Barbič




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Prostor 2 – Čisti prostor

- Projektiran razred prostora: **ISO razred 8**
- Površina čistega prostora: **A = 24,64 m²**
- Stanje prostora pri izvajanju meritev : **mirovanje** (ISO 14644-1)
- Število merilnih točk v prostoru: **N_{L min} = 7** (Tabela A1; ISO 14644-1; dodatek B)
- Delci katere bomo opazovali: **0,5 μm in 5 μm**
- Zahtevani čas merjenja v posamezni točki = **1 min** (A2; ISO 14644-1; dodatek B).

Meritve smo izvajali na delovni višini (ca 0.8 – 1 m).

Delci ≥ 0,5 μm

Merilno mesto	Število delcev (≥ 0,5 μm) / m ³	Zahteva kriterija ISO razred 8	Ustreza kriteriju
T1	161317	< 3 520 000 del./m ³	DA
T2	166897		DA
T3	142142		DA
T4	159764		DA
T5	171417		DA
T6	164037		DA
T7	165167		DA

Iz rezultatov je razvidno, da koncentracija delcev v posameznih točkah ne presega dopustno koncentracijo delcev (ISO razred 8).

- Zahteva kriterija ISO razred 8(≥ 0,5 μm): **< 3 520 000 del./m³**
- Ustreza kriteriju: **DA**

Delci $\geq 5 \mu\text{m}$

Merilno mesto	Število delcev ($\geq 5 \mu\text{m}$) / m^3	Zahteva kriterija ISO razred 8	Ustreza kriteriju
T1	848	< 29 300 del./ m^3	DA
T2	989		DA
T3	812		DA
T4	1448		DA
T5	918		DA
T6	742		DA
T7	459		DA

Iz rezultatov je razvidno, da koncentracija delcev v posameznih točkah ne presega dopustno koncentracijo delcev (ISO razred 8).

- Zahteva kriterija ISO razred 8($\geq 5 \mu\text{m}$): < 29 300 del./ m^3
- Ustreza kriteriju: DA

Datum meritev: 04.12.2023

Meritve opravil: Peter Barbič




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4.5.1 ŠTETJE DELCEV V PROSTORU – Original izpis ⇒ Prostor 1

Prostor 1

Serial #: 181204037
Location: LOC001
04/12/2023, 08:56:28
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 191228.9 192888.7
5.0 1659.8 1659.8

Serial #: 181204037
Location: LOC004
04/12/2023, 09:00:27
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 160116.7 161741.1
5.0 1624.5 1624.5

Serial #: 181204037
Location: LOC002
04/12/2023, 08:57:48
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 185755.1 187238.3
5.0 1483.2 1483.2

Serial #: 181204037
Location: LOC005
04/12/2023, 09:01:37
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 148921.9 149875.4
5.0 953.5 953.5

Serial #: 181204037
Location: LOC003
04/12/2023, 08:59:09
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 168274.3 169651.6
5.0 1377.3 1377.3

Serial #: 181204037
Location: LOC006
04/12/2023, 09:02:51
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 161140.8 161988.3
5.0 847.6 847.6

Gleč. 04. 12. 2023

4.5.1 ŠTETJE DELCEV V PROSTORU – Original izpis ⇒ Prostor 1

2206702 4

Serial #: 181204037
Location: LOC001
04/12/2023, 08:56:28
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 191228.9 192888.7
5.0 1659.8 1659.8

Serial #: 181204037
Location: LOC004
04/12/2023, 09:00:27
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 160116.7 161741.1
5.0 1624.5 1624.5

Serial #: 181204037
Location: LOC002
04/12/2023, 08:57:48
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 185755.1 187238.3
5.0 1483.2 1483.2

Serial #: 181204037
Location: LOC005
04/12/2023, 09:01:37
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 148921.9 149875.4
5.0 953.5 953.5

Serial #: 181204037
Location: LOC003
04/12/2023, 08:59:09
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 168274.3 169651.6
5.0 1377.3 1377.3

Serial #: 181204037
Location: LOC006
04/12/2023, 09:02:51
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 161140.8 161988.3
5.0 847.6 847.6

glej, 04.12. 2023

glej, 04.12. 2023

4.5.2 ŠTETJE DELCEV V PROSTORU – Original izpis ⇒ Prostor 2

PROSTOR 2

Serial #: 181204037
Location: LOC001
04/12/2023, 08:36:36
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 160469.8 161317.4
5.0 847.6 847.6

Serial #: 181204037
Location: LOC005
04/12/2023, 08:43:07
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 170499.2 171417.4
5.0 918.2 918.2

Serial #: 181204037
Location: LOC002
04/12/2023, 08:37:52
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 165908.3 166897.1
5.0 988.8 988.8

Serial #: 181204037
Location: LOC006
04/12/2023, 08:44:18
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 163295.0 164036.6
5.0 741.6 741.6

Serial #: 181204037
Location: LOC003
04/12/2023, 08:39:14
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 141329.3 142141.5
5.0 812.2 812.2

Serial #: 181204037
Location: LOC007
04/12/2023, 08:45:56
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 164707.6 165166.7
5.0 459.1 459.1

glav. 04. 12. 2023

Serial #: 181204037
Location: LOC004
04/12/2023, 08:40:43
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 158315.6 159763.5
5.0 1447.9 1447.9

glav. 04. 12. 2023

4.5.2 ŠTETJE DELCEV V PROSTORU – Original izpis ⇒ Prostor 2

PROSTOR 2

Serial #: 181204037
Location: LOC001
04/12/2023, 08:36:36
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 160469.8 161317.4
5.0 847.6 847.6

Serial #: 181204037
Location: LOC005
04/12/2023, 08:43:07
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 170499.2 171417.4
5.0 918.2 918.2

Serial #: 181204037
Location: LOC002
04/12/2023, 08:37:52
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 165908.3 166897.1
5.0 988.8 988.8

Serial #: 181204037
Location: LOC006
04/12/2023, 08:44:18
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 163295.0 164036.6
5.0 741.6 741.6

Serial #: 181204037
Location: LOC003
04/12/2023, 08:39:14
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 141329.3 142141.5
5.0 812.2 812.2

Serial #: 181204037
Location: LOC007
04/12/2023, 08:45:56
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 164707.6 165166.7
5.0 459.1 459.1

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Serial #: 181204037
Location: LOC004
04/12/2023, 08:40:43
Sample Time: 00:01:00
Flow: 1.0 cfm
Laser: OK
Counts/m³:
Size Diff Cumul
0.5 158315.6 159763.5
5.0 1447.9 1447.9

glic. 04.12.2023

glic. 04.12.2023

5. DIMNI TEST

5.1 Namen

- Vizualno smo s pomočjo dima ugotovili smer gibanja zraka med prostori.

5.2 Uporabljen merilni inštrumenti

- Generator dima Safex Flow Marker 1

5.3 Kriterij sprejemljivosti

- Smer gibanja zraka mora biti vedno iz prostora z višjo stopnjo čistosti proti prostoru z nižjo stopnjo čistosti.

5.4 Rezultati meritev

Čisti prostor 1

Zrak se giblje iz čistega prostora 1 proti predprostoru ($\Delta p = +16,2$ Pa).
Glede na kriterij **USTREZA** zahtevam.

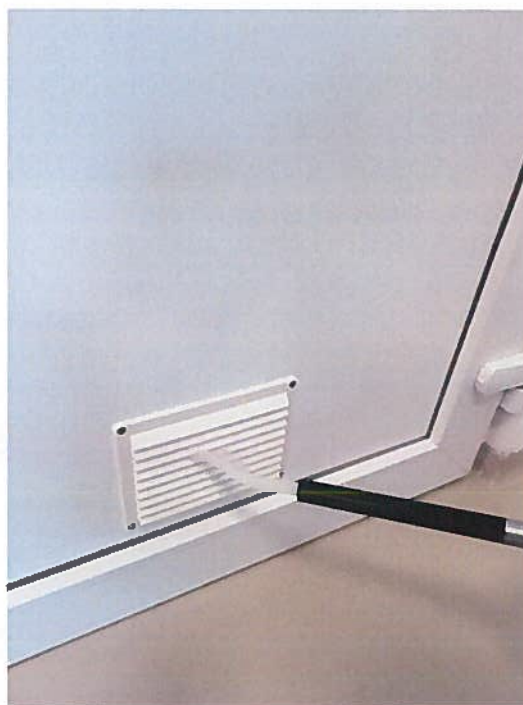
Datum meritev: 04.12.2023

Meritve opravil: Peter Barbič



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SI - 8310 Šentjernej

5.5 Slike dimnega testa - priloge testa



6. PRILOGE

- Certifikati merilnih inštrumentov



CERTIFICATE OF CALIBRATION

TSI Instruments Ltd., Stirling Road, Cressex Business Park,
High Wycombe, Bucks HP12 3RT England
Tel: (Int +44)(UK 0) 1494 459200 Fax: (Int +44)(UK 0) 1494 459700
www.tsiine.co.uk

ENVIRONMENT CONDITION		
TEMPERATURE	22.1	° C
RELATIVE HUMIDITY	43.4	% RH
BAROMETRIC PRESSURE	995	hPa

MODEL	AccuBalance [®] 8380
SERIAL NO.	T83090629008

CALIBRATION STANDARDS USED
Capture Hood Calibration System UK1

☒ AS LEFT	☒ IN TOLERANCE
☐ AS FOUND	☐ OUT OF TOLERANCE

CALIBRATION DATA						
Tolerance: $\pm (3\% \text{ of reading} + 11.9 \text{ m}^3/\text{h})$						
TESTING POINTS	SUPPLY DATA MEASURED IN m^3/h			RETURN DATA MEASURED IN m^3/h		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	3223	3272	3115 - 3331	3237	3204	3128 - 3346
2	2549	2569	2461 - 2637	2549	2523	2461 - 2637
3	2039	2041	1966 - 2112	2041	2032	1968 - 2114
4	1529	1533	1472 - 1586	1522	1533	1465 - 1579
5	1026	1021	984 - 1068	1026	1038	984 - 1068
6	513	503	486 - 540	513	515	486 - 540
7	168	167	152 - 184	170	170	154 - 186

* Indicates out of tolerance condition

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 members of the European co-operation for Accreditation (EA) for example: UKAS, SWEDAC, DAkkS or has been verified with respect to instrumentation whose accuracy is traceable to some member of EA, or is derived from accepted values of physical constants. TSI's calibration system meets ISO-9001:2015 and meets the requirements of ISO 10012:2003.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E006072	06-14-22	06-14-23
Thermometer	E006103	01-31-23	01-31-24
Pressure	E006155	06-14-22	06-14-23
Pressure	E006095	06-14-22	06-14-23
Flow	E005455	05-22-19	05-22-23
Flow	E005456	05-21-19	05-21-23
Flow	E006061	06-14-22	06-14-23

Calibration procedure used: 9011-56


Calibrated By

Apr. 6, 2023

Calibration Date



LIGHTHOUSE
WORLDWIDE SOLUTIONS BENELUX BV



Calibration certificate

Certificate number: A09450

Revision 3.1 b

Applicant:

Iskra PIO
Trubarjeva cesta 5
8310, Šentjernej
Slovenia

Instrument:

Description	Airborne particle counter
Manufacturer	Lighthouse
Model	Solair 3100E
Serial number	181204037

Date of calibration:

21 June 2023

Due date calibration:

June 2024

Calibration method:

Calibration has been accomplished as described in ISO21501-4:2018. All work performed is in accordance with Lighthouse Worldwide Solutions Benelux, Master Calibration Document: 1201 and is recorded and maintained as such.

Results:

The results of the measurements are shown on the following pages.

Readjustments:

The unit is readjusted.

Compliance, As left:

Pass - The measured values were observed in tolerance at the points tested.

Traceability:

The measurements have been executed using standards for which the traceability to (inter)national standards has been demonstrated towards the Raad voor Accreditatie.

Uncertainty:

The reported expanded uncertainty is based on the standard uncertainty of the measurement multiplied by a coverage factor k, such that the coverage probability corresponds to approximately 95%. The standard uncertainty is determined in accordance with EA-4/02. The ILAC-G8:09/2019 Binary statement is used as method for the compliance statement.

Date of issue:

23 June 2023

Authorized by:

M.A.W. van Boxtel
Head of Calibration

Lighthouse Worldwide Solutions Benelux BV
Van Heemstraweg 19A 8857 KD
Boven-Loosdrecht The Netherlands
Tel +31 (0)487 560811
E-mail: csbenelux@golighthouse.com

The Raad voor Accreditatie is one of the signatories of the Multilateral Agreement of the European Cooperation for Accreditation (EA) for the mutual recognition of calibration certificates

Reproduction of the complete certificate is allowed, parts of the certificate may only be reproduced with written approval of the calibration laboratory. This certificate is issued provided that neither Lighthouse Worldwide Solutions Benelux BV nor the Raad voor Accreditatie assumes any liability.



Calibration certificate

Certificate number: A09450

Date of calibration: 21 June 2023
Calibration location: Lighthouse Benelux Calibration laboratory in Boven-Leeuwen
Calibrated by: A.C.G. Gerritse
Function: Calibration & Service Engineer

Environmental conditions: The ambient temperature was 22,1 °C at a relative humidity of 50,0 %rh.

Measurement results. As found

Performance information				
Test	Test result	Expanded uncertainty	Criteria	Pass / Fail
ISO21501-4 Flow	28,92 l/min	0,95 l/min	28,30 l/min $\pm$ 5 %	Pass
JIS B 9921 Zero count	3	N/A	$\leq$ 1 in 5 min	Fail
ISO21501-4 False count rate	Upper confidence level 55 counts per cubic meter	N/A	N/A	N/A
ISO21501-4 Timer check	59,9 seconds	0,4 s	$\pm$ 1 %	Pass
ISO21501-4 Size resolution	5,2 % used size 0,406 μ m	2,3 %SR	< 15 %	Pass
ISO21501-4 Counting efficiency 50%	49,5 % used size 0,309 μ m	3,0 %CE	(50 $\pm$ 20) %	Pass
ISO21501-4 Counting efficiency 100%	101,4 % used size 0,516 μ m	4,7 %CE	(100 $\pm$ 10) %	Pass

Size calibration (criteria $\pm$ 10%)

Channel	Channel size	Threshold value	Calculated size	Expanded uncertainty	Calculated sizing error	Compliance
	[μ m]	[mV]	[μ m]	[μ m]	[%]	
1	0,30	50	0,307	0,007	2,4	Pass
2	0,50	417	0,498	0,010	-0,4	Pass
3	1,00	1136	1,009	0,018	0,9	Pass
4	3,00	3012	2,872	0,055	-4,3	Pass
5	5,00	3596	4,736	0,147	-5,3	Pass
6	10,00	4495	10,456	0,281	4,6	Pass

Reference equipment

Model	S/N	Due date	Certificate number
TSI Mass Flowmeter 4040	40402122005	08 July 2023	80371
Fisher Scientific 11546893	221351734	15 March 2024	1335-13203715
Handheld 2016	150922100	26 July 2023	A01113
MCA8000D	425	09 February 2024	23-13808-1-5

Particle size standards

Size	Description	Due date	Certificate
0,30 μ m	3300A & 3300B, Nanosphere Size Standards	January 2025	D20015
0,40 μ m	3400A, Nanosphere Size Standards	October 2024	D20016
0,50 μ m	3500 & 3500A, Nanosphere Size Standards	March 2024	D20017
1,00 μ m	4009A, 4009A & 4009B Microsphere Size Standards	December 2024	D20020
3,00 μ m	4D-03 Dry Duke Microsphere Size standards	August 2023	D20025
5,00 μ m	4D-05 Dry Duke Microsphere Size standards	September 2024	D21072A
10,00 μ m	Particle powder size standard - 80000 series	January 2028	DM23001



Calibration certificate

Certificate number: A09450

Date of calibration: 21 June 2023
Calibration location: Lighthouse Benelux Calibration laboratory in Boven-Leeuwen
Calibrated by: A.C.G. Gerritse
Function: Calibration & Service Engineer

Environmental conditions: The ambient temperature was 22,1 °C at a relative humidity of 50,0 %rh.

Measurement results. As left

Performance information

Test	Test result	Expanded uncertainty	Criteria	Pass / Fail
ISO21501-4 Flow	28,92 l/min	0,95 l/min	28,30 l/min $\pm 5\%$	Pass
JIS B 9921 Zero count	0	N/A	≤ 1 in 5 min	Pass
ISO21501-4 False count rate	Upper confidence level 21 counts per cubic meter	N/A	N/A	N/A
ISO21501-4 Timer check	59,9 seconds	0,4 s	$\pm 1\%$	Pass
ISO21501-4 Size resolution	3,0 % used size 0,406 μm	2,8 %SR	$< 15\%$	Pass
ISO21501-4 Counting efficiency 50%	47,1 % used size 0,309 μm	2,8 %CE	(50 ± 20) %	Pass
ISO21501-4 Counting efficiency 100%	107,5 % used size 0,516 μm	4,7 %CE	(100 ± 10) %	Pass

Size calibration (criteria $\pm 10\%$)

Channel	Channel size	Threshold value	Calculated size	Expanded uncertainty	Calculated sizing error	Compliance
	[μm]	[mV]	[μm]	[μm]	[%]	
1	0,30	58	0,309	0,007	2,9	Pass
2	0,50	516	0,500	0,010	0,1	Pass
3	1,00	1265	1,001	0,018	0,1	Pass
4	3,00	3202	3,002	0,065	0,1	Pass
5	5,00	3791	5,010	0,146	0,2	Pass
6	10,00	4665	9,998	0,289	0,0	Pass

Reference equipment

Model	S/N	Due date	Certificate number
TSI Mass Flowmeter 4040	40402122005	08 July 2023	80371
Fisher Scientific 11546893	221351734	15 March 2024	1335-13203715
Handheld 2016	150922100	26 July 2023	A01113
MCA8000D	425	09 February 2024	23-13808-1-5

Particle size standards

Size	Description	Due date	Certificate
0,30 μm	3300A & 3300B, Nanosphere Size Standards	January 2025	D20015
0,40 μm	3400A, Nanosphere Size Standards	October 2024	D20016
0,50 μm	3500 & 3500A, Nanosphere Size Standards	March 2024	D20017
1,00 μm	4009A, 4009A & 4009B Microsphere Size Standards	December 2024	D20020
3,00 μm	4D-03 Dry Duke Microsphere Size standards	August 2023	D20025
5,00 μm	4D-05 Dry Duke Microsphere Size standards	September 2024	D21072A
10,00 μm	Particle powder size standard - 80000 series	January 2028	DM23001

CERTIFIKAT O KALIBRACIJI
CALIBRATION CERTIFICATEOznaka
Number 2023D67-1

NAROČNIK CUSTOMER	ISKRA PIO, D.O.O. TRUBARJEVA CESTA 5, SI-8310 ŠENTJERNEJ
NAZIV/OBJECT	DIGITALNI MERILNIK RAZLIKE TLAKOV
Izdelovalec/Manufacturer	TESTO, NEMČIJA
Tip/Type	TESTO 480
Izdel. ozn./Ser. No.	61364769
Dod. ozn./Additional No.	/
Datum prejema in stanje Date and status on receipt	03.10.2023, brez posebnosti/without speciality.
Kalibracijska metoda Calibration Method	D-3928, Kalibracija po internem kalibracijskem postopku/Calibration according to internal calibration procedure "Kalibracije merilnikov tlaka".

Pogoji okolja Ambient Conditions	Temperatura/Temperature (21 ± 1) °C, relativna vlažnost/relative humidity (50 ± 25) %, tlak/pressure (985 $\pm$ 2) mbar abs.
Čas in mesto izvedbe Date, place of calibration	03.10.2023 v/in BELMET MI d.o.o., Ljubljana.
Sledljivost Traceability	Pri meritvah so bili uporabljeni etaloni, ki so v rednih rekalibracijskih intervalih kalibrirani v laboratorijih, ki so jih akreditirali akreditacijski organi v okviru dogovora Mednarodnega združenja za akreditacijo laboratorijev (ILAC). In the measurements, the standards were used, which were calibrated at regular recalibration intervals in laboratories accredited by an accreditation bodies subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement.
Merilna negotovost Measurement Uncertainty	Pri rezultatih podana merilna negotovost pomeni razširjeno merilno negotovost, ki je izražena kot standardna merilna negotovost pomnožena s faktorjem pokritja k, ki ustreza intervalu zaupanja približno 95 %. Standardna merilna negotovost je določena skladno z dokumentom EA-4/02. The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k that corresponds to a coverage probability of approximately 95 %. The standard uncertainty has been determined in accordance with the publication EA-4/02.
Izjave Declarations	Dovoljeno je razmnoževanje celotnega certifikata. Razmnoževanje posameznih delov je dovoljeno samo s pisno odobritvijo laboratorija. Z izdajo certifikata BELMET MI in SA ne prevzemata odgovornosti za posledice uporabe merilnega instrumenta, za katerega je certifikat izdan. Podani rezultati se nanašajo zgolj na opisani merilni instrument v času kalibracije in ne vsebujejo napovedi o njegovi časovni stabilnosti. Reproduction of the complete certificate is allowed. Parts of the certificate may only be reproduced with written approval of the laboratory. The certificate was issued provided that BELMET MI and SA does not assume any liability for consequence of use of stated measuring instrument. Handed results refers only to described measuring instrument in time of calibration and do not contain any time stability predictions.

Odobril Approved by	Vodja Laboratorija za kalibracije Head of Calibration Laboratory Janko Perovnik digitalno podpisano/digitally signed	Datum izdaje Date of issue 04.10.2023
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CERTIFIKAT O KALIBRACIJI CALIBRATION CERTIFICATE

Oznaka
Number 2023D67-1

OPIS OZNAK/LEGEND

ETALON ... etalon/etalon

POGREŠEK ... pogrešek/error

ZVIŠEVANJE ... zviševanje/increasing

ZNIŽEVANJE ... zniževanje/decreasing

SRED_VRED ... srednja vrednost/mean value

MER_INST ... merilni instrument/measuring instrument

MER_NEG ... merilna negotovost/measuring uncertainty

PONOVLJ ... ponovljivost/repeatability

HISTEREZA ... histereza/hysteresis

POGOJI IN REZULTATI/CONDITIONS AND RESULTS

Meritve so bile izvedene v diskretnih kalibracijskih stanjih, rezultati na certifikatu veljajo samo za ta stanja/Measurements were carried out in discreet calibrations states, results on certificate apply to these states only.

Delovni medij pri kalibraciji je bil dušik/Working medium was nitrogen.

Kalibracija je bila izvedena pri horizontalni postavitvi merilnega instrumenta (priključki za tlak so bili spredaj)/Calibration was done in horizontal position of measuring instrument (pressure connections were front).

Referenčna višina merilnika je bila privzeta pri tlačnem priključku/The reference height was taken at the pressure connector.

Pred kalibracijo je bilo kazanje merilnega instrumenta nastavljeno na nič/Before the calibration, the indication of the measuring instrument was set to zero.

ETALON		MER_INST				POGREŠEK	PONOVLJ	HISTEREZA	MER_NEG
		ZVIŠEVANJE	ZNIŽEVANJE	ZVIŠEVANJE	ZVIŠEVANJE	SRED_VRED			
Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa
0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	2,0
10,0	10,0	10,0	/	/	10,0	0,0	0,0	0,0	2,0
20,0	20,0	20,0	20,0	20,0	20,0	0,0	0,0	0,0	2,0
30,0	30,0	30,1	/	/	30,1	0,1	0,1	0,1	2,0
40,0	40,0	40,1	/	/	40,1	0,1	0,1	0,1	2,0
50,0	50,1	50,1	50,1	50,0	50,1	0,1	0,1	0,0	2,0
60,0	60,0	60,1	/	/	60,1	0,1	0,1	0,1	2,0
70,0	70,0	70,1	/	/	70,1	0,1	0,1	0,1	2,0
80,0	80,1	80,1	80,0	80,1	80,1	0,1	0,1	0,0	2,0
90,0	90,0	90,1	/	/	90,1	0,1	0,1	0,1	2,0
100,0	100,0	100,0	/	/	100,0	0,0	0,1	0,0	2,0
2500,0	2502,4	2502,6	2502,3	2502,5	2502,5	2,5	0,2	0,2	5,0
5000,0	5000,7	5001,4	/	/	5001,1	1,1	0,2	0,7	8,3
10000,0	9949,7	9949,8	/	/	9949,8	-50,2	0,2	0,1	8,7

CERTIFIKAT O KALIBRACIJI
CALIBRATION CERTIFICATEOznaka
Number 2023D67-2

NAROČNIK CUSTOMER	ISKRA PIO, D.O.O. TRUBARJEVA CESTA 5, SI-8310 ŠENTJERNEJ
NAZIV/OBJECT	DIGITALNI MERILNIK; SENZOR TEMPERATURE IN RELATIVNE VLAŽNOSTI
Izdelovalec/Manufacturer	TESTO, NEMČIJA
Tip/Type	TESTO 480; 0636 9743
Izdel. ozn./Ser. No.	61364769; 61256768
Dod. ozn./Additional No.	/
Datum prejema in stanje Date and status on receipt	03.10.2023, brez posebnosti/without speciality.
Kalibracijska metoda Calibration Method	D-4171. Kalibracija po internem kalibracijskem postopku/Calibration according to internal calibration procedure "Kalibracije merilnikov temperature", skladno z/in accordance with ITS-90. D-3961. Kalibracija po internem kalibracijskem postopku/Calibration according to internal calibration procedure "Kalibracije merilnikov vlažnosti".
Pogoji okolja Ambient Conditions	Temperatura/Temperature (22 ± 3) °C, relativna vlažnost/relative humidity (50 ± 25) %.
Čas in mesto izvedbe Date, place of calibration	03.10.2023 do/to 04.10.2023 v/in BELMET MI d.o.o., Ljubljana.
Sledljivost Traceability	Pri meritvah so bili uporabljeni etaloni, ki so v rednih rekalibracijskih intervalih kalibrirani v laboratorijih, ki so jih akreditirali akreditacijski organi v okviru dogovora Mednarodnega združenja za akreditacijo laboratorijev (ILAC). In the measurements, the standards were used, which were calibrated at regular recalibration intervals in laboratories accredited by an accreditation bodies subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement.
Merilna negotovost Measurement Uncertainty	Pri rezultatih podana merilna negotovost pomeni razširjeno merilno negotovost, ki je izražena kot standardna merilna negotovost pomnožena s faktorjem pokritja k, ki ustreza intervalu zaupanja približno 95 %. Standardna merilna negotovost je določena skladno z dokumentom EA-4/02. The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k that corresponds to a coverage probability of approximately 95 %. The standard uncertainty has been determined in accordance with the publication EA-4/02.
Izjave Declarations	Dovoljeno je razmnoževanje celotnega certifikata. Razmnoževanje posameznih delov je dovoljeno samo s pisno odobritvijo laboratorija. Z izdajo certifikata BELMET MI in SA ne prevzemata odgovornosti za posledice uporabe merilnega instrumenta, za katerega je certifikat izdan. Podani rezultati se nanašajo zgolj na opisani merilni instrument v času kalibracije in ne vsebujejo napovedi o njegovi časovni stabilnosti. Reproduction of the complete certificate is allowed. Parts of the certificate may only be reproduced with written approval of the laboratory. The certificate was issued provided that BELMET MI and SA does not assume any liability for consequence of use of stated measuring instrument. Handed results refers only to described measuring instrument in time of calibration and do not contain any time stability predictions.
Odobril Approved by	Vodja Laboratorija za kalibracije Head of Calibration Laboratory Janko Perovnik digitalno podpisano/digitally signed
	Datum izdaje Date of issue 04.10.2023

CERTIFIKAT O KALIBRACIJI CALIBRATION CERTIFICATE

Oznaka
Number 2023D67-2

OPIS OZNAK/LEGEND

ETALON ... etalon/etalon

POGREŠEK ... pogrešek/error

MER_INST ... merilni instrument/measuring instrument

MER_NEG ... merilna negotovost/measuring uncertainty

POGOJI IN REZULTATI/CONDITIONS AND RESULTS

Meritve so bile izvedene v diskretnih kalibracijskih stanjih, rezultati na certifikatu veljajo samo za ta stanja/Measurements were carried out in discreet calibrations states, results on certificate apply to these states only.

Globina potopitve senzorja: v celoti/Immersion depth of the sensor: fully.

Meritve relativne vlažnosti so bile izvedene pri temperaturi/The relative humidity was measured at temperature $(25 \pm 0,5) ^\circ\text{C}$.

ETALON	MER_INST	POGREŠEK	MER_NEG
$^\circ\text{C}$	$^\circ\text{C}$	$^\circ\text{C}$	$^\circ\text{C}$
0,03	0,2	0,17	0,18
24,89	25,0	0,11	0,18
40,08	40,1	0,02	0,18

ETALON	MER_INST	POGREŠEK	MER_NEG
%	%	%	%
11,3	11,4	0,1	1,0
39,9	40,9	1,0	1,2
75,3	76,2	0,9	1,6