TEST REPORT

HALO P in situ

Tests conducted by ERLAB at a

Dental Clinic in à Saint Aubin lès Elbeuf, Normandy

Dr Mélanie Thomas-Roger

14 and 15 september, 2021

Tests conducted by :

Alex BEAL
HALO Business Development

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1 CONTEXT

Due to the ongoing COVID-19 pandemic, dental surgeons have expressed concern about the air quality in their clinics. Questions were posed by practitioners concerning the risk of virus transmission during treatments, as well as the prevention measures that might reduce the risks. This led them to contact ERLAB and request the installation of one Halo P air purifier in a typical clinic to measure its impact on particle content.

1.1 Presentation of Halo P

ERLAB specialises in air treatment solutions for chemical laboratories. Since 2015, ERLAB has manufactured and distributed Halo, an air purifier. More recently, ERLAB has launched Halo P, an air purification solution for both biological and non-biological particles. Halo P contains a HEPA H14 filter with a minimum efficiency of 99.995% according to MPPS (approximately 0.1 µm), as stated in standard EN 1822. Halo P filters the air in a given room, reducing particle concentration.

1.2 Test Environment : Typical Clinic

The surface area of a dental clinic generally spans between 20 and 25 m². The room contains a door, windows, a sink unit, a dental chair, and a desk. Halo P was installed on the ceiling. The volume of the room in which Halo P is operating should not exceed 75 m^3 (the maximum recommended value). As far as possible, Halo P was positioned at the centre of the room, above the area to be protected. Their air vents faced the room's widest point.

Measurement of the ambient particle concentration was taken with the prior agreement of the dental practitioner. A sampling point was chosen in the most central position possible, considering equipment already in the room equipment and the accessibility of the patient by nursing staff (see Figure 1).

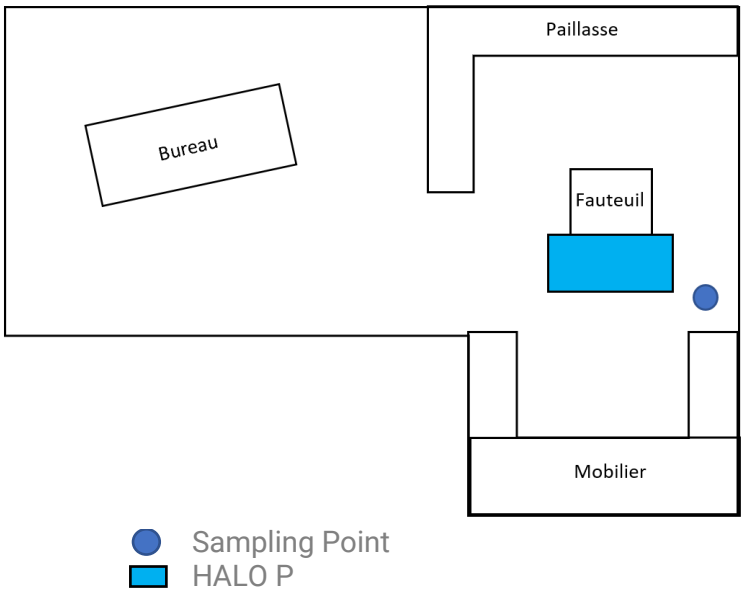


Figure 1 : Representative Diagram of Test Room

1.3 Pollution Monitoring

The concentration of particles of ≥0.5 µm was measured as close as possible to the emission area at a height of 120 cm. This is representative of the height of the patient's airways.

2 TESTING PROCESS

Tests were carried out on one representative day of dental care. Real constraints were respected and efforts were made to limit disturbance to medical staff and patients. The door and windows of the clinic remained closed for the duration of the tests.

2.1 Test Phases

Testing took place over two days in different configurations described in Table 1.

Date	Clinic Occupancy	State of HALO P
Tuesday14/09		
17 :45 – 17 :55	Installation of measuring equipment and calibration of Halo P settings	
17 :55 – 00 :00	Measurements of empty clinic	Halo P switched off
Wednesday 15/09		
00 :00 – 9 :35	Measurements of empty clinic	Halo P switched off
9 :35 – 12 :25	Measurements with patient	Halo P switched off
12 :25 – 14 :20	Measurements with patient	Halo P switched on
14 :20 – 17 :50	Measurements with patient	Halo P switched on

Table 1 : Description of different test phases

2.2 HALO P Settings

With the agreement of the practitioner, the workflow of Halo P was reduced to ensure comfort in the dental clinic (250 m^3/h instead of 300 m^3/h). For this reason, the Halo P fan was set to day/night mode, running at 1,700 rpm from 12:30 to 18:00. For measurements taken without Halo P, the rpm was 0 during the night and morning. Halo P was equipped with both a prefilter and HEPA H14 filter.

2.3 Materials Used

The particle concentration was measured using a portable KANOMAX optical particle counter (model 3889). This allowed for particle measurement on six channels: 0.3, 0.5, 1.0, 3.0, 5.0 and 10.0 µm. Calibrated on 14/05/2021 (certificate n° 38892105003).

2.4 Sampling Pattern

The measurement point, to the right of the dentist's chair, was chosen to avoid disturbing the patient and dental staff (see Figure 1).

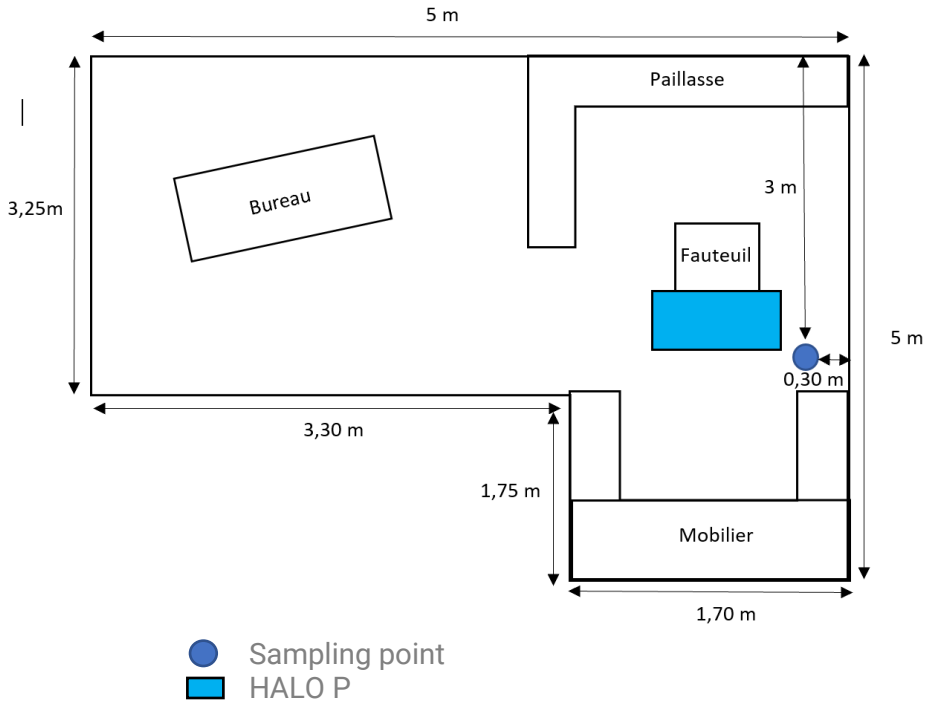


Figure 1 : Placement of sampling point

3 RESULTS

As a reminder, Table 2 shows the different classification of air cleanliness by particle concentration according to ISO 14644-1.

Particles per metre cubed (maximum admissible concentrations of particles of a size equal or superior to those specified below)	
Classe	**0,5 µm**
ISO 1	d
ISO 2	d
ISO 3	35
ISO 4	352
ISO 5	3 520
ISO 6	35 200
ISO 7	352 000
ISO 8	3 520 000
ISO 9	35 200 000

d : Both the sampling and statistical limits of such low concentrations make them unsuitable for classification.

Table 2 : Classification of air cleanliness by particle concentration according to ISO standard 14644-1

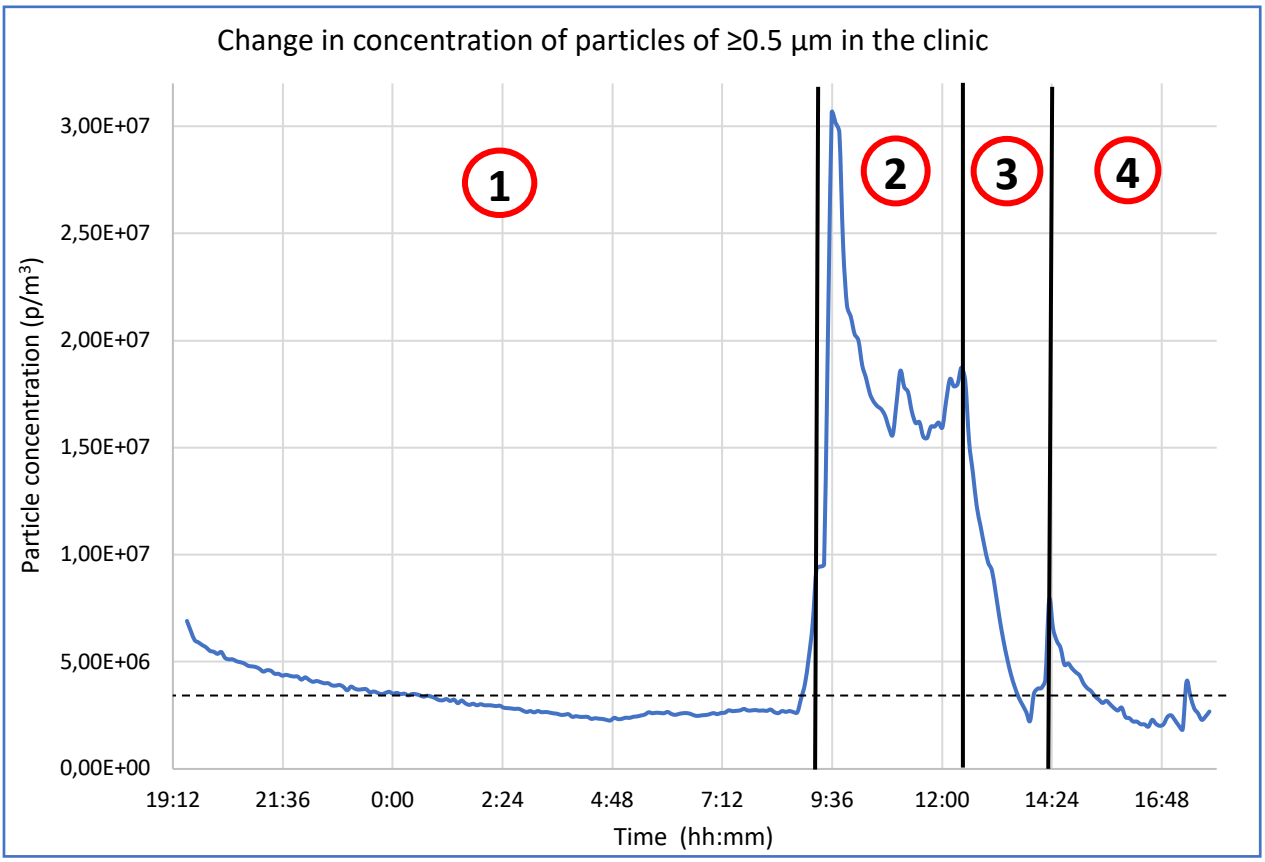
3.1 Sampling Implementation

The door to the clinic remained closed throughout the duration of sampling, except when patients entered or exited.

For these tests, we have chosen to consider only particles of ≥0.5 µm. These are the particles that are least likely to settle. Instead they form an aerosol generated by respiration, speaking, coughing, spitting, sneezing and medical care, etc.

The volume of the room using for testing was 48 m^3, or five air changes per hour with the aforementioned settings.

3.2 Continuous Measurements



1	Measurements without patient and Halo P switched off
2	Measurements without patient and Halo P switched off
3	Measurements without patient and Halo P switched on
4	Measurements with patient and Halo P switched on
------	Threshold for change in particle classification (ISO 9 to ISO 8)

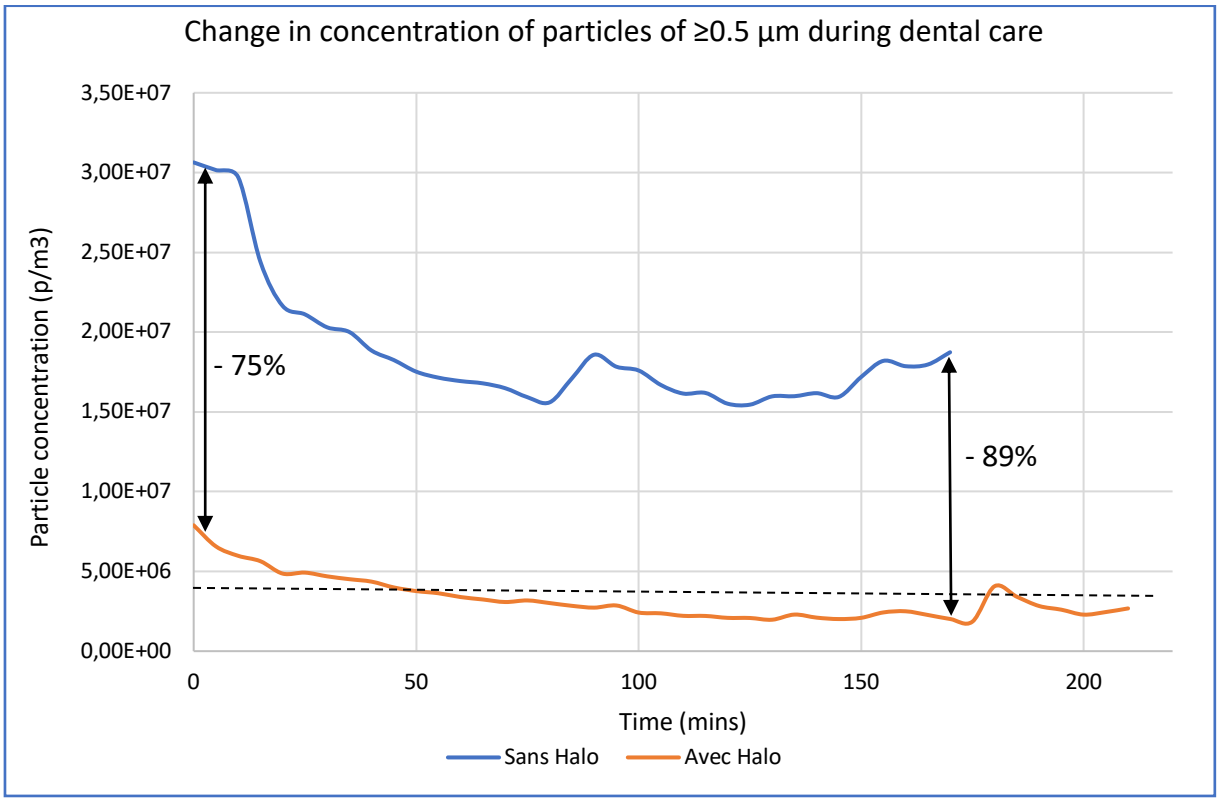
Please note: Halo P was turned off at 17:50, when measurements were taken. This explains the low particle concentration at the beginning of the first phase (measurements without patient and without Halo P).

From power-up at 12:30, the effectiveness of Halo P is clear:

After 90 minutes, we observe a sharp decrease in the concentration of particles of ≥0.5 µm.

The same was observed for afternoon consultations. When Halo P was running, the concentration of particles of ≥0.5 µm was far lower than that of the morning consultations, when Halo P was not in operation.

3.3 Measurements During Consultations



------- : Threshold for change in particle classification (ISO 9 to ISO 8)

This graph compares levels of dust accumulation during dental care, both with and without HALO P.

Dental care was broadly the same over the two test periods, whether Halo P was switched on or not. The impact of Halo P was marked by a lower concentration of particles by up to 75% at the beginning of the period of dental care and up to 89% by the end.

In tests when Halo P was switched on, a lower concentration of particles was observed. This allowed for a transition between ISO Class 9 and ISO Class 8 according to ISO standard 14644-1 for particles smaller than ≥0.5 µm.

4 CONCLUSION

These tests show the improvements brought by Halo P on the particle concentration of a dental clinic.

For optimum safety levels, we recommend starting Halo P before patients arrive. At the beginning of care provision, the concentration of airborne particles of ≥0.5 µm increases dramatically. Throughout the duration of the tests, Halo P limited the rise in concentration of airborne particles of ≥0.5 µm by up to 89%. In this case, Halo P enables air cleanliness to reach classification ISO 8 by particle concentration. For comparison, this level of particulate cleanliness is that of post-operation rooms, sterile medical storage facilities and the corridors of operating theatres.

5 APPENDICES

5.1 Particle Counter Calibration Certificate

CALIBRATION
DUE DATE

JUL 07 2022

KANOMAX

Test Sheet

Kanomax USA Inc
219 US Hwy 206, Andover NJ 07821
973-786-6386

Product Name Handheld Particle Counter
Model Name 3889
Serial Number 850770
Test Date 2021/05/14
Temperature/Humidity 23.6 ℃ / 45.0 %RH
Atmospheric Pressure 1007.0 hPa

Item	Procedure/Standard	Result	Judgement
Sampling air flow rate	The flow rate shall be within 2.83 L/min±5%	2.89 L/min	OK
False count level	The count value measured for 5 minutes should be 1 or less when zero filter is put onto LPC inlet.	0 COUNTS	OK
Computer Threshold voltage	The PSL standard particle threshold voltage for each particle size is 10V or less, and also there is a signal waveform distribution.	$V_{0.3}$ = 0.855 V $V_{0.5}$ = 0.460 V $V_{1.0}$ = 1.211 V $V_{3.0}$ = 3.545 V $V_{5.0}$ = 5.781 V $V_{10.0}$ = 7.806 V	OK
Counting efficiency	For the 0.3μm PSL standard and 0.5μm PSL standard, the particle counts in the 0.3μm range of the instrument to be calibrated should be within 50±20% and within 100±10% of the standard unit.	0.3μmPSL 42.8 % 0.5μmPSL 97.7 %	OK
Particle resolution	In the 0.3μm PSL standard particles, its value should be below 15% .	7.4 %	OK

	Particle resolution(μm)	Particle size(μm)	Manufacturer	Type
PSL standard	0.30	0.303	Thermo	3300A
	0.50	0.496	Thermo	3495A
	1.00	0.994	Thermo	4009A
	3.00	3.007	Thermo	4203A
	5.00	5.049	Thermo	4205A
	10.0	10.02	Thermo	4210A

The procedures and the standards in the above are compliant with ISO 21501-4:2007 and JIS B 9921:2010.

Approved by

Tested by

KANOMAX INSTRUMENT (SHENYANG) INC.
No.9 Zhengkun Road Shenbei new district Shenyang city Liaoning China
TEL +86 (024) 89730178

KANOMAX

Certificate of Calibration

Handheld Particle Counter

Issue Date: 2021/05/14

Model Name	3889
Serial Number	850770
Calibration Date	2021/05/14
CERT No.	38892105003

This is to certify that above instrument was calibrated to following standard units on our operation standard. This calibration complies with ISO 21501-4. The standard units used for the calibration are traced to the national standard regularly based on our traceability chart.

Standards Used:

Particles

Manufacturer	*Particle Size*	*Standard Deviation*	*Lot No.*	*Expiration Date*
Thermo	0.303 µm	0.003 µm	223077	2023.04
Thermo	0.496 µm	0.004 µm	231219	2023.09
Thermo	0.994 µm	0.006 µm	234756	2023.12
Thermo	3.007 µm	0.007 µm	226956	2023.06
Thermo	5.049 µm	0.049 µm	235600	2024.01
Thermo	10.02 µm	0.020 µm	233796	2023.12

Flowmeter

Type	*Manufacturer*	*Serial Number*	*Calibration Date*	*Calibration Due*
Gilibrator2	SENSIDYNE	0801038/1804060-S	2020.06	2021.06

Reference Unit

Type	*Manufacturer*	*Serial Number*	*Calibration Date*	*Calibration Due*
CR LPC3782-06	Kanomax Japan Inc	No.003	2020.07	2021.07

KANOMAX INSTRUMENT (SHENYANG) INC.
The Quality Assurance Div.

Certified by:

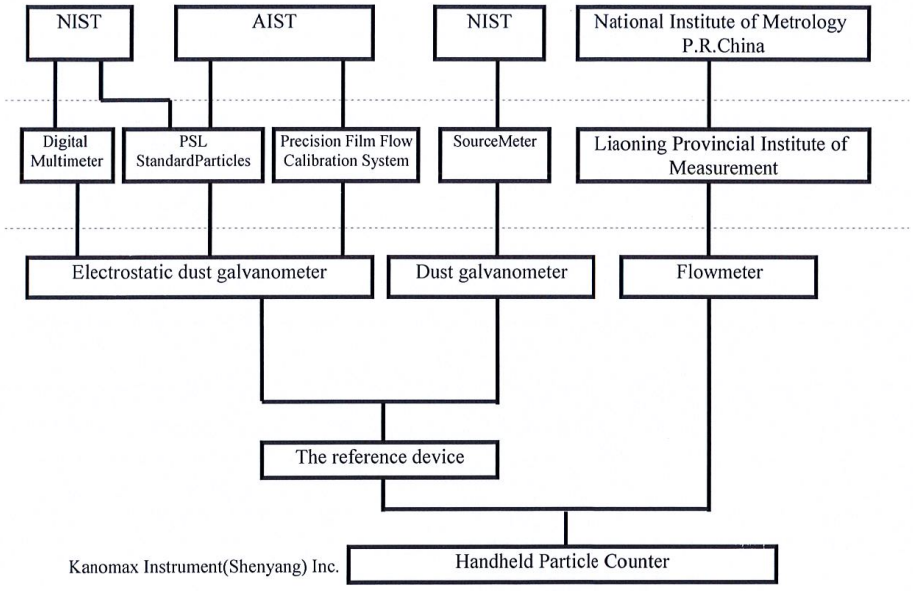
TRACEABILITY CERTIFICATE

KANOMAX INSTRUMENT (SHENYANG) INC.
No.9 Zhengkun Road Shenbei new district Shenyang 110136 Liaoning China

Product Name	Handheld Particle Counter
Model Name	3889
Serial Number	850770
Test Date	2021/05/14

It prove that the product above is calibrated according to our company production standards. And the standards are based on ISO21501-4. The standard units used for the calibration are traced to the national standard regularly based on our traceability chart.

1. Traceable using Kanomax Calibrating system



2. Standard Component

Product Name	Model	Serial Number	Calibrate By	Test Sheet No.
Electrostatic dust galvanometer	3071	82	Kanomax Japan Inc	A026-20210317
Dust galvanometer	3068	65	Kanomax Japan Inc	A025-20210318
Flowmeter	Gilibrator2	0801038/1804060-S	Liaoning Provincial Institute of Measurement.	20020403935
The reference device	CR LPC3782-06	No.003	Kanomax Japan Inc	003-20200731