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Melaphone Cleanroom Tests - November 2015

Summary

Cleanroom usage tests were carried out on Small (244 mm diameter) and Large (318 mm diameter) Melaphone Audio Visual devices.

Units were mounted into a purpose built sealed test rig. The test rig was circulated with ISO 14644-1 clean air filtered to an ISO 5 level (equivalent to EU CGMP Class A/B).

The test rig was pressure tested up to positive level of +350 Pa (n/m²) and negative level of -250 Pa (n/m²) at rest and operational, with no pressure leakage evident.

Particle levels were monitored at positive and negative pressures, at rest and operational with no particle level increase.

Smoke challenges were carried out at positive and negative pressures at rest and operational which detected no air movement or leakage.

Conclusion

These devices are deemed suitable for use as an audio visual aid in cleanrooms walls or windows up to ISO 14644-1 ISO 5 level as they maintain a high positive and negative pressure barrier and do not increase or generate particle at rest and in operation.

Signed,

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Validation Test Report on Melaphone Visual Audio device for application in cleanrooms and controlled environments

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Introduction

Testing two Melaphone devices 244 and 318mm devices in a test rigs to identify suitability of the devices in cleanrooms and controlled environments.

Test requirements

To identify any leakages at different pressures from the Melaphone and contamination egress in the at rest state and during Melaphone operation.

Tests under normal and extreme pressures as a risk factor to identify the limitation of the device.

HEPA Services Ltd

The tests carried out by N A Herriott HEPA Services Validation Engineer with greater than 30 years' experience in Validation Cleanrooms, Controlled environments and Isolators.

Equipment

Test chamber with 244 and 318 mm Melaphone in separate chambers, Test chamber having double HEPA Filters in the Supply test ports, sample port for chamber pressure and two outlet ports for balancing the chamber and sampling particle contamination.

Particle counter, Micro-manometer and smoke tubes for visualisation together with video camera to record the tests.

Pressure / Vacuum pump used to pressurise the chamber for negative and positive tests

Micro-manometer and Particle counter calibrated to national standards.

Drager Smoke tubes

Test

Tests carried out over two separate days (16 and 20th October 2015) the Melaphone and chamber was checked for gasket compression with low to medium tension on the fixing screws.

The Chambers were purged to remove contamination from the chambers with positive pressure and HEPA filters connected.

The Area used for the test is not a controlled environment just a clean space.

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Test	Video	Unit	Status	Conclusion
1	0001	Large 318mm	+ 250 Pa ISO 5 level count	No increase in contamination levels during at rest and operational status
2	0003	Large 318mm	+ 50 Pa ISO 5 level count	No increase in contamination levels during at rest and operational status
3	0004	Large 318mm	+ 15 Pa smoke challenge	No leakages evident
4	0005	Large 318mm	+ 247 Pa smoke challenge	No leakages evident
5	0006	Large 318mm	-203 Pa smoke challenge	No leakages evident
6	0007	Large 318mm	+ 350 Pa ISO 5 level count	No increase in contamination levels during at rest and operational status
7	0008	Small 244mm	+ 50 Pa ISO 5 level count	No increase in contamination levels during at rest and operational status
8	0009	Small 244mm	+ 250 Pa smoke challenge	No leakages evident
9	0010	Small 244mm	+ 66 Pa smoke challenge	No leakages evident
10	0011	Small 244mm	-257 Pa smoke challenge	No leakages evident

Conclusion

Particle contamination test on both units found no increase in particulate levels (ISO 14644-1 5 levels) during at rest and operational tests at normal and high pressure status in the chamber making the device suitable to be used in a cleanroom environment.

Leakage from the Melaphone device was not evident in normal, high positive and negative pressure status making it suitable for a contamination barrier.

N A Herriott

HEPA Services Validation Engineer



22 Oct 2021



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Video identification and description attached to this report

Reference	Unit	Test	Status
0001	Large 318mm	Counts at rest and operational high positive pressure	+250Pa Pressure and counts at ISO 5 levels and no increase in particle contamination during noise activation
0003	Large 318mm	Counts at rest and operational normal positive pressure	+50Pa Pressure and counts at ISO 5 levels and no increase in particle contamination during noise activation
0004	Large 318mm	Smoke leak test normal Positive pressure	+15Pa Pressure and No leakages identified during test
0005	Large 318mm	Smoke leak test High Positive pressure	+247Pa Pressure and No leakages identified during test
0006	Large 318mm	Smoke leak test high negative pressure	-203Pa Pressure and No leakages identified during test
0007	Small 244mm	Counts at rest and operational high positive pressure	+350Pa Pressure and counts at ISO 5 levels and no increase in particle contamination during noise activation
0008	Small 244mm	Counts at rest and operational normal positive pressure	+50Pa Pressure and counts at ISO 5 levels and no increase in particle contamination during noise activation
0009	Small 244mm	Smoke leak test High Positive pressure	+250Pa Pressure and No leakages identified during test
0010	Small 244mm	Smoke leak test normal Positive pressure	+66Pa Pressure and No leakages identified during test
0011	Small 244mm	Smoke leak test high negative pressure	-257Pa Pressure and No leakages identified during test