OCTO PurePlace Car Certification

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The PurePlace system is designed to maintain an healthy context inside the controlled environment (either the car passenger compartment or the house / office environment), reducing the presence of harmful bacteria and viruses, after a proper application cycle, up to the better standards as per the EU practices for the sterile environments. In particular, the minimum time of operation to reach a Class B environmental context (as per the EU standard mentioned before), inside a small / medium size sedan passenger compartment and without injection of new viral/bacterial colonies, is of 60 minutes. However, please be well advised that, notwithstanding the system efficiency and efficacy in containing and controlling the spread of bacteria and viruses, it cannot replace adopting all the necessary measures to prevent a contagion event. Therefore, with this regard, any kind of warranty and/or representation cannot be, and is not, provided by Octo. The active and efficient adoption of such necessary measures remains within the control of the customer.

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Date: 11/02/2021

OCTO PurePlace Car

Declaration of conformity

Declarant: OCTO Telematic SpA, Via Vincenzo Lamaro 51 – 00173 Roma RM
Name of the authorized representative: Nicola Veratelli

Declares:

OCTO hereby confirms that the telematics device is duly certified according to the applicable CE - RoHS standards. As far as the sanitization function is concerned, Octo confirms that voluntary tests conducted by an independent laboratory have demonstrated that a proper utilization of the system allows granting at least a “grade B” as per “EU Guidelines to Good Manufacturing Practice for Medicinal Product for Human and Veterinary Use”, corresponding to a pre-aseptic ambient.

Date: 03/02/2021

Nicola Veratelli
OCTO Group CEO

Document Version: OCTO PurePlace V2

Date: 03/02/2021

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PurePlace Car Device Certifications

Octo PurePlace Car device sold by Octo Telematics has been tested by certified laboratories to meet the following performance requirements:

- Ozone Emissions: The device was tested, investigated and found to meet the standard specifications of UL Electrostatic Air Cleaners, UL 867, Section 40, Fifth Edition, August 4, 2011 revision: August 7, 2018 and CSA 22-2 No.187-15, Section 7, February 2015, April 2016 Revision. The device was tested and demonstrated to meet the criteria for emittance of ozone not exceeding a concentration of 0.050 ppm.

- Air Cleaning Effectiveness: The device was tested, investigated and found to meet ISO 14644-1/2 and VOC (Vapor phase volatile Organic Chemicals) requirements. The device passed testing for air particle cleaning with a test result of more than 99-9% reduction in PM2.5 (particle matter 2.5um) and less than 0.3mg/m3 of residue contents in VOCS (dicholormethane, dichloroethene, dichloropropene, ethylbenzene, toulene, xylene, dichlorobenzene, hexachlorobutadiene and chloroform) of the air extracted from the car after 15' of activity

- In-Air Bacteria Density Elimination Rate: Testing of the device established an elimination ratio of more than 99.9% after one (1) hour of activity in a 2.9 x 1.4 x 2m test chamber.

- Passenger Compartment Bacteria Load Reduction Rate: The voluntary device testing cycle ordered by Octo established that in a small/medium size automobile, the bacterial load is progressively reduced to a bacteria colonies ≤5 cfu (Colony Forming Units) after 60 minutes of sanitation for all the sampling points indicating at least a B level under the rules governing medicinal products in the European Union - EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use - Annex 1 Manufacture of Sterile Medicinal Products.

- Safety: The device was tested, investigated and found to safe as the device remained cool to the touch during operation and eco-friendly as no toxic chemicals are generated or released during operation.

- Noise Level: The device was tested, investigated and found to produce less than 25 decibels (dB) constituting an acceptable level for human use.

- Maintenance Free: The device was visually inspected and found to be maintenance free as no cleaning, service or maintenance is required of the filterless technology.

In addition to the above referenced testing, Octo, having noted that the international standards are not fully mature yet to qualify these advanced purifying technologies (the available standards rather refer to chemical and ozone-based methodologies, without a specific reference to operations inside a vehicle passenger compartment), and aiming to reassure its customers on the effectiveness and safeness of the Octo solutions, has ordered a voluntary testing cycle with the guidance of the academic chemistry experts.

Starting from tests already performed on the system core (the purifier PCO-enhanced cell) by recognized international laboratories, namely Ganesh Scientific Research Foundation, which confirmed the system's performances, Octo, in cooperation with scientists from the Tor Vergata University of Rome, has developed a specific test protocol, representative of the actual on-field utilization of PurePlace. The protocol is based on monitoring the microorganisms' growth in a controlled space and how it is stopped by the exposure to the system as operated in a real-world, passenger compartment environment. The bacteria colonies, sampled in multiple points and surfaces of the passenger compartment, are collected and exactly measured, at specific time intervals, demonstrating the purifying action. The results obtained, together with the exact protocol adopted, are duly reported in the documentation attached.

When the worldwide boundary conditions will allow for specific COVID-19 tests, an appropriate testing cycle could be designed and scheduled. Currently, this is not viable in a real-world context, like the one targeted by Octo.

At the same time, the evolution of the international standards will progressively address these technologies and this shall create conditions to move from voluntary on-field tests to standardized certification procedures.

What included in the attached documents is the result of tests voluntary conducted by Octo therefore Octo does not guarantee, represent or warrant that the use of a photocatalytic oxidation purifier will prevent a vehicle's occupant(s) from contracting any type of bacteria or virus based illness, including, but not limited to, the common cold, coronavirus or influenza.

Client:

Octo Telematics SpA
Via Lamaro, 51
00173 Rome, Italy

Test Certificate

Date: November 22th, 2020
Project number: 2020/18
PO number: 18-OCTO2020
Testing date: October 2020

Project / Test description	Verification of the effectiveness and efficiency of the Octo Telematics PurePlace car system in sanitation of air inside a car passenger compartment.
Test sample identification	PurePlace Car assembly S/N 000856
Test equipment / Test procedure	Test performed on board of a small / medium size car, according to the test procedure attached (annex A), using Petri dishes for environment characterization and samples collection in different testing points, and subsequent bacterial growth monitoring after 48 hours incubation.
Test results	Applying the system for the specified time (after 30 and 60 minutes respectively), the bacterial load is progressively reduced to a bacteria colonies average ≤5 cfu after 60 minutes of sanitation for all the sampling points. These results indicate at least a grade B level in the **European Union Good manufacturing Practice** scale, meaning a pre-aseptic ambient. The grade A indicates aseptic condition (annex A)

Released by:

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Annex A

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Premises

The sanification core chamber of Octo PurePlace Car device (a PCO enhanced cell, composed by a PCO catalytic cell and a Cold Plasma generator cell) had been previously tested by Certified International Laboratories (namely Ganesh Scientific Research Foundation, Intertek) to meet the following performance requirements:

- Ozone Emissions: the sanification core chamber was tested, investigated and found to meet the standard specifications of UL Electrostatic Air Cleaners, UL 867, Section 40, Fifth Edition, August 4, 2011 revision: August 7, 2018 and CSA 22-2 No.187-15, Section 7, February 2015, April 2016 Revision. The device was tested and demonstrated to meet the criteria for emittance of ozone not exceeding a concentration of 0.050 ppm.
- Air Cleaning Effectiveness: the sanification core chamber was tested, investigated and found to meet ISO 14644-1/2 and VOC (Vapour phase Volatile Organic Compounds) requirements. The device passed testing for air particle cleaning with a test result of more than 99-9% reduction in PM2.5 (particle matter 2.5um) and less than 0.3mg/m3 of residue contents in VOCS (dicholormethane, dichloroethene, dichloropropene, ethylbenzene, toulene, xylene, dichlorobenzene, hexachlorobutadiene and chloroform) of the air extracted from the car after 15' of activity
- Safety: The sanification core chamber was tested and found eco-friendly, as no toxic chemicals are generated or released during operation.
- Noise Level: The sanification core chamber was tested, investigated and found to produce less than 25 decibels (dB) constituting an acceptable level for human use (noise originating from the air circulation fan)

- Maintenance Free: The sanification core chamber was found to be maintenance free, as no cleaning, service or maintenance is required, thanks to the filterless technology adopted

In addition to the above referenced testing, Octo, having noted that the international standards are not fully mature yet to qualify these advanced purifying technologies (the available standards rather refer to chemical and ozone-based methodologies, without a specific reference to operations inside a vehicle passenger compartment), and aiming to reassure its customers on the effectiveness and safeness of the Octo solutions, has commissioned a voluntary testing cycle with the guidance of the academic chemistry experts.

Starting from tests already performed (see before), Octo, in cooperation with scientists from the Tor Vergata University of Rome, has developed a specific test protocol, representative of the actual on-field utilization of PurePlace. The protocol is based on monitoring the microorganisms' growth in a controlled space and how it is stopped by the exposure to the system as operated in a real-world, passenger compartment environment. The bacteria colonies, sampled in multiple points and surfaces of the passenger compartment, are collected and exactly measured, at specific time intervals, demonstrating the purifying action. Details about the protocol adopted and the results obtained are reported hereafter.

As soon as the worldwide boundary conditions will allow for specific COVID-19 tests, an appropriate testing cycle will be designed and scheduled. Currently, this is not viable in a real-world context, like the one targeted by Octo.

At the same time, the evolution of the international standards will progressively address these technologies, allowing Octo to move as soon as possible from voluntary on-field tests to standardized certification procedures.

Octo voluntary tests and protocol

The first testing cycle has been designed around the **measurement of the residual bacterial load**, within the air space inside, and over the surfaces of, the passenger compartment of a small / medium size car, after the application of the system for a given amount of time. All in all, the test has been structured in a way of being representative of the actual use cases for the final customers, both on-trip[1] and off-trip. The execution of tests in the frame of a bacterial environment is justified by the following considerations.

Virus are small protein and lipids particles assembles, ranging from 20 to 300 nm in size. Even if they are considered as microorganism, from a scientific point of view, they are not alive at all, because their inability to duplicate from their own. Virus, indeed, needs an organism with a cell cycle and metabolic pathway to duplicate its genetic material. Furthermore, you can distinguish from DNA or RNA virus, and viruses with an enveloped or naked capsid. Depending on their genetic material you can have different way of infections, while the resistance to chemical-physical agents is a function of the capsid structure. For example, viruses with enveloped capsid are more resistant to UV-light than naked one. However, oxidant treatments, as hypochlorite, ozone, and titanium-dioxide photocatalytic reaction, have demonstrated a flat and strong disinfection property. They can easily destroy whatever they are in contact with.

Bacteria, on the other hand, are microorganism with a cell cycle and a metabolism. They have a birth, a growing period during which they replicate, and a death. Bacteria cell structure is quite complex. They can be distinguished in Gram Positive or Negative, according to their cell wall structure. Namely, Gram Positive bacteria have a complex cell wall structure, composed by different layers of peptides, proteins and lipids, preserving the inner cell membrane from external agents, such as hypochlorite or radical oxygen species (ROS). Gram Negative, instead, are simpler, having only a tiny cell wall.

(1) It's worth remembering that PurePlace, due to its own intrinsic innocuity, can be operated, without any time limitation, also on-trip, with the vehicle populated by passengers

It's understood and documented that chemical or physical agents, which have effects on Gram Positive bacteria, can also break up viruses. In conclusion, **sanitizing methods, which are able to destroy bacteria, are likely more active in destroying virus**.

Despite the mentioned overall context of lack of standardization for these kind of in-vehicle sanitizing systems, there are certain norms, namely the EU Guidelines to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use[2], that, identifying the sterile and pre-sterile environmental characteristics of the production sites, represent an optimal reference and benchmark for characterizing the passenger compartment space as well (being evidently more stringent, in relation to our use case). Namely, this Guidelines identifies four possible environments, as follows:

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2008_11_25_gmp-an1_en.pdf

19. Recommended limits for microbiological monitoring of clean areas during operation:

	Recommended limits for microbial contamination (a)			
Grade	air sample cfu/m^3	settle plates (diameter 90 mm) cfu/4 hours (b)	contact plates (diameter 55 mm) cfu/plate	glove print 5 fingers cfu/glove
A	< 1	< 1	< 1	< 1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

Notes
(a) These are average values.
(b) Individual settle plates may be exposed for less than 4 hours.

In the light of these guidelines, OCTO decided to refer to them and more specifically to the Microbal Conamination In order to assess the effectiveness of the PurePlace device.

(2) https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2008_11_25_gmp-an1_en.pdf

Sampling criteria

Counting credits is currently the only effective method and the most important parameter for quantifying microorganisms in the air. It can be implemented with active or passive air sampling.

The passive method measures the quantity of microorganisms (bacteria and fungi) that are deposited on a surface consisting of 9 cm diameter Petri dishes containing a solid culture medium (Triptic Soy Agar, Liofilchem®) as per UNI EN ISO 14698- 1: 2004. The plates are left open exposed to the air for a known interval of time away from walls or obstacles. The microorganisms, transported by the inert particles, are deposited on the surface of the plate (fall-out). Results are expressed in CFU (Colony Forming Units) / plate / time.

CFU is a parameter to quantify the bacteria in a sample. In particular it is the amount of bacteria colonies growth in a Petri plates after the set experiment. In general, the lower this amount is, the lower is the bacteria concentration. This number depends on the sampling methods. In a not sanitized place in normal conditions, the quantity is in a range between 20 and 100 CFU, collecting the bacteria in air using our protocol.

The passive method has been standardized according to the Index of Microbial Air contamination (IMA), applied in non-hospital environments, which guarantees comparable results at any time and in any place it is applied.

Test activity description

Purpose: A small-medium sized car was used to verify the effectiveness of sanitation inside the passenger compartment. The microbial load of the air is determined before and after sanitization using a passive sampling method

STUDY SETTING	MONITORED SURFACES	SAMPLING PERIOD	SAMPLING TIME	CONDITIONS
Small / medium sized car	Driver dashboard Passenger Dashboard Driver Mat Passenger Mat Rear seat SX Rear seat DX Middle rear Mat Rear central dashboard	T0 (pre-sanitation) T1 (post-sanitation)	30 min. & 1 h	Sanitation without air recycling Sanitation with air recycling

Protocol: The study was conducted in October. The sampling was carried out simultaneously in the following 8 points: Driver Dashboard, Passenger Dashboard, Driver Mat, Passenger Mat, Left Rear Seat, Right Rear Seat, Center Rear Mat, Trunk Floor.

The samples were carried out using plates with a diameter of 9 cm with non-selective nutrient medium (Triptic Soy Agar, Liofilchem®), suitable for the evaluation of the bacterial and fungal load according to the EN ISO 11133 standard. The plates were left open exposed to the air for 1h, thus collecting the airborne particulate with bacteria and fungi (fall-out).

For each test, the sampling was repeated:

- before sanitation (T0 - calibration)
- immediately after sanitation (T1)

At each T, the operator always entered the car from the driver's door and closed it immediately behind him, to minimize the exchange of air between the outside and inside of the passenger compartment.

The sanitation procedure was performed by connecting the appropriate device to the car's cigarette lighter socket, leaving the windows closed for

the entire duration of the tests. The air vents were left open, therefore in contact with the ventilation ducts, both by letting the air circulation off and by setting the air recirculation at minimum speed.

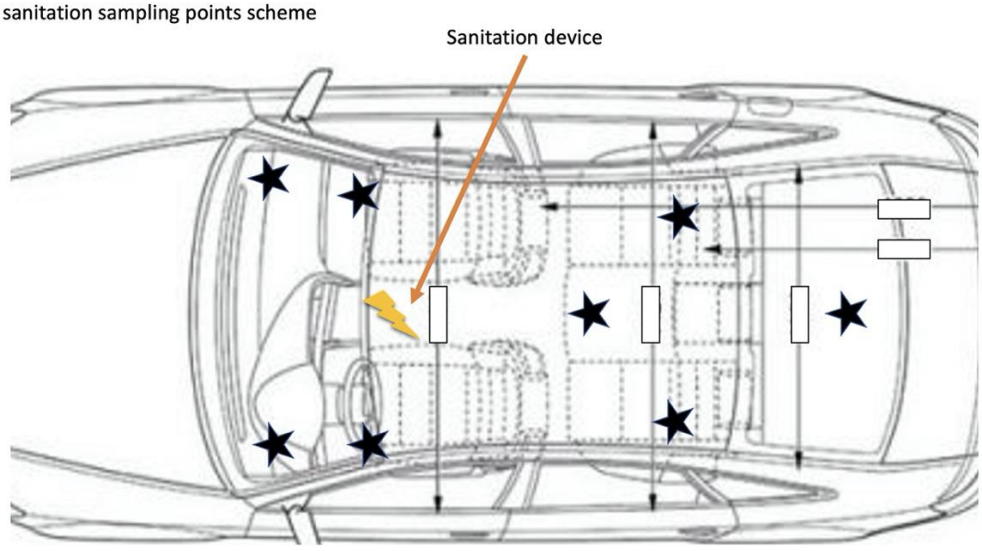
The following sanitation cycles were evaluated:

- 30 min without air recirculation
- 30 min with air recirculation[3]
- 1h with air recirculation[4]

After sampling, the plates were closed and transported to the laboratory, where they were incubated for 48h at 22 ° C ± 1 ° C. After the incubation time, the plates were read to determine the microbial load. The result is expressed as the number of CFU per plate obtained in 1h of sampling.

The sampling point scheme is as follows:

Car sanitation sampling points scheme



(3,4) The air recirculation has been set at minimum speed, directed to the front vents (the ones located on the dashboard) and to the lower vents (the ones located just above the mats); the air temperature has been set half way in the hot-cold range.

Test Results

Octo voluntary tests put into evidence that the PurePlace system, after 60 minutes of application inside the passenger compartment, is able to reduce the bacterial load within the limit of **5 CFU** (Colony Forming Units), so indicating at least a B grade microbial contamination according to "*EU Guidelines to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use*".

This B Grade corresponds to a pre-aseptic environment, specified for aseptic medicine preparation and filling, and being the background environment for the grade A zone (the fully sterile zone, for high-risk operations).

References:

Napoli, C., Marcotrigiano, V., and Montagna, M.T. "Air sampling procedures to evaluate microbial contamination: a comparison between active and passive methods in operating theatres." *BMC Public Health* 12.1 (2012): 594. Pasquarella, C., Pitzurra, O., and Savino, A. "The index of microbial air contamination." *Journal of hospital infection* 46.4 (2000): 241-256.

Pasquarella, C., et al. "Microbial air monitoring in operating theatre: active and passive samplings." *Annali di igiene: medicina preventiva e di comunita* 16.1-2 (2004): 375-386.

Viani, I., et al. "Passive air sampling: the use of the index of microbial air contamination." *Acta bio-medica: Atenei Parmensis* 91.3-S (2020): 92

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