

# **O<sub>3</sub> Matic Antimicrobial Ice Protection**

## **Technical and Certification Summary**



**April, 2016**

# O<sub>3</sub> Matic Antimicrobial Ice Protection

## Overview

**Section I: Technical Summary** presents information to support the O<sub>3</sub> Matic antimicrobial ice protection and its effectiveness as a preventative method for biofilm growth; to address questions of consumer and worker safety; and to assess its impact on ice machine reliability.

**Section II: Certification Summary** lists the independent testing bodies employed as well as regulatory approvals achieved.

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## Executive Summary of Section I

The Technical Summary addresses four key topics, as follows:

### 1. Efficacy: Summary of Biological Testing

The antimicrobial efficacy of the O<sub>3</sub> Matic dissolved ozone generator was evaluated in three parts:

- E. Coli Lab Testing was done at an independent microbial lab with two identical machines--one with O<sub>3</sub> Matic and one without. A “total kill,” or 5-log reduction, was achieved after 48 hours of exposure time when ozonated ice was used.
- Biofilm Growth Lab Testing was side-by-side testing of ice machines in a laboratory environment over a 6-month period of operation. In prevention of biofilm build-up, the ozone machine outperformed the one without.
- Biofilm Growth Field Testing was designed to validate laboratory findings in working, commercial kitchens. Nine sites were tested; at all of them, O<sub>3</sub> Matic showed significant ability to slow down the growth of bacteria, yeast and mold.

### 2. Competitive Analysis of Core Technology

O<sub>3</sub> Matic novel use of solid synthetic diamonds overcomes the challenges of traditional electrolytic ozone production methods, particularly in the areas of space and energy efficiency; reliability; and efficacy. The O<sub>3</sub> Matic electrolytic method of producing dissolved ozone “from-water, in-water” has been optimized to enable compact antimicrobial applications in which purity and resource efficiency are at a premium and off-gassing levels are to be minimized.

### 3. Water Quality

The O<sub>3</sub> Matic unit’s unique ozone production method is designed to counter the build-up of scale. However, high calcium levels—greater than 150 ppm—may adversely affect the life of the unit (and most other kitchen equipment). As such, it is recommended that O<sub>3</sub> Matic supplied with water treated by a conventional filtration device.

Studies of ozone's reaction with minerals in water, as well as the by-products of ozonation in potable water, indicate that O<sub>3</sub> Matic raises no operational or human safety issues stemming from chemical reactions.

#### **4. Human & Materials Exposure**

##### Consumer Exposure: Ozone Ingestion

There are no regulatory standards established by FDA, USDA, or EPA for dissolved ozone ingestion. Based on a review of available data by independent toxicological experts, the limited exposures associated with ingestion of the small amounts of ozone resulting from the O<sub>3</sub> Matic device are anticipated to be without any significant human health effects.

##### Worker Exposure to Ozone

We have tested the off-gassing levels of O<sub>3</sub> Matic units for cubers up to 2000 lbs./day, and any size or number of related ice storage bins, and they are all well below OSHA PEL (Permissible Exposure Limit). O<sub>3</sub> Matic has been tested to CE and UL standards by a third party.

##### Ice and Beverage Taste/Odor

Ozone leaves behind none of the chemical trace odors associated with some equipment sanitation methods. Rather, ozone is widely recognized by government agencies to be an effective oxidant used to reduce unpleasant taste and odors in drinking water.

##### Ice Machine Reliability

Ozone compatibility of ice machines depends on components used in the machine. O<sub>3</sub> Matic produces only a low level of dissolved and gaseous ozone within the ice storage bin. Therefore, it avoids high concentrations of ozone that can have adverse effects on ice machine materials. Materials used in particular ice machine models should be reviewed and tested for ozone compatibility.

# Part I: Technical Summary

## 1. Efficacy: Summary of Biological Testing

### 1.1 Technology Overview

Ozone is proven and widely accepted for numerous FDA-approved drinking-water and food-related applications. Ozone in general has the ability to rapidly kill virtually all of common microorganisms including bacteria, viruses, fungi, algae, yeast, mold, parasites and other known sources of foodborne illness. Properly applied, ozone kills at the same time it eliminates sources of odors.

O<sub>3</sub> Matic is a unique technology development that resolves the limitations and safety issues inherent in the use of ozone-generating devices in foodservice. O<sub>3</sub> Matic is a compact device that attaches to the incoming water line of a commercial ice cube maker and generates dissolved ozone, “from-water, and in-water.” Ozonated water flows through the water path, and is subsequently frozen into ice. The ozone is present throughout the ice cube, with a higher concentration in the outermost layer. The amount of residual ozone in the ice is well below levels of taste detection.

The resulting, low-level ozone effectively reduces microbes on surfaces in both the ice machine (water lines, reservoir, evaporator, etc.) and the ice holding bin (bin surfaces, drain, etc.). The process significantly retards biofilm growth within the ice machine and extends the required time between routine cleanings.

Ozone is well preserved in ice and dissipates very gradually in the ice bin over a period of several days. The ice gradually melts and the resulting water drains from the bin. The “ice melt” contributes to the ozone’s ability to reduce microbes and their growth on surfaces as well as on the drain fixture and line.

The antimicrobial efficacy of the O<sub>3</sub> Matic dissolved ozone generator was evaluated in three phases:

- Part I of the study (E. coli Lab Testing) was designed to determine the level of dissolved ozone concentration needed to be effective against bacteria and still remain within defined safe limits.
- Part II of the study (Biofilm Growth Lab Testing) was comprised of side-by-side testing of ice machines in a laboratory environment over a 6-month period of operation.
- Part III of the study (Biofilm Growth Field Testing) was designed to validate laboratory findings in working, commercial kitchens.

## 1.2 E. coli Lab Testing

In Part I of the biological testing, a side-by-side comparison of the effect of ozone on E. coli in an ice machine bin was conducted. Two identical ice machines were set up on site at the microbiology lab, one equipped with the O<sub>3</sub> Matic unit and one without.



**Figure 1: Coupon and lab set-up of ice machines.**

Duplicate stainless steel coupons of 4.0" X 4.0" were inoculated with  $1.0 \times 10^7$  E. coli and placed in the ice cube machine. The coupons were tested at three different time intervals to determine the log reduction of the E. coli. Ice production was limited to 4 hours to provide a manageable but realistic layer of ice cubes over the coupons. Proper care was taken to remove the coupons to prevent any incidental removal of the E. coli bacterium.

The log reductions were determined for both machines after 2, 4, and 48 hours. At the end of each exposure time, four coupons from 'Experiment Ice Maker' and four coupons from 'Control Ice Maker' were retrieved and the approximate number of surviving bacteria was determined. Once the target bacteria were extracted from the challenged surface of the coupons, the resulting solutions were plated on both TSA and VRB agar and were incubated at  $32.5 \pm 2.5^\circ\text{C}$  for 22 to 24 hours. A "total kill," or 5-log reduction in bacterial counts was achieved after 48 hours of exposure time.

### Results of Bacteria Kill

Time	Bacterial Kill with Ozone	Bacterial Kill without Ozone
2 hr	Log reduction 1.8	Log reduction <0.4
4 hr	Log reduction 2.8	Log reduction 0.6
48 hr	Log reduction 5.0	Log reduction 1.6

## 1.3 Biofilm Growth Lab Testing

In Part II of the biological testing, a side-by-side comparison of two identical ice machines was made in the product development lab. Each ice machine was equipped with a conventional water filter and was connected to the municipal water supply. One ice machine was outfitted with an in-line O<sub>3</sub> Matic dissolved ozone generator and the other was not.

A grid was drawn on the floor of both ice bins to ensure that swabbing over the subsequent months was distributed appropriately over the bottom of the ice bin and that both machines were swabbed in the same location in the same time period. The ice bin of each machine was emptied every day during the week. Every two weeks a microbial swab was taken from five

Locations on each machine plus a control. The floor of each ice machine was swabbed at the same location in the grid and the swab sticks were collected and processed at the outside lab. At the lab the swabs were plated on both TSA and VRB agar and incubated at 35.5 deg. C for 22 to 24 hours.

The results for the O<sub>3</sub> Matic ozonated ice machine indicated an improved cleanliness compared to the ice machine without the O<sub>3</sub> Matic unit. Specifically, testing found a reduction of microbial growth in the ozonated ice machine. These data led directly into Part III of the testing, a field study to confirm these findings in a “real world” setting.

#### 1.4 Biofilm Growth Field Testing

In Part III of the biological testing, a field study was conducted on nine randomly selected restaurants and fast food chains within the greater Boston area. Establishments that made dough and bread were included. The ice machines were cleaned prior to installing the IST unit. A swab test was taken before and after cleaning to establish a baseline.

Each ice machine in the restaurant was swabbed in four locations:

- 1- Ice bin (red bar in graphs below)
- 2-Ice thickness gauge (yellow bar)
- 3-Ice tray (blue bar)
- 4-Water reservoir (tan bar)

The standard plate count for each location was recorded. The machines were operating as they were prior to the installation of the device. Samples of the four locations within the ice machine were collected once every two weeks. The overall results show that the installation of the O<sub>3</sub> Matic dissolved ozone unit clearly retarded bacteria growth.

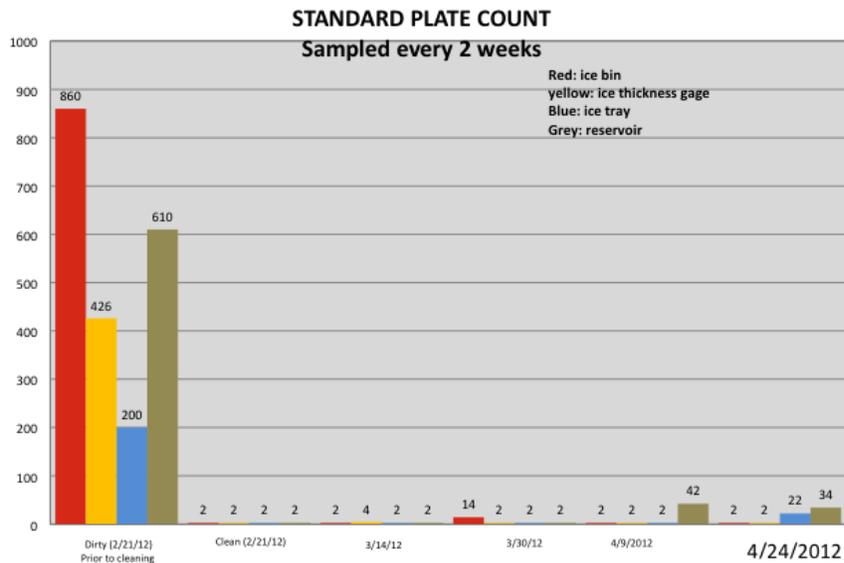
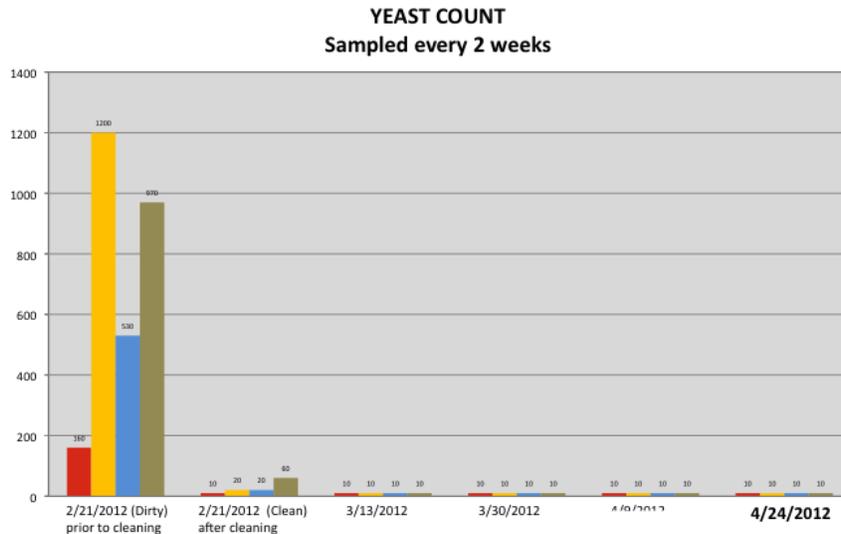


Figure 2: Standard Plate Count over 5-week period.



**Figure 3: Yeast Count in field locations that bake bread.**

The preliminary results of the expanded testing to evaluate the effect of the O<sub>3</sub> Matic unit on 'mold' & 'yeast' indicate a positive effect as well.

## 1.5 Conclusions

Test results demonstrate that the amount of dissolved ozone in water supplying the ice machine was sufficient to reduce the "bio-burden" while ensuring that ozone gas inside the unit was kept below OSHA permissible exposure limits at all times.

Testing also demonstrates that the O<sub>3</sub> Matic device is an effective and practical method for controlling and reducing biofilm formation, as well as effectively reducing pathogens in the ice machines.

## 2. Competitive Analysis of Core Technology

The O<sub>3</sub> Matic electrolytic method of producing dissolved ozone "from-water, in-water" has been optimized to enable compact applications in which purity and resource efficiency are at a premium and off-gassing levels must be minimized. This method effectively reduces and retards bacteria and other microorganisms within the ice bin, while keeping ozone gas levels far below OSHA PEL (permissible exposure limits) standards.

The O<sub>3</sub> Matic unit's solid, boron-doped diamond technology enables greater efficiency, reliability and greater antimicrobial power as compared to coated synthetic diamond electrodes used in electrolytic ozone production.

### 2.1 Space and Resource Efficiency

Through the use of diamond electrodes, a higher current density is possible for more efficient ozone production and a more compact ozone cell—two to four times smaller than those using coated electrodes. Alternative ozone technologies, namely "corona discharge," have not been suited to confined spaces and require more complex systems.

## 2.2 Reliability

The solid synthetic diamond technology used in O<sub>3</sub> Matic doesn't suffer the safety and stability issues known to plague lead oxide electrodes, and are found to be more efficient than platinum coated electrodes.

- Lead oxide electrodes can require complex systems, may experience low current efficiencies, and may pose a safety risk, especially in applications where the purified water is eventually consumed.
- Other metals used to coat electrodes, such as platinum, have been found to be less efficient than solid diamond, and may require larger electrodes or increased power requirements.
- Coated electrodes are subject to hydrogen “embrittlement” of the metal substrate. This issue can plague coated electrodes when they are used as a cathode. De-lamination, where the coatings break off, can negatively impact reliability and effectiveness of coated electrodes.
- Symmetric electrode construction enables a patent-pending reverse polarity scheme that helps to reduce scale.

## 2.3 Antimicrobial Power

O<sub>3</sub> Matic solid diamond electrodes can be driven at a higher current density which allows much greater efficiency at producing ozone.

- Smaller aperture spacing means greater dissolution of ozone and less off-gassing.
- The use of symmetric electrodes means more continuous ozone production, even in hard water.

## 3. Water Quality Considerations

### 3.1 Reliability

As noted, O<sub>3</sub> Matic unique ozone production method is designed to counter the build-up of scale. However, high calcium levels—greater than 150 ppm—may adversely affect the life of the O<sub>3</sub> Matic (and most other kitchen equipment). As such, we recommend that O<sub>3</sub> Matic be supplied with water treated by a conventional filtration device.

### 3.2 Reaction with Minerals in Water

Ozone is a strong oxidizing agent. It does react with cations in the water forming oxides. Manganese oxide and iron oxide can coagulate and precipitate out of the water. Sodium, potassium, and calcium oxides stay in solution; however, they do not freeze in the ice machine and they are purged from the ice machine after each freeze cycle. They are not expected to cause any issues in the ice.

### 3.3 Hazardous By-Products

There are no known hazardous, disinfection by-products generated by ozone treatment of potable water other than bromate, which is produced from water containing bromide. Some studies have shown that bromate is formed at ozone exposure (CT) 0.4 ppm. The level of ozone exposure in the O<sub>3</sub> Matic unit is well below this level.

## 4. Human & Materials Impact

### 4.1 Consumer Exposure: Ozone Ingestion

Based on a review of available data by independent toxicological experts, the limited exposures associated with ingestion of the small amounts of ozone resulting from the O<sub>3</sub> Matic device are anticipated to be without any significant human health effects.

Ozone is presently used in both food and water applications. The USDA National Organic Program allows ozone to be used as an ingredient in or on processed products labeled as "organic" or "made with organic ingredients" per 7 CFR section 205.605. Under FDA 21 CFR Section 184.1563, the presence of ozone in bottled water is permitted when limited to 0.4 ppm ozone per liter of bottle water. By comparison, we estimate that at the time O<sub>3</sub> Matic ozonated ice is served, ozone levels have dropped dramatically to approximately 0.05ppm or less. At this residual concentration, the taste and odor of ozone is not anticipated to be detectable. The device may in fact remove odors, which may have otherwise been resident in the inlet water and ice.

### 4.2 Worker Ozone Exposure

EPA and OSHA regulatory requirements exist for only for gaseous ozone. The off-gassing levels of the O<sub>3</sub> Matic unit are well below OSHA PEL limits. This stands in contrast to the off-gassing risk inherent in technologies which inject ozone into the water via large bubbles.

### 4.3 Ice and Beverage Taste/Odor

Ozone leaves behind none of the chemical trace odors associated with other equipment sanitation methods. Rather, ozone is recognized to be an effective oxidant used to reduce unpleasant taste and odors in drinking water. The EPA Guidance Manual, *Alternative Disinfectants and Oxidants*, refers to ozone treatment for removal of unpleasant taste and odor.

### 4.4 Ozone Exposure: Ice Machine Reliability

Our method of producing ozone from-water in-water gradually releases ozone in a dissolved, liquid form within the ice storage bin, preventing high concentrations of ozone that can have adverse effects on ice machine materials. Users who have concerns about specific materials used in particular ice machine models should consult Franke.

## 5. Application

The first release of the O<sub>3</sub> Matic dissolved-ozone unit is optimized for cubers up to 2000 lbs. /day, and any size or number of related ice storage bins.

The O<sub>3</sub> Matic unit is designed to accept a water supply with a flow rate of 0.5 to 1.5 gpm (1.9-5.7 lpm); a maximum temperature of 100 deg. F. (38 deg C.); and a maximum pressure of 125 Psi (8.61 bar). Support for flake and nugget ice is under discussion, though no development program is underway at present.

## Part II: Certification Summary

### 1. Bacteriological Testing

Lapuck Laboratories, certified and registered by the FDA and USDA, has executed all bacteriological testing.

### 2. Device Safety Certification

TUV/ SUD - Mass has been selected as the Safety Certification Agency for all components supplied by EOI. (See certificate herein.)

### 3. EMI Certification

Retlif Test Labs has been selected as the Emissions and Immunity Testing lab. (See certificate herein.)

Because the O<sub>3</sub> Matic unit utilizes high frequency switching internally, the device must be certified not to cause or be sensitive to EMI. The Retlif testing certifies the device to this requirement; the resulting reports are kept on file as part of the manufacturer's self-certification and application of both FCC and CE marks.

### 4. Material Safety Certification

O<sub>3</sub> Matic was tested to NSF 2 by Intertek Testing Services, NA Inc. Specifically, Intertek performed NSF/ANSI 2-2010: Food Equipment Materials, Section 4.1-Toxicological Review and FDA Extraction Testing at its microbiological laboratory in Columbus, Ohio.

O<sub>3</sub> Matic ozone cell samples were evaluated for their concentration of non-volatiles and extraction of heavy metals. Test sample evaluations were conducted at the Columbus lab between May 18, 2012 and June 18, 2012. The ozone cell complies with the FDA's extraction requirements for polymers that are used at room temperature.

### 5. Non-U.S. Certification

Reports from the various above-named sources prove compliance to the European Directives required for this device and allow us to certify to the CE mark as well as US and Canadian safety standards.

### 6. Certificate Exhibits

(Attached, below.)

**CERTIFICATE OF CONFORMANCE  
EUROPEAN COMMUNITY  
COUNCIL DIRECTIVE 2004/108/EC**

Date of Issue: December, 2011  
 Issued By: Retlif Testing Laboratories  
 101 New Boston Road  
 Goffstown, NH 03045  
 Issued To: Electrolytic Ozone, Inc.  
 66-K Concord Road  
 Wilmington, MA 01887  
 Reference: Retlif Report Number R-5529N-1

Retlif Testing Laboratories hereby acknowledges that compliance testing in accordance with the below listed standards was performed on a representative sample of the equipment listed below. Retlif Testing Laboratories further acknowledges that the test sample listed below was found to be in compliance with these standards. This certificate is hereby issued to the above named grantee and is valid only for the equipment identified below.

**Manufacturer:** Electrolytic Ozone, Inc.  
 66-K Concord Road  
 Wilmington, MA 01887

**Equipment Tested:** Ice Machine Filter

**Model Number:** A1979

**Serial Number:** SCM0221011

**Brand Name:** EOI

**Product Type:** Household Appliance, Category II

- Notes: 1) See attached report R-5529N-1 for details and/or conditions pertaining to this certificate.  
 2) Conforms to the emissions requirements of EN 55014-1:2006/A1:2009.  
 Terminal Disturbance Voltages, 150 kHz to 30 MHz  
 Disturbance Power, 30 MHz to 300 MHz  
 3) Conforms to the immunity requirements of EN 55014-2:1997/A1:2001/A2:2008 (for Category II Appliances):  
 IEC 61000-4-2:1995 Electrostatic Discharge  
 IEC 61000-4-3:1995 Radiated Immunity  
 IEC 61000-4-4:1995 EFT/Burst, Power Ports  
 IEC 61000-4-5:1995 Surge Immunity, Power Ports  
 IEC 61000-4-6:1996 Conducted Immunity, Power Ports  
 IEC 61000-4-11:1994 Voltage Dips and Interruptions  
 4) Conforms to the requirements of:  
 EN 61000-3-2:2006/A1:2009/A2:2009  
 EN 61000-3-3:1996/A1:2001/A2:2005

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 IEC 61000-4-3:1995 Radiated Immunity  
 IEC 61000-4-4:1995 EFT/Burst, Power Ports  
 IEC 61000-4-5:1995 Surge Immunity, Power Ports  
 IEC 61000-4-6:1996 Conducted Immunity, Power Ports  
 IEC 61000-4-11:1994 Voltage Dips and Interruptions  
 4) Conforms to the requirements of:  
 EN 61000-3-2:2006/A1:2009/A2:2009  
 EN 61000-3-3:1996/A1:2001/A2:2005

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## CERTIFICATE

No. U8 12 02 79026 003

**Holder of Certificate:** Electrolytic Ozone Inc.  
66K Concord Street  
Wilmington MA 01887  
USA

**Production Facility(ies):** 79026

**Certification Mark:**



**Product:** Electrical equipment in general  
Ozone Ice Filter

**Model(s):** Cuber-201, Cuber-401, Flaker-201 and Flaker-401  
See certificate attachment for model descriptions

**Parameters:**

Rated Input Voltage:	100-240 V AC
Rated Frequency:	50/60 Hz
Rated Input Current:	0.24 A
Protection Class:	II

**Tested according to:** CANCISA-E335-1-2003  
IEA 60335-1-2004  
EN 60335-1/A2-2006

The product was voluntarily tested according to the relevant safety requirements and mentioned properties. It can be marked with the certification mark shown above. The certification mark must not be altered in any way. This product certification system operated by TÜV SÜD America Inc. most closely resembles that described by ISO/IEC Guide 67, Conformity assessment - Fundamentals of product certification, System 3. See also notes overleaf.

**Test report no.:** 090-1109968-000

**Date:** 2012-02-01


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### Attachment to Certificate U8 12 02 79026 003

**Electrolytic Ozone Inc.**  
66K Concord Street  
Wilmington, MA, 01887, USA

**Model Information:**

Cuber-201 (No Filter cartridge)  
Flaker-201 (No Filter cartridge)

Cuber-401 (Filter Cartridge), Provided with 1, 2 or 3 electrode configurations  
Cuber-401 (Filter Cartridge), Provided with 1, 2 or 3 electrode configurations

**Number of Electrode Configurations:**  
3 Electrodes (type- Adept 73/A-75)  
Or  
2 Electrodes (type- Adept 50/A-50)  
Or  
1 Electrodes (type- Adept 25/A-25)

**Test Report No.:** 090-1109968-000

**Date:** 2012-02-01


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Ref. Certif. No.  
DE 3 - 14940

### CB TEST CERTIFICATE CERTIFICAT D'ESSAI OC

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

<p><b>Product</b> Product</p> <p><b>Name and address of the applicant</b> Nom et adresse du demandeur</p> <p><b>Name and address of the manufacturer</b> Nom et adresse du fabricant</p> <p><b>Name and address of the factory</b> Nom et adresse de l'usine</p> <p><b>Rating and principal characteristics</b> Valeurs nominales et caractéristiques principales</p> <p><b>Trade mark (if any)</b> Marque de fabrication (si elle existe)</p> <p><b>Model/type Ref.</b> Ref. de type</p> <p><b>Additional information (if necessary)</b> Information complémentaire (si nécessaire)</p> <p><b>A sample of the product was tested and found to be in conformity with</b> Un échantillon de ce produit a été essayé et a été considéré conforme à la</p> <p><b>as shown in the Test Report Ref. No.</b> which form part of this certificate: comme indiqué dans le Rapport d'essais numéro de référence qui constitue une partie de ce certificat</p>	<p>Electrical equipment in general Ozone Ice Filter</p> <p>Electrolytic Ozone Inc. 66K Concord Street Wilmington MA 01887, USA</p> <p>Electrolytic Ozone Inc., 66K Concord Street, Wilmington MA 01887, USA</p> <p>Electrolytic Ozone Inc., 66K Concord Street, Wilmington MA 01887, USA</p> <p>Rated Input Voltage: 100-240 V AC Rated Frequency: 50/60 Hz Rated Input Current: 0.24 A Protection Class: II</p> <p>FRANKE</p> <p>Cuber-201, Cuber-401, Flaker-201 and Flaker-401 See certificate attachment for model descriptions</p> <p>IEC 60335-1/A2-2006</p> <p>090-1109968-000</p>
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This CB Test Certificate is issued by the National Certification Body  
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

**Date:** 2012-02-01  
CB 12 02 79026 004

  
 William Stinson  


TÜV SÜD Product Service GmbH • Certification Body • Rattenstrasse 65 • D-80339 München



Ref. Certif. No.  
DE 3 - 14940

### Attachment to Certificate CB 12 02 79026 004

**Electrolytic Ozone Inc.**  
66K Concord Street  
Wilmington, MA, 01887, USA

**Model Information:**

Cuber-201 (No Filter cartridge)  
Flaker-201 (No Filter cartridge)

Cuber-401 (Filter Cartridge), Provided with 1, 2 or 3 electrode configurations  
Cuber-401 (Filter Cartridge), Provided with 1, 2 or 3 electrode configurations

**Number of Electrode Configurations:**  
3 Electrodes (type- Adept 73/A-75)  
Or  
2 Electrodes (type- Adept 50/A-50)  
Or  
1 Electrodes (type- Adept 25/A-25)

**Test Report No.:** 090-1109968-000

**Date:** 2012-02-01


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