

**World's First<sup>\*1</sup> Verification by Clinical Trial of the Effectiveness of High-Density Plasmacluster Ions<sup>\*2</sup> in Decreasing the Rate of Influenza Virus Infection**

Clinical Trial Conducted in Dialysis Hospitals Under the Supervision of Professor Yasuo Ohashi of The University of Tokyo's School of Public Health

Sharp Corporation's contracted research has proven, through the world's first verification by clinical trial<sup>\*3</sup>, that high-density Plasmacluster Ions (with an ion density of 10,000 ions/cm<sup>3</sup>) tend to decrease the influenza virus infection rate. This was verified by professors from The University of Tokyo's School of Public Health, including Professor Yasuo Ohashi, whose specialty is biostatistics.

This clinical trial was carried out in the treatment rooms of Japanese dialysis hospitals, totaling 44 facilities that housed 3,407 patients and 745 Plasmacluster Ion Generators. The treatment rooms were divided into areas with ions and areas without ions. The trial lasted for around six months and used the double-blind method<sup>\*4</sup>, a common trial method, while examining the number of influenza cases that occurred among patients (management of the trial was consigned to the Public Health Research Foundation).

The trial results verified that the influenza virus infection rate decreased by approximately 30% in the areas where ions were present compared to areas with no ions. During the trial there were a total of 23 influenza cases (14 cases without ions and 9 cases with ions), proof of its tendency (one-sided  $p = 0.10$ ) to be effective at decreasing the rate of influenza virus infection<sup>\*5</sup>.

It should also be noted that Professor Yasuo Ohashi of the School of Public Health of The University of Tokyo is scheduled to make a presentation about this trial at the annual Japan Epidemiological Association meeting on January 21 and 22, 2011.

Based on the results of its academic marketing<sup>\*6</sup>, Sharp, working in collaboration with academic research organizations around the world since the year 2000, has proven that Plasmacluster technology is effective in inhibiting the activity of 29 different kinds of harmful microorganisms, including viruses, bacteria, and

allergens. Furthermore, it has been proven safe to humans<sup>\*7</sup>. This clinical trial effectively advanced these findings with a directly proven merit to human health.

In the future, Sharp will continue its efforts to advance Plasmacluster technology, further prove its efficacy, create a healthy environment, and contribute to society.

### **Comments by Mr. Yasuo Ohashi, Professor of the University of Tokyo's Public Health**

This randomized double blind clinical trial on influenza virus infection prevention is truly unique, and these tests demonstrate a high level of leadership and pioneering spirit. The results suggest the possibility that Plasmacluster is able to reduce the risk of catching the influenza virus, which is said to infect 10 million people every year in Japan. I think that this clinical trial contributes to the development of methodology, and shows that Plasmacluster Technology will be a great contribution to society. Further clinical and epidemiological studies are still required, but I look forward to seeing Plasmacluster Technology as another step people can take in their daily lives to reduce the risk of influenza infection, much like gargling and hand-washing.

\*1 As of November 9, 2010.

\*2 Plasmacluster is a registered trademark of Sharp Corporation.

\*3 This project was carried out in cooperation with the Ministry of Education's Translational Research Educational Program, a program that The University of Tokyo participates in.

\*4 A widely used statistical examination method for clinical trials where neither the patient nor the doctor know whether a medicine or a placebo was used during the patient's treatment.

\*5 Last season showed fewer signs of influenza infections than normal, affecting the number of infections during the clinical trial. For this reason, the trial was under-powered and the p-value (one-sided) did not reach to the statistically significant level ( $p = 0.05$ ).

\*6 A marketing technique where a product has its benefits scientifically verified in cooperation with top-of-the-line research facilities.

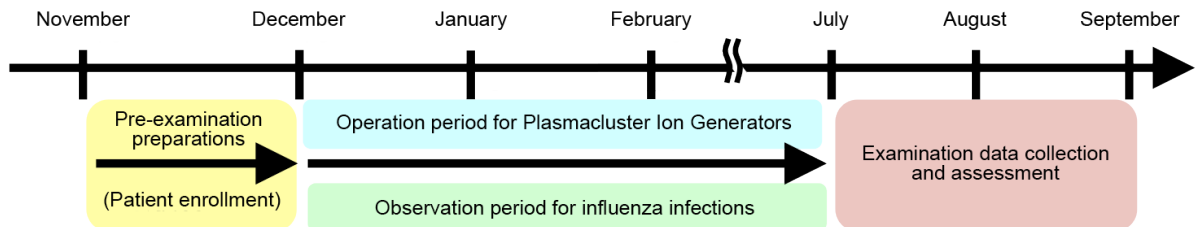
\*7 Testing conducted by Mitsubishi Chemical Medience Corporation, including tests for inhalation toxicity and for skin and eye irritancy and corrosivity.

## The Method Used to Verify Influenza Infection Inhibition Effectiveness in a Clinical Setting and the Results

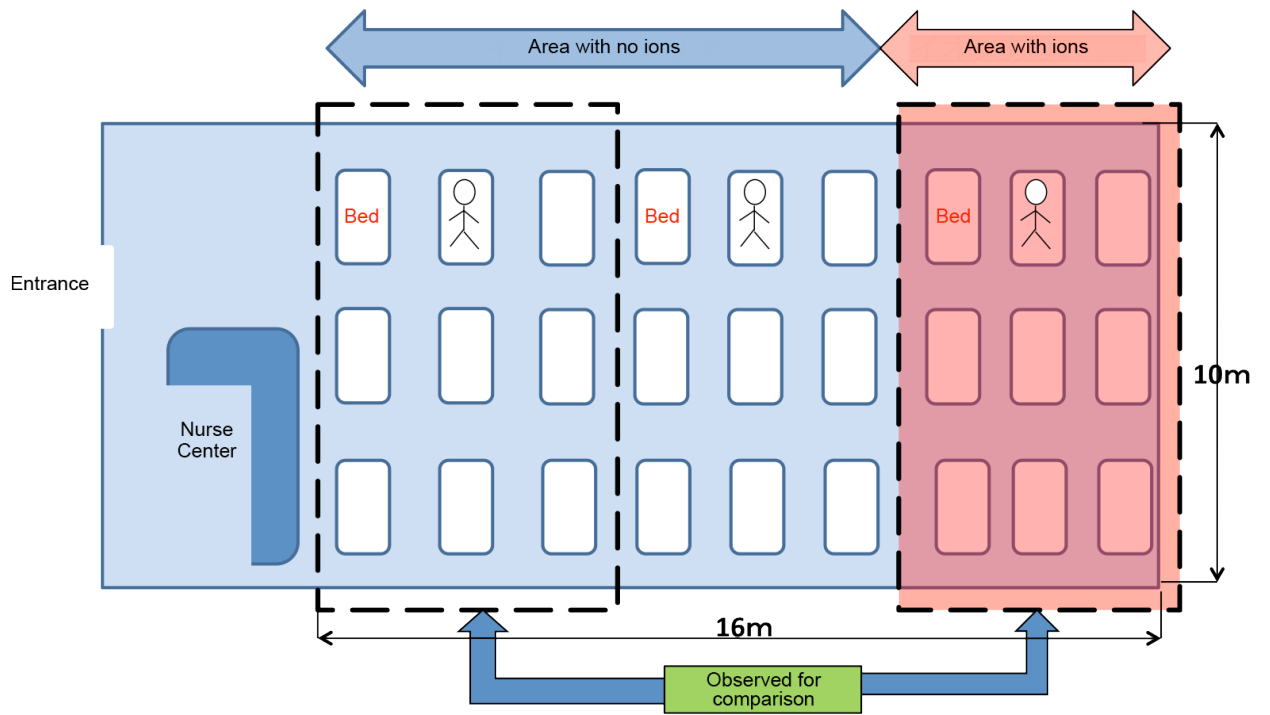
Evaluation parameters	Number of cases of infection by the influenza virus (new strains and seasonal strains), and the total number of observation days
Examination facilities	Dialysis hospitals (44 facilities; 3,407 patients)
Duration	December 1, 2009 to June 30, 2010
Comparison method	Double-blind study that divided the treatment space into areas with ions and areas without ions
Ion density	10,000 ions/cm <sup>3</sup>
Statistical analysis method	Cochran-Mantel-Haenszel (CMH) Test <sup>*8</sup> , permutation test <sup>*9</sup>
Trial results	<p>Found a 30% reduction in the rate of influenza virus infection; statistically confirmed this figure to have a 10% one-sided p-value</p> <p><u>Areas with ions:</u>            number of cases observed: 1,154            number of cases of influenza infection: 9            number of observation days: 219,057 (total)</p> <p><u>Areas without ions:</u>            number of cases observed: 1,274            number of cases of influenza infection: 14            number of observation days: 237,167 (total)</p>

\*8, 9 A statistical analysis method that measures the association between the intervention and the results.

**Figure 1 Clinical Trial Timeline**



**Figure 2 Examination Area Image**



**Picture A Dialysis Hospital**



## **Profile of Mr. Yasuo Ohashi, Professor of Department of Biostatistics, School of Public Health, School of Public Health, The University of Tokyo**

Professor for the Department of Biostatistics, School of Public Health, The University of Tokyo. He is the managing director of the Public Health Research Foundation and he is involved in a wide range of activities, including clinical trials and epidemiologic studies.

- Public Health Research Foundation  
    Managing Director
- Non-Profit Organization Japan Clinical Research Support Unit  
    The Chairman of the Board of Directors
- Statcom Company Limited  
    Chairman
- Japan Medical and Scientific Communicators Association  
    The Chairman of the Board of Directors
- Japan Society of Clinical Trials and Research  
    The Chairman of the Board of Director

## **Profile of the Public Health Research Foundation**

Established in 1984, the Public Health Research Foundation conducts stress and life science-related research. In addition, the foundation uses the results from their research to promote disease prevention methods, contributing to their main mission, better health for all. The Chairman is Takayasu Okushima.

With both biomedical and stress research institutes, the foundation is involved in health promotion business (health screening, health evaluation, health guidance), clinical research support (support for breast cancer research, optimum therapy for osteoporosis research, lifestyle disease related clinical research, health outcome research), public relations, as well as ethical review board on medical and mental health research.

## Efficacy of Plasmacluster Ions in Inhibiting Activity of Various Pathogens Confirmed Through Collaborative Research

Target Substance	Species	Testing & Verification Organization
Bacteria	Serratia bacteria	Harvard School of Public Health (Dr. Melvin W. First, Professor Emeritus), U.S.
	Coliform bacteria (E. coli)	Ishikawa Health Service Association, Japan
	E. coli, Staphylococcus (aureus), Candida	Shanghai Municipal Center for Disease Control and Prevention, China
	Bacillus subtilis	Kitasato Research Center of Environmental Sciences, Japan
		CT&T (Professor Gerhard Artmann, Aachen University of Applied Sciences), Germany
	MRSA (methicillin-resistant Staphylococcus aureus)	Kitasato Research Center of Environmental Sciences, Japan
		Kitasato Institute Medical Center Hospital, Japan
	MDRP (multi-drug resistant Pseudomonas aeruginosa)	Kitasato Institute Medical Center Hospital, Japan
	Pseudomonas, Enterococcus, Staphylococcus	University of Lübeck, Germany
Enterococcus, Staphylococcus, Sarcina, Micrococcus	CT&T (Professor Gerhard Artmann, Aachen University of Applied Sciences), Germany	
Allergens	Mite allergens, pollen	Graduate School of Advanced Sciences of Matter, Hiroshima University, Japan
	Mite allergens	Osaka City University Medical School's Department of Biochemistry & Molecular Pathology, Japan

Fungi	Cladosporium	Ishikawa Health Service Association, Japan
		University of Lübeck, Germany (growth-suppressing effect)
		CT&T (Professor Gerhard Artmann, Aachen University of Applied Sciences), Germany
	Penicillium, Aspergillus	University of Lübeck, Germany (growth-suppressing effect)
	Aspergillus, Penicillium (two species), Stachybotrys, Alternaria, Mucorales	CT&T (Professor Gerhard Artmann, Aachen University of Applied Sciences), Germany
Viruses	H1N1 human influenza virus	Kitasato Research Center of Environmental Sciences, Japan
		Seoul University, Korea
		Shanghai Municipal Center for Disease Control and Prevention, China
		Kitasato Institute Medical Center Hospital, Japan
	H5N1 avian influenza virus	Retroscreen Virology, Ltd., London, U.K.
	New-type H1N1 influenza virus	Retroscreen Virology, Ltd., London, U.K.
	SARS virus	Retroscreen Virology, Ltd., London, U.K.
	Polio virus	Kitasato Research Center of Environmental Sciences, Japan
	Coxsackie virus	Kitasato Research Center of Environmental Sciences, Japan
		Kitasato Institute Medical Center Hospital, Japan
	Corona virus	Kitasato Institute Medical Center Hospital, Japan
Canine Parvovirus	Shokukanken Inc., Japan	

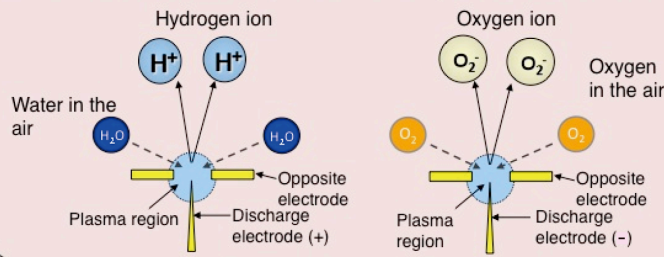
Note: Efficacy in inhibiting activity of the airborne target substances noted above was verified by exposing the substances to an ion concentration of at least 3,000 ions/cm<sup>3</sup>.

## Overview of Plasmacluster Technology

Sharp's proprietary air purification technology in which positive ions  $[H^+(H_2O)_n]$  and negative ions  $[O_2^-(H_2O)_m]$  are released into the air simultaneously. These positive and negative ions instantly recombine on the surface of bacteria, mold fungus, viruses and allergens floating in the air to form hydroxyl (OH) radicals, which have extremely high oxidation ability, and this chemical reaction decomposes proteins on the surface of bacteria and other pathogens, thereby inhibiting their activity.

### Plasmacluster Ion Generation

Applying positive and negatively charged voltages to discharge electrodes electrically decomposes water molecules in the air into hydrogen molecules and oxygen molecules. Positive hydrogen ions ( $H^+$ ) and negative oxygen ions ( $O_2^-$ ) are generated in this way.



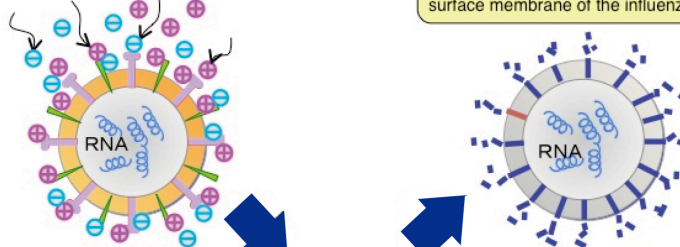
Water molecules in the air cluster around the ions like a bunch of grapes. Each ion forms part of a stable "bunch of grapes" or ion cluster.



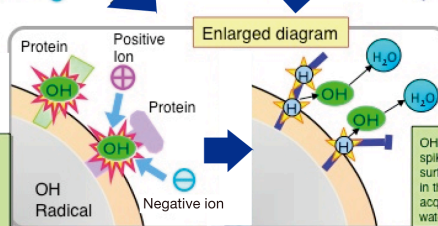
### Working Mechanism to Inhibit Infection by Airborne Viruses

Positive and negative ions surround the surface membrane of the airborne virus.

A chemical reaction takes place that physically breaks down proteins in the surface membrane of the influenza virus.



Through a chemical reaction occurring on the virus membrane surface, the ions are transformed into OH radicals, which are powerfully active but unstable.



(Information taken from collaborative research done in association with Professor Gerhard Artmann of Aachen University of Applied Sciences in Germany.)

OH radicals steal hydrogen atoms from the spike-like proteins that protrude from the surface of the virus membrane, opening holes in the membrane. When the OH radicals acquire a second hydrogen atom, they form water ( $H_2O$ ).



### **Oxidizing Substances Produced by Plasmacluster Ions**

Plasmacluster ions adhere to airborne viruses, and the positive and negative ions react to form OH (hydroxyl) radicals, which have the most powerful oxidation ability (standard oxidation potential of 2.81 V), thereby inhibiting the infectivity of the airborne virus.

Active Substance	Chemical Formula	Standard Oxidation Potential [V]
Hydroxyl radical	• OH	2.81
Oxygen atom	• O	2.42
Ozone	O <sub>3</sub>	2.07
Hydrogen peroxide	H <sub>2</sub> O <sub>2</sub>	1.78
Hydroperoxide radical	• OOH	1.7
Oxygen molecule	O <sub>2</sub>	1.23

Source: *Ozon no kiso to ouchou* [Ozone—Its Basis and Applications]