Patent Right	Date	July 20, 2021	Court	Intellectual Property High Court, Fourth Division
	Case number	2020 (Gyo-Ke) 10054		
- A case in which the court found that the structure related to the difference could have been easily conceived of by a person skilled in the art based on the primary cited document and secondary cited document and on well-known art and common general technical knowledge as well, and rescinded the JPO Decision that is contrary to the above. - A case in which the court made a judgment regarding whether the structure of the corrected invention that was added by the correction after rendering of a judgment to rescind the first trial decision (First Judgment) could have been easily conceived of by a person skilled in the art based on the binding range of the First Judgment.				

Case type: Rescission of Trial Decision (Patent)
Result: Granted
References: Article 123, paragraph (1), item (ii); Article 29, paragraph (2); Article 123, paragraph (1), item (iv); Article 36, paragraph (4), item (i) and paragraph (6), item (i) of the Patent Act
Numbers of related rights, etc.: Patent No. 5463378, Invalidation Trial No. 2017-800004

Summary of the Judgment

1. Details leading to this lawsuit are as indicated below.
(1) The Plaintiff requested a trail for patent invalidation (Invalidation Trial No. 2017-800004) concerning the patented invention (Patent No. 5463378; hereinafter the relevant patent is referred to as the "Patent") titled "Device for nucleolytic degradation" of the Defendant and another company (later, the Defendant received the transfer of the company's share of the patent right and the transfer was registered).

Concerning the aforementioned request for a trial for patent invalidation, the Japan Patent Office (JPO) approved the correction made by the Defendant (First Correction) and rendered a trial decision to maintain the patent (hereinafter referred to as the "First JPO Decision"). Dissatisfied with the decision, the Plaintiff filed an appeal for rescission of the First JPO Decision (Intellectual Property High Court, 2018 (Gyo-Ke) 10064). The Intellectual Property High Court determined, based on Exhibit Ko 1 Invention (Examined Patent Application Publication No. 2010-51692) and Exhibit Ko 2 (International Publication No. 01/026697), that the structure related to the Difference

2, which was found in the First JPO Decision, could have been easily conceived of by a person skilled in the art, and rescinded the First JPO Decision. This judgment then became final and binding.

(2) The JPO conducted a further examination of the aforementioned trial for patent invalidation, approved the correction by the Defendant "to make inner differential pressure of the exposed unit constant by negative pressure" for Claim 2 (hereinafter referred to as the "Correction"; the underlined part is the addition by the Correction) in addition to the First Correction, and then made a trial decision to maintain the invention related to Claims 2 through 4 of the Patent and dismiss the request for the trial concerning the invention related to Claim 1 of the Patent (hereinafter referred to as the "JPO Decision"). Dissatisfied with the decision, the Plaintiff filed the lawsuit seeking rescission of the secondary decision.

(3) The Plaintiff alleged the grounds for rescission of the JPO Decision as follows: [i] Grounds for Rescission 1-1 (error in judgment on an inventive step of Claim 2 after the Correction that uses Exhibit Ko 1 as the primary cited document (hereinafter referred to as "Corrected Invention 2")); [ii] Grounds for Rescission 1-2 (error in judgment on inventive steps of Claims 3 (hereinafter referred to as "Corrected Invention 3") and 4 (hereinafter referred to as "Corrected Invention 4") after the Correction that uses Exhibit Ko 1 as the primary cited document (hereinafter these claims are referred to as "Corrected Invention 3" and "Corrected Invention 4," respectively); [iii] Grounds for Rescission 2 (error in determination concerning a violation of support requirements); and [iv] Grounds for Rescission 3 (error in determination concerning a violation of enablement requirements).

2. This judgment granted the Plaintiff's request by determining that Grounds for Rescission 1-1 and 1-2 are well-grounded.

(1) Grounds for Rescission 1-1

A. In light of the determination in the First Judgment and the developments of the trial decision after the First Judgment became final and binding, in order to make a judgment on an inventive step of Corrected Invention 2, whether the structure of Corrected Invention 2 "to make inner differential pressure of the exposed unit constant by negative pressure" can be said to have been easily conceived of by a person skilled in the art should be examined on the assumption that the structure of Difference 2, which was found in the First JPO Decision, has been disclosed in Exhibit Ko 2.

B. According to the statement in Exhibit Ko 2, the technical meaning of Exhibit Ko 2 Invention is that it can control formaldehyde gas concentration, humidity, and temperature in the space subject to sterilization, and can maintain room pressure

constant even in cases where room air expands due to increases in room temperature, thereby showing fully certifiable sterilizing effects. It should be said that the form of maintaining room pressure at a positive pressure (10 to 20Pa) by a room pressure adjustment device is merely one of the embodiments.

Based on the instruction in the First Judgment, it is found that Exhibit Ko 2 discloses that a means for detecting inner differential pressure is equipped and that pressure in the space subject to sterilization is maintained constant by feedback of the information on the aforementioned inner differential pressure obtained from the results detected by the means for detecting inner differential pressure to the means to control the exhaust amount and by controlling the exhaust amount of formaldehyde gas that is discharged from the space subject to sterilization by the aforementioned means to control the exhaust amount.

C. Exhibit Ko 1 discloses that the purpose is to maintain the catalytic reaction temperature constant for radical formation and to provide a sterilization gas generating device to generate MR gas at stable concentrations. As mentioned in B. above, Exhibit Ko 2 discloses that fully certifiable sterilizing effects can be obtained because the adoption of the structure of the formaldehyde gas sterilization device of Exhibit Ko 2 Invention makes it possible to control formaldehyde gas concentration, humidity, and temperature in the space subject to sterilization at the specified values respectively, and also to maintain room pressure constant even in cases where room air expands due to increases in room temperature. Based on the above, a person skilled in the art who comes across Exhibits Ko 1 and Ko 2 has the motivation to adopt a structure to control formaldehyde gas concentration, humidity, and temperature in the space subject to sterilization as stated in Exhibit Ko 2 at the specified values respectively and maintain the room pressure of the space subject to sterilization constant for the purpose of generating sterilization gas at stable concentrations in Exhibit Ko 1 Invention and obtaining fully certifiable sterilization effects.

At the time of the filing date of the application in question, it had been well-known art that, in cases where there are harmful substances to the human body in a room, such as in biohazard facilities, chemical hazard facilities, etc., room pressure should be controlled at a negative pressure against outside pressure so that the substances do not leak from inside the room to outside the room, and that in cases of sterilizing inside a room using ozone gas that is harmful to the human body, room pressure is controlled at a negative pressure against outside pressure so that ozone gas does not leak from inside the room to outside the room. In addition, when using formaldehyde gas for sterilization and disinfection, it is common general technical knowledge that there are cases where

formaldehyde gas is used under conditions where pressure inside the treatment room is at a negative pressure against the pressure outside the treatment room. Therefore, when applying the matters disclosed in Exhibit Ko 2 to Exhibit Ko 1 Invention, in light of the conditions of the space subject to sterilization and the purpose, and in consideration of the aforementioned well-known art and common general technical knowledge, it can be said that a person skilled in the art could have easily conceived of maintaining the pressure in the space subject to sterilization at a negative pressure. In addition, there is no evidence to find that any significant effects that a person skilled in the art could not predict were obtained by applying a structure to maintain "inner differential pressure at a negative pressure" in the space subject to sterilization as a result of considering and applying well-known art and common general technical knowledge to Exhibit Ko 1 Invention and the matters disclosed in Exhibit Ko 2.

D. Consequently, based on the matters stated in Exhibits Ko 1 and Ko 2, well-known art, and common general technical knowledge, an inventive step also cannot be found in the structure of Corrected Invention 2 "to make inner differential pressure of the exposed unit constant by negative pressure" out of Difference 1.

(2) Grounds for Rescission 1-2

The JPO Decision determined as follows: Corrected Invention 3 is an invention citing Corrected Invention 2 and Corrected Invention 4 is an invention citing Corrected Invention 3; since it cannot be said that a person skilled in the art could have easily invented Corrected Invention 2, it cannot be said either that a person skilled in the art could have easily invented Corrected Inventions 3 and 4.

However, there is an error in the determination of the JPO Decision concerning whether Corrected Invention 2 could have been easily conceived of by a person skilled in the art. As long as it is found that Corrected Invention 2 could have been easily conceived of by a person skilled in the art, there is an error in the aforementioned determination of the JPO Decision to deny that Corrected Inventions 3 and 4 could have been easily conceived of by a person skilled in the art only on the grounds that Corrected Invention 2 could not have been easily conceived of by a person skilled in the art.

Judgment rendered on July 20, 2021
2020 (Gyo-Ke) 10054, Case of seeking rescission of the JPO decision
Date of conclusion of oral argument: June 10, 2021

Judgment

Plaintiff: Wingturf Co., Ltd.

Defendant: Sealive, Inc.

Main text

1. The part "Patent No. 5463378 shall be maintained with regard to the invention related to Claims 2 through 4 of said patent" of the decision made by the Japan Patent Office (JPO) on March 17, 2020, concerning Invalidation Trial No. 2017-800004, shall be rescinded.

2. The Defendant shall bear the court costs.

Facts and reasons

No. 1 Claim

Same as the main text.

No. 2 Outline of the case

(Hereinafter documentary evidence is simply referred to as "Exhibition Ko 1," etc.)

1. Procedures, etc. at the JPO (There are no disputes between the parties.)

(1) The Defendant and Nobelto Co., Ltd. (hereinafter referred to as "Nobelto") filed a patent application for an invention titled "Device for nucleolytic degradation" (Patent Application No. 2012-62880; hereinafter referred to as the "Patent Application") on March 19, 2012, and obtained patent right registration on January 24, 2014 (Patent No. 5463378; number of claims: 4; hereinafter the registered patent is referred to as the "Patent").

(2) The Plaintiff requested a trial for invalidation seeking invalidation of the patent of the invention related to Claims 1 through 4 of the Patent (Invalidation Trial No. 2017-800004) on January 17, 2017.

The Defendant and Nobelto received the announcement of the trial decision dated November 30, 2017, and requested corrections concerning the group of claims consisting of Claims 1 through 4 on December 27, 2017, to correct Claims 2 through 4, to delete

Claim 1, and to correct descriptions attached to the Patent Application (hereinafter referred to as "Descriptions," including drawings) (hereinafter this series of corrections is referred to as the "Primary Corrections").

Subsequently, the JPO approved the aforementioned corrections and made the decision that "the request for the trial is groundless" (hereinafter referred to as the "Primary JPO Decision") on March 27, 2018 and delivered a certified copy thereof to the Plaintiff on April 5, 2018.

During this period, Nobelto transferred its share of the patent right related to the Patent to the Defendant and the transfer of that fact was registered (acceptance date: January 5, 2018).

(3) On May 2, 2018, the Plaintiff filed a litigation seeking a rescission of the Primary JPO Decision (Intellectual Property High Court, 2018 (Gyo-Ke) 10064).

The Intellectual Property High Court rendered a judgment to rescind the Primary JPO Decision (hereinafter referred to as the "Primary IP High Court Judgment") on February 28, 2019, and the judgment subsequently became final and binding.

(4) The JPO then conducted an additional examination concerning the aforementioned trial for invalidation.

The Defendant received the announcement of the trial decision dated September 4, 2019, and requested corrections on November 8, 2019 concerning the group of claims consisting of Claims 1 through 4, to correct Claims 2 through 4, to delete Claim 1, and to correct the Descriptions (hereinafter referred to as "Corrections").

The JPO approved the Corrections and made the decision to the effect that "Patent No. 5463378 shall be maintained with regard to the invention related to Claims 2 through 4 of said patent, and the request for the trial concerning the invention related to Claim 1 of said patent shall be dismissed" (hereinafter referred to as the "JPO Decision") on March 17, 2020, and delivered a certified copy thereof to the Plaintiff on March 26, 2020.

(5) The Plaintiff filed this lawsuit to seek rescission of the part related to Claims 2 through 4 of the Patent of the JPO Decision on April 24, 2020.

2. Claims

The statements in Claims 2 through 4 of the Patent after the Corrections are as stated below (hereinafter the invention related to Claim 2 after the Corrections is referred to as "Corrected Invention 2," etc.; Corrected Inventions 2 through 4 are referred to as "Corrected Inventions"; and the invention related to Claim 2 after the Primary Corrections and before the Corrections is referred to as "Primarily Corrected Invention 2"; parts of the Corrections with the same details as the parts of the Primary Corrections are underlined and parts that are different than the Primary Corrections are double-

underlined.).

[Claim 2]

A device for nucleolytic degradation with the features that it is composed of a methanol gas generation unit including a nozzle that sprays methanol supplied from a methanol tank in mist form, vaporizes the methanol sprayed through the nozzle, and generates methanol gas; a cylindrical unit that is positioned above the methanol gas generation unit, consists of upper and lower parts that are separated from each other by heat-reflective porous metal material, has an air supply unit for supplying air connected to the upper part, serves as a flow channel to transfer the methanol gas generated from the methanol gas generation unit into the upper part by natural convection, and mixes air supplied from the air supply unit with the methanol gas at the predetermined ratio; and a catalyst unit that is located above the cylindrical unit and radicalizes the methanol gas into which air is mixed at the predetermined ratio in the cylindrical unit by catalytic reaction, wherein the catalyst unit is composed of a biogas generation unit that is composed of radical reaction catalysts made from thin metal plates formed into a honeycomb structure by laminating multiple radical reaction catalysts, and that generates composite gas by radicalizing the methanol gas mixed with air by catalytic reaction and contains at least active species derived from methanol (hereinafter referred as "biogas"),

a means of controlling the generated gas amount that controls the amount of gas generated in the biogas generation unit by the amount of supplied air and the amount of methanol,

an exposure unit into which the biogas generated in the biogas generation unit is supplied,

a means of controlling the temperature of the exposed area of the exposure unit,

a means of controlling the humidity of the exposed area of the exposure unit,

an exhaust gas treatment unit that exhausts the biogas supplied to the exposure unit,

a means of controlling the exhaust biogas amount that controls the amount of biogas exhausted from the exposure unit by the exhaust gas treatment unit,

a means of measuring the formaldehyde component concentration of biogas in the exposure unit,

a means for detecting or measuring odor,

wherein the gas concentration information obtained as measurement results by the means of measuring the formaldehyde component concentration is fed back to the means of controlling the generated gas amount, wherein the amount of gas generated in the biogas generation unit is controlled by the means of controlling the generated gas amount by the amount of supplied air and the amount of methanol so that the biogas is at a

constant catalyst self-reaction temperature and concentration in the biogas generation unit, and wherein the chamber gas concentration in the exposure unit is kept constant by controlling the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount, and

a means of detecting differential chamber pressure that is generated by exhaust biogas treatment in the exposure area of the exposure unit by the means of exhaust gas treatment controlled by the means of controlling the exhaust gas amount,

wherein the differential chamber pressure information obtained from detection results through the means of detecting differential chamber pressure is fed back to the means of controlling the exhaust gas amount, and the differential chamber pressure in the exposure unit is kept constant at negative pressure by controlling the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount.

[Claim 3]

A device for nucleolytic degradation as stated in Claim 2 wherein the biogas generation unit has the feature of generating composite radical gas composed of active oxygen containing at least components of methanol, formaldehyde, carbon monoxide, carbon dioxide, hydrogen, and oxygen, and free radicals.

[Claim 4]

A device for nucleolytic degradation as stated in Claim 3 wherein the biogas generation unit has the feature of controlling the self-reaction temperature within the range of 400°C to 500°C.

3. Summary of the Primary JPO Decision and the Primary IP High Court Judgment

(1) Primary JPO Decision

A. The invention stated in Exhibit Ko 1 (Examined Patent Application Publication No. 2010-51692; laid-open disclosure date: March 11, 2010) that was found by the Primary JPO Decision (hereinafter referred to as "Exhibit Ko 1 Invention") is as stated in 4. (2) A. below and common features and differences between Exhibit Ko 1 Invention and Primarily Corrected Invention 2 are as stated below.

(Common features)

It is "a DNA destruction device that is composed of a methanol gas generation unit including a nozzle that sprays methanol supplied from a methanol tank in mist form, vaporizes the methanol sprayed through the nozzle, and generates methanol gas; a cylindrical unit that is positioned above the methanol gas generation unit, consists of upper and lower parts that are separated from each other by heat-reflective porous metal material, has an air supply unit for supplying air connected to the upper part, serves as a flow channel to transfer the methanol gas generated from the methanol gas generation

unit to the upper part by natural convection, and mixes air supplied from the air supply unit with the methanol gas at the predetermined ratio; and a catalyst unit that is located above the cylindrical unit and radicalizes the methanol gas into which air is mixed at the predetermined ratio in the cylindrical unit by catalytic reaction, wherein the catalyst unit is composed of an MR gas generation device that is composed of radical reaction catalysts made from thin metal plates formed into a honeycomb structure by laminating multiple radical reaction catalysts and that generates MR gas by radicalizing the methanol gas mixed with air by catalyst reaction, a means of controlling the generated MR gas amount in the MR gas generation device by the amount of supplied air and the amount of methanol, and a sterilization tank that supplies MR gas generated from the MR gas generation device."

(Difference 1)

Primarily Corrected Invention 2 has a means of controlling the temperature in the sterilization tank, a means of controlling the humidity in the sterilization tank, an exhaust gas treatment unit that exhausts MR gas supplied to the sterilization tank, a means of controlling the amount of MR gas exhausted from the sterilization tank by the exhaust gas treatment unit, a means of measuring the formaldehyde component concentration of MR gas in the sterilization tank, and a means for detecting or measuring odor, wherein the gas concentration information obtained as measurement results by the means of measuring the formaldehyde component concentration is fed back to the means of controlling the generated MR gas amount, the amount of MR gas generated in the MR gas generation device is controlled by the means of controlling the generated MR gas amount by the amount of supplied air and the amount of methanol so that the MR gas is at a constant catalyst self-reaction temperature and concentration in the MR gas generation device, and the chamber gas concentration in the sterilization tank is kept constant by controlling the amount of MR gas exhausted from the sterilization tank by the means of controlling the exhaust gas amount. However, said structure is not stated for Exhibit Ko 1 Invention.

(Difference 2)

Primarily Corrected Invention 2 has a means of detecting differential chamber pressure that is generated from MR gas exhaust treatment in the sterilization tank by the means of exhaust gas treatment that is controlled by the means of controlling the exhaust gas amount, wherein the differential chamber pressure information obtained from detection results by the means of detecting differential chamber pressure is fed back to the means of controlling the exhaust gas amount and it keeps the differential chamber pressure of the sterilization tank constant by controlling the amount of MR gas exhausted

from the sterilization tank by the means of controlling the exhaust gas amount. However, said structure is not stated for Exhibit Ko 1 Invention.

B. Summary of the Primary JPO Decision (however, limited to Grounds for Invalidation 1 [error in the determination of an inventive step of Primarily Corrected Invention 2 that cites Exhibit Ko 1 as the principal cited document])

(A) Regarding Primarily Corrected Invention 2, it is found that Difference 1 could have been easily conceived of by a person skilled in the art; however, it is not found that Difference 2 could have been easily conceived of by a person skilled in the art.

(B) Summary of the determination in the Primary JPO Decision concerning whether Difference 2 could have been easily conceived of by a person skilled in the art is as stated below.

[i] According to the statements in [0143] through [0147] of the Descriptions, "a means of detecting differential chamber pressure" in Primarily Corrected Invention 2 is found to be "a means of detecting differential chamber pressure for detecting that the pressure in the sterilization tank is negative compared to outside the tank and for detecting the differential chamber pressure caused by the MR gas exhaust treatment in the sterilization tank"; [ii] pressure in the sterilization tank is controlled to maintain negative pressure in Primarily Corrected Invention 2. While it is stated in Exhibit Ko 2 (International Publication No. 01/026697 (issued on May 7, 2003)) that pressure in the sterilization tank is controlled to maintain positive pressure, keeping the differential chamber pressure in the sterilization tank constant by controlling the amount of MR gas exhausted from the sterilization tank so that pressure in the sterilization tank is kept at negative pressure cannot be derived from the statements in Exhibit Ko 2. Therefore, even if the invention stated in Exhibit Ko 2 and well-known art with Exhibit Ko 1 Invention are combined, the structure of the "means of detecting differential chamber pressure" of Primarily Corrected Invention 2 related to Difference 2 could not have been easily conceived of by a person skilled in the art.

(2) Outline of Primary IP High Court Judgment

[i] According to statements in the Claims (Claim 2) after the Primary Corrections and statements in the Descriptions, it should be understood that the "differential chamber pressure" that is subject to detection by "a means of detecting differential chamber pressure" of Primarily Corrected Invention 2 is not limited to a specific range of figures if it is a differential pressure between the pressure "in the chamber" (in the exposure area of the exposure unit) and the pressure outside the exposure area and it is not limited to the range of figures of negative pressure. [ii] "A Micro differential pressure detector 56," "a Control unit 58" and "an Exhaust gas amount adjustment solenoid valve 74 and a Fan

82," which comprise the second embodiment of "this invention" in Exhibit Ko 2, are respectively found to be equivalent to "the means of detecting differential chamber pressure," "the means of controlling the exhaust gas amount" to which "the differential chamber pressure information obtained from detection results by the means of detecting differential chamber pressure... is fed back," and "the means of exhaust gas treatment controlled by the means of controlling the exhaust gas amount" in Primarily Corrected Invention 2. Therefore, it is found that structure of Primarily Corrected Invention 2 related to Difference 2 is disclosed in Exhibit Ko 2. [iii] It is found that a person skilled in the art who comes across Exhibits Ko 1 and Ko 2 has the motivation to apply the structure to control the formaldehyde gas concentration, humidity, and temperature in the space subject to sterilization as stated in Exhibit Ko 2 and to keep the room pressure of the area subject to sterilization constant in order to generate sterilization gas at a stable concentration and to obtain fully certifiable sterilization effects in Exhibit Ko 1 Invention. [iv] Therefore, it is found that a person skilled in the art could have easily conceived of the structure of Primarily Corrected Invention 2 related to Difference 2 by applying the aforementioned structure stated in Exhibit Ko 2 to Exhibit Ko 1 Invention based on Exhibits Ko 1 and Ko 2.

4. Summary of the JPO Decision

(1) The Summary of the JPO Decision is as follows: [i] It cannot be said that Corrected Invention 2 could have been easily invented by a person skilled in the art by combining the invention stated in Exhibit Ko 1, which is a publication distributed before the Patent Application, (Exhibit Ko 1 Invention) and Exhibit Ko 2 Invention and common general technical knowledge; since Corrected Invention 3 is an invention that has all the matters defining the invention of Corrected Invention 2 and Corrected Invention 4 is an invention that has all the matters defining the invention of Corrected Invention 3, and it cannot be said that a person skilled in the art could have easily invented Corrected Invention 2, and therefore, it cannot also be said that a person skilled in the art could have easily invented Corrected Inventions 3 and 4; consequently, it cannot be said that a patent cannot be granted to the Corrected Invention based on the provisions of Article 29, paragraph (2) of the Patent Act. [ii] It can be said that the Claims after the Corrections meet the requirements provided for by Article 36, paragraph (6), item (i) of the Patent Act (hereinafter referred to as the "supporting requirements"). [iii] Statements in the Descriptions after the Corrections (hereinafter referred to as the "Corrected Descriptions") meet the requirements provided for by Article 36, paragraph (4), item (i) of the Patent Act (hereinafter referred to as the "enablement requirements").

(2) Exhibit Ko 1 Invention that was found by the JPO Decision and common features and

differences between Corrected Invention 2 and Exhibit Ko 1 Invention are stated below.

A. Exhibit Ko 1 Invention

It is "a sterilization device composed of a methanol gas generation unit including a nozzle that sprays methanol supplied from a methanol tank in mist form, vaporizes the methanol sprayed through the nozzle, and generates methanol gas; a cylindrical unit that is positioned above the methanol gas generation unit, consists of upper and lower parts that are separated from each other by heat-reflective porous metal material, has an air supply unit for supplying air connected to the upper part, serves as a flow channel to transfer the methanol gas generated from the methanol gas generation unit to the upper part by natural convection, and mixes air supplied from the air supply unit with the methanol gas at the predetermined ratio; a catalyst unit that is located above the cylindrical unit and radicalizes the methanol gas into which air is mixed at the predetermined ratio in the cylindrical unit by catalytic reaction, wherein the catalyst unit is composed of an MR gas generation device that is composed of radical reaction catalysts made from thin metal plates formed into a honeycomb structure by laminating multiple radical reaction catalysts and that generates MR gas by radicalizing the methanol gas mixed with air by catalytic reaction, a means of controlling the MR gas concentration in the MR gas generation device by the amount of supplied air and the amount of methanol, and a sterilization tank that implements sterilization using MR gas generated from the MR gas generation device; and a sterilization device that can destroy DNA."

B. Common features and differences

[Common features]

"A device for nucleolytic degradation with the features that it is composed of a methanol gas generation unit including a nozzle that sprays methanol supplied from a methanol tank in mist form, vaporizes the methanol sprayed through the nozzle, and generates methanol gas; a cylindrical unit that is positioned above the methanol gas generation unit, consists of upper and lower parts that are separated from each other by heat-reflective porous metal material, has an air supply unit for supplying air connected to the upper part, serves as a flow channel to transfer the methanol gas generated from the methanol gas generation unit to the upper part by natural convection, and mixes air supplied from the air supply unit with the methanol gas at the predetermined ratio; and a catalyst unit that is located above the cylindrical unit and radicalizes the methanol gas into which air is mixed at the predetermined ratio in the cylindrical unit by catalytic reaction, wherein the catalyst unit is composed of a biogas generation unit that is composed of radical reaction catalysts made from thin metal plates formed into a honeycomb structure by laminating multiple radical reaction catalysts, and that generates

composite gas that is generated by radicalizing the methanol gas mixed with air by catalytic reaction and contains at least active species derived from methanol (hereinafter referred as "biogas"), a means of controlling the generated gas amount in the biogas generation unit by the amount of supplied air and the amount of methanol, and an exposure unit into which biogas generated in the biogas generation unit is supplied."

[Difference 1]

Corrected Invention 2 has the following features: It has a means of controlling the temperature of the exposure area of the exposure unit, a means of controlling the humidity of the exposure area of the exposure unit, an exhaust gas treatment unit that exhausts biogas supplied to the exposure unit, a means of controlling the amount of biogas exhausted from the exposure unit by the exhaust gas treatment unit, a means of measuring the formaldehyde component concentration that measures the concentration of the formaldehyde component of biogas in the exposure unit; a means of detecting differential chamber pressure generated by biogas exhaust treatment in the exposure area of the exposure unit by the means of exhaust gas treatment that is controlled by the means of controlling the exhaust gas amount, wherein the gas concentration information obtained as measurement results by the means of measuring the formaldehyde component concentration is fed back to the means of controlling the generated gas amount, wherein the amount of gas generated in the biogas generation unit is controlled by the amount of supplied air and the amount of methanol by the means of controlling the generated gas amount so that the biogas is at a constant catalyst self-reaction temperature and concentration in the biogas generation unit, wherein the chamber gas concentration is kept constant in the exposure unit by controlling the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount; and it feeds back the differential chamber pressure information obtained from detection results by the means of detecting differential chamber pressure to the means of controlling the exhaust gas amount and it keeps the differential chamber pressure of the exposure unit at constant negative pressure by controlling the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount. However, this structure is not stated for Exhibit Ko 1 Invention.

[Difference 2]

Corrected Invention 2 has a means for detecting or measuring odor; however, there is no statement on such structure for Exhibit Ko 1 Invention.

(3) Summary of the JPO Decision related to the allegation of the Plaintiff is stated below.

A. Grounds for Invalidation 1 (Article 123, paragraph (1), item (ii) of the Patent Act)

[i] A person skilled in the art who comes across Exhibits Ko 1 and Ko 2 has the

motivation to apply the structure to control the formaldehyde gas concentration, humidity, and temperature of the area subject to sterilization as indicated in Exhibit Ko 2 respectively at the predetermined values, and to keep the room pressure of the area subject to sterilization constant in order to generate sterilization gas at a stable concentration and to obtain fully certifiable sterilization effects in Exhibit Ko 1 Invention. [ii] However, it is found that, out of the structure of Corrected Invention 2 related to Difference 1, Exhibit Ko 2 discloses that "the invention has the following features: It is composed of a means of controlling the temperature of the exposure area of the exposure unit, a means of controlling the humidity of the exposed area of the exposure unit, an exhaust gas treatment unit for exhausting the biogas supplied to the exposure unit, a means of controlling the amount of biogas exhausted from the exposure unit by the exhaust gas treatment unit, a means of measuring the formaldehyde component concentration of biogas in the exposure unit, a means of detecting differential chamber pressure caused by biogas exhaust treatment in the exposure area of the exposure unit by the means of exhaust gas treatment that is controlled by the means of controlling the exhaust gas amount, wherein the gas concentration information obtained as measurement results by the means of measuring the formaldehyde component concentration is fed back to the means of controlling the generated gas amount, wherein the amount of gas generated in the biogas generation unit is controlled by the amount of supplied air and the amount of methanol by the means of controlling the generated gas amount so that the biogas is at a constant catalyst self-reaction temperature and concentration in the biogas generation unit, and the chamber gas concentration in the exposure unit is kept constant by controlling the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount; it feeds back the differential chamber pressure information obtained from detection results by the means of detecting differential chamber pressure, it controls the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount, and thereby it keeps the differential chamber pressure in the exposure unit constant." However, Exhibit Ko 2 does not disclose that "the differential chamber pressure of the exposure unit is maintained at constant negative pressure." Therefore, the structure of Corrected Invention 2 related to Difference 1 is not disclosed in Exhibit Ko 2. Even by applying the structure stated in Exhibit Ko 2 to Exhibit Ko 1 Invention, a person skilled in the art could not have easily conceived of the structure of Corrected Invention 2 related to Difference 1. [iii] The demandant (Plaintiff) alleged that it was common general technical knowledge that MR gas, etc. may be used in conditions where treatment room pressure is at negative pressure against the pressure outside the treatment room when using MR gas, etc. inside the treatment room, and therefore, taking into consideration the

statements in Exhibit Ko 2 in Exhibit Ko 1 Invention, it was easy to control the differential chamber pressure at negative pressure. However, controlling the pressure in the treatment room where MR gas, etc. is used at negative pressure against the pressure outside the treatment room is not disclosed in any of the documents alleged by the demandant (Exhibits Ko 23 through Ko 27). Therefore, based on these documents, it cannot be said that the aforementioned points were common general technical knowledge, and in Exhibit Ko 1 Invention, a person skilled in the art could not have easily conceived of controlling the differential chamber pressure at negative pressure based on the statements in Exhibit Ko 2.

B. Grounds for Invalidation 2 (Article 123, paragraph (1), item (iv) of the Patent Act)

Even if none of the spectrum diagrams of "90 min." in Figure 19B and Figure 19C of the Corrected Descriptions fall under the spectrum of criteria shown in Figure 18 and, according to the spectrum diagram indicated by the demandant (Plaintiff), it is unknown whether nucleic acid could have been completely dissolved in 90 minutes of exposure time with these sample amounts, it can be understood from the other spectrum diagrams shown in Figure 19B and Figure 19C that nucleic acid can be completely dissolved in a shorter period than 90 minutes with any of these sample amounts. Therefore, it can be said that the Corrected Invention can resolve the problem to be solved by the invention and the statements in the Corrected Descriptions meet the supporting requirements.

C. Grounds for Invalidation 3 (Article 123, paragraph (1), item (iv) of the Patent Act)

The allegation of the demandant (Plaintiff) is based on the premises that there are cases where the Corrected Invention cannot fully dissolve nucleic acid even after 90 minutes have elapsed from the start of treatment. However, there is an error in the premises as indicated in B. above, and the statements in the Corrected Descriptions meet the enablement requirements.

(omitted)

No. 4 Judgment of this Court

1. Statements in the Corrected Descriptions

The Corrected Descriptions contain statements as shown in Attachment 1. According to the statements, it is found that the following matters are disclosed in the Corrected Descriptions in relation to the Corrected Invention.

(1) A conventional method of nucleolytic degradation using a gas-phase substance (MR gas) derived from radical species methanol required 60 minutes of exposure time or longer in the range of temperature of 50℃ or higher, and effects and efficacy were

demonstrated with the formaldehyde component concentration being 2000ppm or higher; however, there were the following problems: in practical working conditions, the demanded temperature range was from normal temperature to body temperature and demonstration of effects and efficacy in a short period of time according to sample types was demanded ([0009], [0011], and [0012]).

(2) "This invention" aims to provide a device for nucleolytic degradation that can define conditions to demonstrate high efficacy in a short period of time according to sample types ([0013]), and it adopted the following structure as a means to solve the aforementioned problems: the device is composed of a methanol gas generation unit, a biogas generation unit that radicalizes the methanol gas into which air is mixed by catalyst reaction and generates composite gas that contains at least active species derived from methanol, a means of controlling the generated gas amount that controls the amount of gas generated in the biogas generation unit by the amount of supplied air and the amount of methanol, an exposure unit into which biogas generated from the biogas generation unit is supplied, a means of controlling the temperature of the exposure area, a means of controlling the humidity of the exposure area, an exhaust gas treatment unit that exhausts biogas supplied to the exposure unit, a means of controlling the amount of biogas exhausted from the exposure unit, a means of measuring the formaldehyde component concentration of biogas in the exposure unit, a means of detecting or measuring odor, a means of detecting differential chamber pressure caused by the exhaust gas treatment of biogas in the exposure area by the means of exhaust gas treatment controlled by the means of controlling the exhaust gas amount, wherein the gas concentration information obtained as measurement results by the means of measuring the formaldehyde component concentration is fed back to the means of controlling the generated gas amount, wherein the amount of gas generated in the biogas generation unit is controlled by the amount of supplied air and the amount of methanol by the means of controlling the generated gas amount, and wherein the chamber gas concentration of the exposure unit is kept constant by controlling the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount; and it feeds back the differential chamber pressure information obtained from detection results by the means of detecting differential chamber pressure to the means of controlling the exhaust gas amount and it keeps the differential chamber pressure of the exposure unit at constant negative pressure by controlling the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount (structure of Corrected Invention 2) ([0016], [0017]).

Based on this structure, "this invention" demonstrates the effect that it can perform quantitative control of the temperature, humidity, and concentration in the exposure area

of the exposure unit by feedback control and can define conditions to demonstrate high efficacy in a short period of time according to sample types ([0021], [0196]).

2. Statements in Exhibit Ko 1

Exhibit Ko 1 contains statements as shown in Attachment 2. According to the statements, it is found that the following matters have been disclosed related to Exhibit Ko 1 Invention.

(1) In the case of a conventional MR gas generation device equipped with a catalyst unit with the size of approximately 150mm to 180mm, it was difficult to keep the temperature necessary for the radicalizing reaction of methanol gas constant and it was impossible to generate MR gas at a constant concentration. Therefore, it was necessary to equip an electric heater for heating; however, there were the problems that the size of the catalyst unit necessarily became large and this made it difficult to downsize the MR gas generation device to increase convenience ([0006], [0007]).

(2) "This invention" was proposed in consideration of these conventional problems and it aims to keep the catalyst reaction temperature for radicalization constant, to generate sterilization gas at a stable concentration, and to provide a sterilization gas generation device that can be downsized ([0008]).

The inventors of "this invention" discovered that using a catalyst that has a honeycomb structure would make it possible to keep catalyst reaction temperature constant for radicalization and completed "this invention" ([0009]).

"This invention" adopted a structure using radical reaction catalysts made from thin metal plates formed into a honeycomb structure and thereby increased the surface area of the catalyst unit and increased reaction efficiency, making it possible to cause a self-reaction where the catalyst reaction temperature is kept constant and to generate MR gas at a stable concentration. Furthermore, improvement of reaction efficiency in the catalyst unit made it possible to downsize the catalyst unit and downsize the sterilization treatment device itself, thereby demonstrating the effect of increasing convenience ([0013]).

3. Statements in Exhibit Ko 2

Exhibit Ko 2 contains statements as shown in Attachment 3. According to the statements, it is found that the following matters have been disclosed related to Exhibit Ko 2.

(1) In order to obtain fully certifiable sterilization effects from the formaldehyde gas sterilization device, it is necessary to control the concentration, humidity, and temperature of formaldehyde gas in the area subject to sterilization and to control room pressure since the area subject to sterilization is a sealed area (room) (Attachment 3, 2 (2)).

"This invention" is composed of the following devices as a means of solving the

aforementioned problems: a formaldehyde gas supply and exhaust device that supplies and exhausts formaldehyde gas into and from the sealed room and a room pressure adjustment device that adjusts room pressure; the formaldehyde gas supply and exhaust device is composed of a formaldehyde gas generator, a formaldehyde gas humidity adjuster, a formaldehyde gas temperature adjuster, a gas carrier that transports and introduces formaldehyde gas into the room, an exhaust gas processor that treats exhaust gas exhausted from the room, an exhaust gas ejector, and a control unit that controls the formaldehyde gas concentration, humidity, and temperature in the room at the predetermined concentration, humidity, and temperature; the room pressure adjustment device is composed of a unit that supplies air outside the room into the room, a unit that exhausts room air to outside the room, a means of detecting differences in pressures for detecting differences in pressures between inside and outside the room, a means of controlling the air supply unit and exhaust air unit based on the values detected by the means of detecting differences in pressures, and a means of outputting the control status of the aforementioned room pressure based on the aforementioned detected values.

Based on the structure, the "invention" can control the formaldehyde gas concentration, humidity, and temperature of the area subject to sterilization respectively at the predetermined values and can keep room pressure constant even in cases where room air expands due to increases in room temperature. Therefore, fully certifiable sterilizing effects can be obtained (Attachment 3, 2. (3) and (4)).

(2) The second embodiment of "this invention" (Figure 2) is a formaldehyde gas sterilization device that is composed of a Formaldehyde gas supply and exhaust device 4 and a Room pressure adjustment device 6. The Formaldehyde gas supply and exhaust device 4 has a Controller 24 that controls a Formaldehyde gas generator 36, a Temperature adjuster 34, a Humidity adjuster 32, and Pumps 26 and 28, based on the values of the formaldehyde gas concentration, humidity, and temperature in the Area subject to sterilization 100 that were obtained from a Concentration sensor 12, a Humidity sensor 14, and a Temperature sensor 16. The Room pressure adjustment device 6 has a Control unit 58 that controls an Air supply unit 52 and a Gas exhaust unit 54 based on the values detected by a Minor differential pressure detector 56 that detects differences in the pressure inside the room and the pressure outside the room (Attachment 3, 2. (5) and (7)).

The formaldehyde gas sterilization device related to the second embodiment maintains room pressure at positive pressure by the Control unit 58 of the Room pressure adjustment device 6, "while the predetermined time, room temperature, humidity, and formaldehyde gas concentration are within a temperature range of 20℃ to 40℃, a humidity range of 50% to 90% (relative humidity), and a formaldehyde gas concentration

of 160ppm or higher, respectively" (Attachment 3, 2. (9)).
4. Common general technical knowledge, etc. on or around the date of the Patent Application
(1) A. Exhibits Ko 23 and Ko 82 through Ko 84 that were distributed before the date of the Patent Application contain statements as shown in Attachment 4, respectively.
B. Combining the statements of the documents mentioned in A. above, it can be found that it had been well-known art on or around the date of the Patent Application that, in cases where there are substances that are harmful to the human body in a room, such as in biohazard facilities, chemical hazard facilities, etc., the room pressure should be controlled at negative pressure against outside pressure so that the substances do not leak from inside to outside the room, and that in cases of sterilizing inside a room using ozone gas that is harmful to the human body, room pressure should be controlled at negative pressure against outside pressure so that ozone gas does not leak from inside to outside the room.
(2) A. Exhibits Ko 81, Ko 85, Ko 88, Ko 94, and Ko 95 that were distributed before the date of the Patent Application contain statements as shown in Attachment 5, respectively.
B. Combining the statements in the documents mentioned in A. above, it can be found that it had been well-known on or around the date of the Patent Application that formaldehyde gas is harmful to human body and it had been common general technical knowledge on or around the date of the Patent Application that when using formaldehyde gas in a treatment room for the purpose of sterilization and disinfection, there are cases where it is used under conditions where the treatment room pressure is set at negative pressure against the pressure outside the treatment room.
5. Grounds for Rescission 1-1 (error in the determination of an inventive step in Corrected Invention 2 that cites Exhibit Ko 1 as the principal cited document)
(1) When the judgment to rescind a JPO decision becomes final and binding in a litigation seeking a rescission of a JPO decision concerning a patent invalidation trial case, the hearing officers are required to make an additional examination and decision concerning the trial case in accordance with the provisions of Article 181, paragraph (2) of the Patent Act. A litigation to rescind a trial decision is subject to the application of the Administrative Case Litigation Act and therefore the aforementioned judgment rescinding a trial decision binds the second-round examination and trial decision pursuant to the provisions of Article 33, paragraph (1) of the Administrative Case Litigation Act, and the binding effect applies to fact finding and legal findings that are essential for deriving the main text of the judgment. Therefore, it is not allowed to make a finding or determination that infringes on the aforementioned finding and determination of the

judgment rescinding a trial decision (the judgment of the Third Petty Bench of the Supreme Court rendered on April 28, 1992, Minshu Vol. 46, No. 4, at 245) and a determination in a litigation seeking a rescission of a trial decision should also be made based on the above.

As stated in No. 2, 3. (2) above, the Primary IP High Court Judgment determined that [i] "a Micro differential pressure detector 56," "a Control unit 58" and "an Exhaust gas amount adjustment solenoid valve 74 and a Fan 82," which comprise the second embodiment of "this invention" in Exhibit Ko 2, are respectively found to be equivalent to "the means of detecting differential chamber pressure," "the means of controlling the exhaust gas amount" to which "the differential chamber pressure information obtained from detection results by the means of detecting differential chamber pressure... is fed back," and "the means of exhaust gas treatment controlled by the means of controlling the exhaust gas amount" in Invention 2 before the Corrections; therefore, it can be said that the structure of the invention of Claim 2 before the Corrections related to Difference 2 is disclosed; [ii] it is found that a person skilled in the art who comes across Exhibits Ko 1 and Ko 2 has the motivation to apply the structure to generate sterilization gas at a stable concentration in Exhibit Ko 1 Invention, to control the formaldehyde gas concentration, humidity, and temperature in the area subject to sterilization respectively at the predetermined values as stated in Exhibit Ko 2 in order to obtain fully certifiable sterilization effects, and to keep the room pressure of the area subject to sterilization constant; and [iii] therefore, a person skilled in the art could have easily conceived of the structure of the invention related to Claim 2 before the Corrections related to Difference 2 by applying the aforementioned structure stated in Exhibit Ko 2 to Exhibit Ko 1 Invention.

In the trial procedures after the Primary IP High Court Judgment became final and binding, the Defendant corrected the wording as stated in No. 2, 2. above to "keeps the differential chamber pressure of the exposure unit constant at negative pressure" in Claim 2, in addition to the details of the Primary Corrections (the double-lined part is the corrected part in question), and the JPO Decision, as stated in No. 2, 4. (2) B. above, deemed a combination of structures of Difference 1 (excluding Difference 2 that is found by the JPO Decision) and Difference 2 in the Primary JPO Decision as Difference 1 and added to Difference 1 the point "the following features: ... to maintain the differential chamber pressure of the exposure unit at constant negative pressure," which is a structure added in Corrected Invention 2 by the Corrections.

Based on the aforementioned development, concerning the determination of an inventive step in Corrected Invention 2, on the assumption that the structure of Difference

2, which was found by the Primary JPO Decision, is disclosed, a determination should be made as to whether the structure of Corrected Invention 2 that "maintains the differential chamber pressure in the exposure unit at constant negative pressure" could have been easily conceived of by a person skilled in the art.

The examination based on the assumption of the above follows.

(2) Disclosed matters in Exhibit Ko 2

The detailed explanation of the invention in Exhibit Ko 2 [i] contains statements that the formaldehyde gas sterilization device in Exhibit Ko 2 Invention has a means of detecting differences in pressures between inside and outside the room and a means of controlling the air supply unit and gas exhaust unit based on the values detected by the means of detecting differences in pressures, and therefore it can keep room pressure constant even if room air expands due to increases in room temperature (Attachment 3, 2. (4)) and [ii] discloses that, as a "second embodiment" that is one of "the best embodiments of the invention," it is composed of a Minor differential pressure detector 56 that detects differences in pressures inside and outside the room and a Control unit 58 that controls an Air supply unit 52 and Gas exhaust unit 54 based on the values detected by the Minor differential pressure detector 56, and that the Control unit 58 controls an Air supply amount adjustment solenoid valve 62, a Fan 66, an Exhaust gas amount adjustment solenoid valve 74, and a Fan 82, etc. based on the values detected by the Minor differential pressure detector 56; and the following modes are disclosed that a Controller 24 adjusts the room temperature and humidity that are obtained from a Humidity sensor 14 and a Temperature sensor 16 to be the predetermined temperature range of 20℃ to 40℃ and humidity range of 50% to 90% (relative humidity) respectively by a Humidity adjuster 32 and a Temperature adjuster 32, maintains the predetermined time by adjusting formaldehyde gas concentration so that it is maintained at 160ppm or higher by a Formaldehyde gas generator 36 and a Pump 26, and maintains the room pressure at positive pressure (10Pa to 20Pa) by a room pressure adjustment device while the predetermined time, room temperature, humidity, and formaldehyde gas concentration are maintained at the aforementioned figures; and it contains the following statements that since differences in pressures inside and outside the room can always be maintained at 10Pa to 20Pa by a Room controlling device 6, in cases of sterilizing a room with formaldehyde gas, even if the volume of room air is increased due to increases in room temperature, formaldehyde gas can be prevented from leaking outside the room without being treated because formaldehyde gas is exhausted after treatment in an Air processing device 76 (Attachment 3, 2. (7) through (9)).

As mentioned above, the structure that is disclosed in Exhibit Ko 2 to maintain

pressure inside the room, which is an area subject to sterilization, at positive pressure by a room pressure adjustment device is for the second embodiment. In addition, as matters defining the invention, concerning a room adjustment device for adjusting room pressure, the Claim (Claim 3) in Exhibit Ko 2 only states that room pressure is adjusted by a means of detecting differences in pressures between inside and outside the room and by a means of control based on the values detected by the means of detecting differences in pressures, and it does not specify that the area subject to sterilization is controlled at positive pressure. Based on this fact, the technical meaning of Exhibit Ko 2 Invention is, as stated in 3. (1) above, that it can control the formaldehyde gas concentration, humidity, and temperature in the area subject to sterilization respectively at the predetermined values, can maintain constant room pressure even in cases where room air expands due to increases in room temperature, and can demonstrate fully certifiable sterilizing effects. It should be said that the form of maintaining room pressure at positive pressure (10Pa to 20Pa) by a room pressure adjustment device is merely one of the embodiments.

In consideration of the instructions in the Primary IP High Court Judgment that "a Minor differential pressure detector 56," "a Control unit 58," and "an Exhaust gas amount adjustment solenoid valve 74 and a Fan 82," which comprise the second embodiment of "this invention" in Exhibit Ko 2, are respectively found to be equivalent to "the means of detecting differential chamber pressure," "the means of controlling the exhaust gas amount" to which the "differential chamber pressure information obtained from detection results by the means of detecting differential chamber pressure... is fed back," and "the means of exhaust gas treatment that is controlled by the means of controlling the exhaust gas amount" in Invention 2 before the Corrections, it is found that Exhibit Ko 2 discloses the matters that a means for detecting differential chamber pressure is equipped, that the differential chamber pressure information that is obtained from detection results by the means of detecting differential chamber pressure is fed back to the means of controlling the exhaust gas amount, and that pressure in the area subject to sterilization (inside the chamber) is kept constant by controlling the amount of formaldehyde gas exhausted from the area subject to sterilization by the means of controlling the exhaust gas amount.

(3) Whether Difference 1 could have been easily conceived of by a person skilled in the art

As mentioned in 2. (2) above, Exhibit Ko 1 discloses that the purpose is to keep the catalytic reaction temperature for radicalization constant and to provide a sterilization gas generation device to generate MR gas at a stable concentration. As mentioned in 3. (1) above, Exhibit Ko 2 discloses that fully certifiable sterilizing effects can be obtained because the adoption of the structure of the formaldehyde gas sterilization device of

Exhibit Ko 2 Invention makes it possible to control the formaldehyde gas concentration, humidity, and temperature in the area subject to sterilization respectively at the predetermined values, and also to keep room pressure constant even in cases where room air expands due to increases in room temperature. Based on the above, a person skilled in the art who comes across Exhibits Ko 1 and Ko 2 has the motivation to apply the structure to control the formaldehyde gas concentration, humidity, and temperature in the area subject to sterilization as stated in Exhibit Ko 2 respectively at the predetermined values and to keep the room pressure of the area subject to sterilization constant for the purpose of generating sterilization gas at a stable concentration and obtaining fully certifiable sterilization effects in Exhibit Ko 1 Invention.

Based on the above, on or around the date of the Patent Application, it had been well-known art that, in cases where there are substances that are harmful to the human body in a room, such as in biohazard facilities, chemical hazard facilities, etc., the room pressure should be controlled at negative pressure against outside pressure so that the substances do not leak from inside to outside the room, and that in cases of sterilizing inside a room using ozone gas that is harmful to the human body, room pressure should be controlled at negative pressure against outside pressure so that ozone gas does not leak from inside to outside the room (4. (1) above). In addition, when using formaldehyde gas for the purpose of sterilization and disinfection, it is also common general technical knowledge that there are cases where formaldehyde gas is used under conditions where pressure inside the treatment room is at negative pressure against the pressure outside the treatment room (4. (2) above). Therefore, when applying the matters disclosed in Exhibit Ko 2 to Exhibit Ko 1 Invention, in light of the conditions of the space subject to sterilization and the purpose, and in consideration of the aforementioned well-known art and common general technical knowledge, it can be said that a person skilled in the art could have easily conceived of maintaining the pressure in the space subject to sterilization at negative pressure. In addition, there is no evidence to find that any significant effects that a person skilled in the art could not predict were obtained by applying a structure to maintain "the differential chamber pressure at negative pressure" in the area subject to sterilization as a result of considering and applying well-known art and common general technical knowledge to Exhibit Ko 1 Invention and the matters disclosed in Exhibit Ko 2.

Consequently, based on the matters stated in Exhibits Ko 1 and Ko 2, well-known art, and common general technical knowledge, an inventive step also cannot be found in the structure of Corrected Invention 2 "to maintain the differential chamber pressure of the exposed unit at constant negative pressure" out of Difference 1.

(4) Allegation of the Defendant

A. The Defendant alleged as follows: As it is stated in No. 3, 1. (2) A. through C. above, Corrected Invention 2 assumes that the exposure unit of biogas is a narrow area, such as a chamber, etc., and therefore, detailed control is required for the temperature, humidity, biogas concentration, and differential chamber pressure of the exposure unit; since the invention adopted a structure wherein it can adjust the generated gas and exhaust gas amounts based on two pieces of information, i.e., the chamber gas concentration information and the differential chamber pressure information, wherein it can conduct quantitative control of the temperature, humidity, concentration, and differential chamber pressure of the exposure area of the exposure unit by feedback control to keep both the chamber gas concentration and the differential chamber pressure constant, thereby maintaining the differential chamber pressure of the exposure unit at constant negative pressure by such feedback control, the technical meaning to "maintain the differential chamber pressure of the exposure unit at constant negative pressure" should be determined together with the structure of conducting the feedback control; the documents listed by the Plaintiff only state that the subject room pressure is to be maintained at negative pressure when sterilizing the room with ozone or another sterilization gas and that the treatment room pressure is to be maintained at negative pressure against the pressure outside the room when using MR gas, etc. in the treatment room for the purpose of sterilization and disinfection; and there is no statement or suggestion to conduct the feedback control as stated for Corrected Invention 2.

However, as found by the Primary IP High Court Judgment, Exhibit Ko 2 discloses the structure of Difference 2 that was found by the Primary JPO Decision out of the structure of Corrected Invention 2 (the structure that the invention has a means of detecting differential chamber pressure that is caused by MR gas exhaust treatment in the sterilization tank by the means of exhaust gas treatment controlled by the means of controlling the exhaust gas amount, wherein the differential chamber pressure information obtained from detection results by the means of detecting differential chamber pressure is fed back to the means of controlling and processing exhaust gas, and it keeps the differential chamber pressure of the sterilization tank constant by controlling the amount of MR gas exhausted from the sterilization tank by the means of controlling the exhaust gas amount). The court's determination on this point has binding force as mentioned in (1) above. The Defendant also admitted that the feedback control, which was alleged by the Defendant as the technical meaning of Corrected Invention 2, is disclosed in Exhibit Ko 2 (No. 3, 1. (2) C. (A) above). As mentioned in (2) above, Exhibit Ko 2 discloses the control to keep the pressure of the area subject to sterilization (chamber) constant. If the pressure control is applied to Exhibit Ko 1 Invention as control

to maintain the pressure at constant negative pressure in consideration of the well-known art (4. (1) above) and common general technical knowledge (4. (2) above), a person skilled in the art could have easily conceived of the structure "to control the differential chamber pressure at constant negative pressure" of Difference 1, as stated in (3) above.

Therefore, the aforementioned allegation of the Defendant is groundless.

B. The Defendant alleged, as stated in No. 3, 1. (2) D. above, that Exhibit 2 aims to control pressure at positive pressure; the technical meaning is, as it is found by the JPO Decision, to prevent air from entering from outside into the treatment room during sterilization and to maintain the cleanliness of the treatment room; if the positive pressure control as stated in Exhibit Ko 2 is changed to negative pressure control, it upsets the technical meaning to maintain the cleanliness of the area subject to sterilization in Exhibit Ko 2 and therefore it is a disincentive to changing the differential chamber pressure in Exhibit Ko 2 from positive pressure control to negative pressure control.

However, although Exhibit Ko 2 contains a statement concerning a mode to maintain room pressure at positive pressure (10Pa to 20Pa) using the room pressure adjustment device, it is stated merely as one of the embodiments of the invention and the technical meaning of the device related to Exhibit Ko 2 is to demonstrate effects wherein the formaldehyde gas concentration, humidity, and temperature of the area subject to sterilization can be controlled respectively at the predetermined values and the room pressure can be kept constant even in cases where room air expands due to increases in room temperature, and fully certifiable sterilizing effects can be obtained, as mentioned in (2) above. Based on such technical meaning, it is not a disincentive to controlling the differential chamber pressure at negative pressure by using the room pressure adjustment device in Exhibit Ko 2.

The JPO Decision determined that "Exhibit Ko 23 is public information related to another patent application of the identical inventor, for which the application date is the same as the priority date of the patent application related to Exhibit 2. Since the treatment room pressure of the device that uses formalin gas, etc. for sterilization is controlled at positive pressure in both cases, it is strongly presumed that the basic idea is common." However, it is well-known art to control room pressure at negative pressure against the pressure outside the room so that ozone gas does not leak from inside to outside the room when sterilizing inside a room using ozone gas that is harmful to the human body (4. (1) B. above). Concerning a sterilization device using formaldehyde gas (formalin gas) that is also harmful to the human body, although there is no statement or suggestion of the technical meaning to control a room pressure adjustment device at positive pressure in Exhibit Ko 2, it cannot be found that the technical meaning of positive pressure control,

which is stated in Exhibit Ko 23 related to another patent application, is the technical meaning of the positive pressure control in Exhibit Ko 2 on the grounds that the application was filed on the same date as the priority date of Exhibit Ko 2 by the same inventor as Exhibit Ko 2. Therefore, it must be said that the determination of the JPO Decision was wrong in that it found the technical meaning in a case where the room pressure control device in Exhibit Ko 23 works as a positive pressure control device as the technical meaning related to the device in Exhibit Ko 2.

Therefore, there are no grounds in the Defendant's allegation that it is a disincentive to changing the differential chamber pressure in Exhibit Ko 2 from positive pressure control to negative pressure control based on the technical meaning of Exhibit Ko 2 Invention that was found by the JPO Decision.

(5) Summary

Based on the above, it is found that a person skilled in the art could have easily conceived of the structure of Corrected Invention 2 related to Difference 1.

Consequently, since there was an error in the determination of the JPO Decision, there are grounds for the Plaintiff's Grounds for Rescission 1-1.

6. Grounds for Rescission 1-2 (error in the determination of inventive steps in Corrected Inventions 3 and 4 that cite Exhibit Ko 1 as the principal cited document)

The JPO Decision determined as follows: Corrected Invention 3 is an invention citing Corrected Invention 2 and Corrected Invention 4 is an invention citing Corrected Invention 3; since it cannot be said that a person skilled in the art could have easily invented Corrected Invention 2, it cannot also be said that a person skilled in the art could have easily invented Corrected Inventions 3 and 4.

However, as mentioned in 5. above, there is an error in the determination of the JPO Decision concerning whether Corrected Invention 2 could have been easily conceived of by a person skilled in the art. As long as it is found that Corrected Invention 2 could have been easily conceived of by a person skilled in the art, there is an error in the aforementioned determination of the JPO Decision that denied that Corrected Inventions 3 and 4 could have been easily conceived of by a person skilled in the art only on the grounds that Corrected Invention 2 could not have been easily conceived of by a person skilled in the art.

Consequently, there are reasons for the Plaintiff's Grounds for Rescission 1-2.

7. Conclusion

Based on the above, there are reasons for the Plaintiff's Grounds for Rescission 1-1 and 1-2 and therefore, the JPO Decision should be rescinded without having to make determinations on the other remaining points.

Consequently, the judgment shall be rendered as indicated in the main text.

Intellectual Property High Court, Fourth Division
Presiding judge: KANNO Masayuki
Judge: NAKAMURA Kyo
Judge: OKAYAMA Tadahiro

(Attachment 1)
[Detailed explanation of the invention]
[Technical field]
[0001]

The invention relates to a device for nucleolytic degradation for performing nucleolytic degradation using a biogas containing an active species derived from methanol.

[Background art]
[0002]

In conducting a test, study, etc. related to biochemistry, etc., if nucleic acids that are sparingly water-soluble polymers are unnecessarily attached to the surface of a solid, such as a container that is used, etc., or are mixed unnecessarily in a liquid, such as a reaction solution, etc., or if cells are unnecessarily attached to the surface of a solid, such as a container, etc., or are mixed unnecessarily in a liquid, such as a reaction solution, etc., it may have a major impact on the test, study, etc.

[0003]

A sterilization system using radical (methanol radical: MR) gas generated from methanol by catalytic reaction has a sterilizing power superior to ethylene oxide gas (EOG) or ozone, etc. which have been widely used as a gas for sterilizing medical devices, etc. It has been confirmed that the system is free from persistence or corrosiveness and has excellent permeability and diffusivity. And the system has therefore been drawing attention from many fields today.

[0004]

Biogas is a radical composite gas with a strong sterilizing effect generated from methanol by a catalyst, has high permeability, and can sterilize the inside of a sterilization target even at atmospheric pressure. Since it is not a contact sterilization mist, it has excellent features, such as being free from metal corrosion or plastic deterioration (corrosiveness). It can also be used with non-sterile materials and does not remain in sterilization targets (residual properties). It has a wide diffusivity and can expose every corner evenly, penetrate fine clearances, and expose precision equipment and electronic equipment, etc. even when they are being charged. It has a strong safety record.

[0009]

In addition, it has been proposed as a method to resolve nucleic acid effectively in conditions other than the liquid phase (non-wet state) to irreversibly dissolve and inactivate nucleic acid under temperatures where nucleic acid can survive by using a gas phase substance (MR gas) derived from radical species methanol containing at least a

hydroxymethyl radical, a hydroperoxyl radical, a hydrogen radical, and a hydroxyl radical (for example, see Patent Document 3).

[Outline of the invention]

[Problems to be solved by the invention]

[0011]

However, in the conventional method of degrading nucleic acids using a non-wet nucleic acid degrading agent that is proposed in Patent Document 3, 60 minutes of exposure time or longer was required in the range of temperature of 50°C or higher, and effects and efficacy were shown (demonstrated) with the formaldehyde component concentration being 2000ppm or higher.

[0012]

However, in practical working conditions, the demanded temperature range was from normal temperature to body temperature and demonstration of effects and efficacy in a short period of time was demanded.

[0013]

Therefore, in consideration of the aforementioned conventional situation, an object of this invention is to provide a device for nucleolytic degradation that can define conditions for demonstrating high efficacy in a short period of time according to sample types.

[0014]

This device for nucleolytic degradation also covers nucleic acid (DNA, RNA) floating in space as an exposure target while considering it as contamination.

[Means of solving problems]

[0017]

This invention is a device for nucleolytic degradation that is composed of a methanol gas generation unit including a nozzle that sprays methanol supplied from a methanol tank in mist form, vaporizes the methanol sprayed through the nozzle, and generates methanol gas; a cylindrical unit that is positioned above the methanol gas generation unit, consists of upper and lower parts that are separated from each other by heat-reflective porous metal material, has an air supply unit for supplying air connected to the upper part, serves as a flow channel to transfer the methanol gas generated from the methanol gas generation unit into the upper part by natural convection, and mixes air supplied from the air supply unit with the methanol gas at the predetermined ratio; and a catalyst unit that is located above the cylindrical unit and radicalizes the methanol gas into which air is mixed at the predetermined ratio in the cylindrical unit by catalytic reaction, wherein the catalyst unit is composed of a biogas generation unit that is composed of radical reaction catalysts made from thin metal plates formed into a honeycomb structure by laminating

multiple radical reaction catalysts, and that generates composite gas by radicalizing methanol gas mixed with air by catalytic reaction and contains at least active species derived from methanol (hereinafter referred as "biogas"), a means of controlling the generated gas amount that controls the amount of gas generated in the biogas generation unit by the amount of supplied air and the amount of methanol, an exposure unit into which the biogas generated in the biogas generation unit is supplied, a means of controlling the temperature of the exposed area of the exposure unit, a means of controlling the humidity of the exposed area of the exposure unit, an exhaust gas treatment unit that exhausts the biogas supplied to the exposure unit, a means of controlling the exhaust biogas amount that controls the amount of biogas exhausted from the exposure unit by the exhaust gas treatment unit, a means of measuring the formaldehyde component concentration that measures the formaldehyde component concentration of biogas in the exposure unit, and a means of detecting or measuring odor, wherein the gas concentration information obtained as measurement results by the means of measuring the formaldehyde component concentration is fed back to the means of controlling the generated gas amount, wherein the generated gas amount in the biogas generation unit is controlled by the means of controlling the generated gas amount by the amounts of supplied air and the amount of methanol, and wherein the chamber gas concentration of the exposure unit is kept constant by controlling the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount, and a means of detecting differential chamber pressure that is generated by biogas exhaust treatment in the exposure area of the exposure unit by the means of exhaust gas treatment controlled by the means of controlling the exhaust gas amount, wherein the differential chamber pressure information obtained from detection results by the means of detecting differential chamber pressure is fed back to the means of controlling the exhaust gas amount and the differential chamber pressure in the exposure area is kept constant at negative pressure by controlling the amount of biogas exhausted from the exposure unit by the means of controlling the exhaust gas amount.

[0019]

In addition, in the device for nucleolytic degradation related to this invention, the biogas generation unit can generate composite radical gas that is composed of active oxygen containing at least the components of methanol, formaldehyde, carbon monoxide, carbon dioxide, hydrogen, and oxygen, and free radicals.

[0020]

Furthermore, in the device for nucleolytic degradation related to this invention, the biogas generation unit can control the self-reaction temperature to be in the range of

400°C to 500°C, for example.

[Effects of the invention]

[0021]

The device for nucleolytic degradation related to this invention can perform quantitative control of the temperature, humidity, and concentration in the exposure area of the exposure unit by feedback control and can define conditions to demonstrate high efficacy in a short period of time according to sample types.

[0022]

This device for nucleolytic degradation requires an environmental temperature where it can demonstrate the effects and efficacy of nucleolytic degradation within the range of body temperature of 37°C, has the capacity to effectively dissolve double-stranded DNA nucleic acid (broken into pieces of 10bp or lower) in a short period of within 15 minutes and at the formaldehyde component concentration of 100ppm or lower, and it can achieve nucleolytic degradation by 99.99% to 100% as the gas-phase nucleolytic degradation method.

[0023]

In addition, this device for nucleolytic degradation demonstrates 99.99% effectiveness with non-wet type agents and 95% effectiveness with wet type agents (100μl).

[0024]

Thanks to advanced technology based on this invention, this invention can be applied to the highly advanced medicine (cell therapy, gene therapy, regenerative medicine) field, marine research field, aerospace field, crisis management field (defense, firefighting, police, etc.), as well as fields required to be DNA and RNA-free (decontamination of bio-based nucleic acid) in medical care, nursing care, etc. and the field of sterilization and disinfection by controlling effects and efficacy level.

[Embodiment of the invention]

[0026]

Hereinafter, embodiments of this invention are explained in detail using drawings. It is needless to say that this invention is not limited to the following examples, and it can be changed arbitrarily within a range that does not deviate from the gist of this invention.

[0027]

This invention is applied to a Device for nucleolytic degradation 100 with the structure shown in Figure 1, for example.

[0028]

The Device for nucleolytic degradation 100 performs nucleolytic degradation using

biogas that contains active species derived from methanol and is composed of a Biogas generation unit 110, an Exposure unit 120, an Exhaust gas treatment unit 140, and a Control unit 150 that controls the operations of these units.

[0029]

In the Device for nucleolytic degradation 100, the Biogas generation unit 110 radicalizes the methanol gas into which air is mixed by a catalyst reaction and generates biogas that contains at least active species derived from methanol.

[0030]

The Biogas generation unit 110, as shown in Figure 2 for example, is composed of a Vaporizer 10 which is installed under an Inner cylinder 12 and into which methanol, a raw material, which is drawn in by a Methanol pump 7 from a Methanol sub-tank 3 that is connected to a detachable Methanol supply tank 1 that supplies methanol via a Direct-acting on-off valve 2 that is composed of a solenoid valve, is supplied via a Methanol control valve 17, and a Methanol gas generation unit 11 which has a Catalyst cartridge 18 attached on its top and which is installed in an Outer cylinder 12B.

[0042]

The amount of biogas generated in the Biogas generation unit 110 can be controlled by the amount of air (an Air pump 9) and the amount of methanol (a Fuel pump 7) that are supplied to the Methanol gas generation unit 11.

[0044]

That is, the Biogas generation unit 110 is, as shown in Figure 3, composed of a Vaporizer 10 of a Methanol gas generation unit 11 that has a Nozzle 23 that sprays methanol supplied from the Methanol sub-tank 3 in mist form, vaporizes the methanol sprayed through the Nozzle 23, and generates methanol gas; the Cylindrical unit 12A that is positioned above the Vaporizer 10, consists of upper and lower parts that are separated from each other by heat-reflective porous metal material, with the Air pump 9 for supplying air connected to its upper part, serves as a flow channel to transfer the methanol gas generated from the Methanol gas generation unit 11 to the upper part by natural convection, and mixes air supplied from the Air pump 9 with the methanol gas at the predetermined ratio; and a catalyst unit that is located above the Inner cylinder 12A and radicalizes the methanol gas into which air is mixed at the predetermined ratio in the Inner cylinder 12A by catalytic reaction; and the catalyst unit is composed of radical reaction catalysts made from thin metal plates formed into a honeycomb structure and consists of a Catalyst cartridge 18 formed by laminating multiple radical reaction catalysts.

[0049]

More specifically, when current is applied to a Vaporizer heater 20, a Heat medium

21 that electrically connects methanol that is supplied through a Methanol supply communication tube 24 in Figure 4 from the Methanol sub-tank 3 starts to be heated by the heat from the Vaporizer heater 20 to 100°C to 200°C. When the methanol supplied from the Methanol sub-tank 3 passes through the Heat medium 21, the methanol is heated and vaporized by the heat generated in the Heat medium 21, and methanol gas is generated. When the methanol gas is generated in this manner, the methanol gas is dispersed through a Vaporizing nozzle 22 and a Vaporizing cover 14 in Figure 3, and moves to the Catalyst cartridge 18 by natural convection through the Inner cylinder 12A.
[0059]

In this procedure, in contrast to the conventional MR gas sterilization treatment, it is not necessary to keep sterilization environment at the predetermined humidity. The nucleolytic degradation efficacy that conventionally required exposure at a temperature of 50℃ or higher and humidity of 75% for 60 minutes can be obtained by exposure at a temperature of 37℃ or higher and humidity of 30% to 45% or higher for 15 minutes. Therefore, humidity control in sterilization environment (nucleolytic degradation) no longer needs to be strict, and humidity control is implemented to the extent where no condensation is generated under the biogas generation environment focused on temperature control.
[0063]

In addition, in order to control the temperature in the Biogas generation unit 11 and to generate and supply biogas stably, an Abnormal temperature sensor 14A in Figure 2 is located at a lower part of the Inner cylinder 12A and a Catalyst temperature sensor 15 is located at a lower part of the Inner cylinder 12 A. Temperature is managed and controlled by supplying each piece of temperature information obtained from the Abnormal temperature sensor 14A and the Catalyst temperature sensor 15 to the Control unit 150 and thereby it can prevent ignition, etc. of methanol and increase safety.
[0077]

Optimization of ratios of the air amount and the methanol amount depending on the purpose is structurally possible based on the concentration measurement results, by means such as setting the amount of supplied air at 4.5L/min. when the capacity of the Exposed unit 120 is within 1 cubic meter, or at 5.0L/min. or decreasing the methanol amount and reducing the air amount when the capacity is 0.5 cubic meter or lower.
[0080]

The Biogas generation unit 110 can control the temperature of the radicalization catalyst reaction by changing the amount of supplied air. The reaction temperature required for the radicalization catalyst reaction of methanol gas is approximately 400°C

to 500°C. The Biogas generation unit 110 changes the air amount supplied from the Cylinder upper part 12a in the range of approximately 3.5L/min to 6.0L/min. for an amount of supplied methanol of approximately 3.0cc. This enables the change of the radicalization catalyst reaction temperature in the range of approximately 400°C to 500°C. Therefore, the temperature of the radicalization catalyst reaction can be easily controlled by changing the air amount supplied from the Air pump 9.

[0081]

As described above, the Biogas generation unit 110 does not require occasional heating to maintain the temperature of the radicalization catalyst reaction and can generate a radicalization reaction by a stable self-reaction. Therefore, the radicalization reaction temperature can be controlled easily just by changing the amount of supplied air. Since the concentration of the generated biogas depends on the radicalization catalyst reaction temperature, the biogas concentration can be easily controlled by controlling the reaction temperature by changing the amount of supplied air as described above. Thereby, the biogas concentration can be easily changed depending on the exposure target, and sterilization can be performed on various exposure targets.

[0097]

Moreover, in this Device for nucleolytic degradation 100, the Exposure unit 120 as shown in Figure 8 for example, is composed of a constant temperature and humidity bath that can control temperature and humidity by a Chamber heater 130A and Chamber cooler 130B.

[0101]

In addition, outside air (air) is introduced into the Exposure unit 120 from an Outside air introduction valve 125 via a HEPA filter 124, and external gas, such as nitrogen N2 and carbon dioxide CO2, etc., can be introduced via an External gas introduction valve 131. The outside air (air) introduced into the Exposed unit 120 via the HEPA filter 124 can be heated by an Air heater 24A.

[0103]

The Exposure unit 120 has various sensors, including a Gas concentration sensor 129, a Chamber pressure sensor 132, a Humidity sensor 133, a Temperature sensor 134, an Exposure sensor (nucleic acid sensor) 135, and Odor sensors 136A and 136B, etc. The gas concentration information, pressure information, humidity information, temperature information, exposure (effects and efficacy on nucleic acid, etc.) information, and order information (inside and outside) that are obtained from the Gas concentration sensor 129, Chamber pressure sensor 132, Humidity sensor 133, Temperature sensor 134, Exposure sensor 135, and Odor sensors 136A and 136B are provided to the Control unit 150.

Naturally, the temperature (room temperature) information outside the Exposure unit 120 is also provided to the Control unit 150.

[0104]

The biogas supplied to the Exposure unit 120 can be exhausted by opening an Exhaust side open-close valve 128.

[0107]

In addition, in the Device for nucleolytic degradation 100, the Exhaust gas treatment unit 140 exhausts the biogas supplied to the Exposure unit 120. As shown in Figure 9 for example, it has an Exhaust gas blower 143 that is connected to the Exhaust side open-close valve 128 of the Exposure unit 120 via a Gas introduction tube attachment 141, and an Exhaust gas degradation catalyst unit 145 where the exhaust gas sent from the Exposure unit 120 by the Exhaust gas blower 143 via the Gas rectifier bath 144 is degraded, and it exhausts the exhaust gas from an Exhaust gas tube 149 by detoxifying it by catalyst reaction in the Exhaust gas degradation catalyst unit 145.

[0108]

The Exhaust gas treatment unit 140 can introduce outside air (air) via the Outside air introduction valve 142.

[0111]

In the Device for nucleolytic degradation 100, the Control unit 150 controls the Biogas generation unit 110, the Exposure unit 120, and the Exhaust gas treatment unit 140 as follows using the control system shown in Figure 10.

[0140]

While monitoring the chamber pressure of the Exposure unit 120, the Exhaust gas treatment unit 140 performs exhaust and intake so that the chamber is at negative pressure (-0MPa to -0.01MPa).

[0141]

Subsequently, after the negative pressure is confirmed by the Chamber pressure sensor 132, the Control unit 150 gives an instruction to the Biogas generation unit 110 to activate a Methanol supply pump 7 when the temperature of the Biogas generation unit 110, chamber temperature of the Exposure unit 120, and the temperature of the Exhaust gas treatment unit 140 reach the specified values and preparation for activation is complete.

[0142]

Gas introduction, stirring, and exhaust gas conditions in the chamber of the Exposure unit 120 are maintained.

[0143]

Then, the Biogas generation unit 110 is controlled as follows based on the gas concentration information obtained by the Gas concentration sensor 129 so that the concentration in the chamber of the Exposure unit 120 is kept constant.

[0144]

The generated amount of biogas, that is nucleolytic degradation gas, in the Biogas generation unit 110 is determined by the mixing ratio of the amount of air and the amount of methanol in the Biogas generation unit 110. The amount of supplied air is determined by the balance between the capacity of the chamber of the Exposure unit 120 and the generation time. It is also determined within the balance of the intake and exhaust where the chamber of the Exposure unit 120 reaches negative pressure. The amount of methanol is determined within an appropriate range of the catalyst self-reaction temperature.

[0145]

Concerning the negative pressure control in the Exposure unit 120, the balance between the supplied air amount and the intake amount of the exhaust gas blower is to be within the range of -0MPa to -0.01MPa. It is adjusted to the optimal negative pressure balance based on sample parameters (concentration, time, temperature, humidity).

[0146]

Concerning the gas concentration control in the chamber of the Exposure unit 120, the negative pressure balance is adjusted based on the parameter information of the exposure target so that the concentration is kept constant.

[0147]

When the intake amount of the Exhaust gas blower 143 of the Exhaust gas treatment unit 140 is decreased, the concentration increases, and when the intake amount is increased, the concentration decreases. The intake amount of the Exhaust gas blower 143 is controlled within the negative pressure range of the chamber of the Exposed unit 120. If it cannot be adjusted within the negative pressure balance range, the amount of supplied methanol is to be controlled. When the amount of supplied methanol in the Biogas generation unit 110 is increased, the concentration increases, and when it is decreased, the concentration decreases. This range is controlled within the catalyst self-reaction temperature range.

[0148]

For example, in the gas concentration control in the chamber of the Exposure unit 120, the gas concentration information obtained from the Gas concentration sensor 129 is set as the process value PV, and the concentration in the chamber of the Exposure unit 120 is controlled to remain constant by the control system as shown in Figure 12 using the threshold value SP of the chamber concentration and the process value PV

[0150]

The gas concentration determined by the amount of supplied methanol GP1 by the Methanol pump 7 and the amount of supplied air by the Air pump 9 is detected by the Gas concentration sensor 129 together with the disturbance element in the Exposure unit 120, and the gas concentration information GF obtained from the Gas concentration sensor 129 is fed back as the process value PV and thereby concentration in the chamber of the Exposure unit 120 is controlled to remain constant.

[0153]

For example, in the humidity control in the chamber of the Exposure unit 120, the chamber humidity information obtained from the Humidity sensor 134 is set as the process value PV, and the chamber humidity in the Exposure unit 120 is controlled to be constant by the control system as shown in Figure 13 using the threshold value SP of the chamber humidity and the process value PV.

[0155]

Then, the chamber humidity of the Exposure unit 120 that is controlled by the dehumidification function of the Cooling zone 121 or the Chamber cooler 130B is detected by the Temperature sensor 134 together with the disturbance element, and the chamber humidity information GF obtained from the Temperature sensor 134 is fed back as the process value PV and thereby the chamber humidity of the Exposure unit 120 is controlled to remain constant.

[0157]

In addition, in the chamber temperature control in the Exposure unit 120, the chamber temperature information that is obtained from the Temperature sensor 134 is set as the process value PV, and the chamber temperature of the Exposure unit 120 is controlled to remain constant by the control system as shown in Figure 14 using the threshold value SP of the chamber temperature and the process value PV.

[0159]

The chamber temperatures corresponding to the control by the Chamber heater 130A and the Chamber cooler 130B are detected by the Temperature sensor 134 together with the disturbance element in the Exposure unit 120, the chamber temperature GF that is obtained by the Temperature sensor 314 is fed back as the process value PV, and thereby chamber temperature of the Exposure unit 120 is controlled to remain constant.

[0161]

In addition, in the chamber pressure control in the Exposure unit 120, a follow-up operation to the target values of the chamber pressure or differential pressure and the exhaust gas reaction temperature is conducted. In this chamber pressure control, the

exhaust gas amount is controlled by the PI control based on the combination of proportional (P) and integral (I) control. The chamber pressure control is performed with the target value within the negative pressure range. The target value is determined automatically based on the exhaust gas reaction temperature.

[0162]

For example, in the differential chamber pressure control in the Exposure unit 120, the differential chamber pressure information that is obtained from the Differential pressure sensor 134 is set as the process value PV, and the differential chamber pressure in the Exposure unit 120 is controlled to remain constant by the control system as shown in Figure 15 using the threshold value SP of the differential chamber pressure and the process value PV.

[0163]

It means that the open-close degree of the Exhaust gas introduction valve 142 of the Exhaust gas treatment unit 140 is controlled by the third Control value C13 to which the first Control amount C11 responding to the threshold value SP of the differential chamber pressure and the difference between the threshold value SP of the differential chamber pressure and the process value PV as the second Control value C12 are added, and the number of rotations of the Exhaust gas blower 143 of the Exhaust gas treatment unit 140 is controlled by the sixth Control amount C23 to which the fourth Control amount C21 responding to the threshold value SP of the differential chamber pressure and the difference between the threshold value SP of the differential chamber pressure and the process value PV as the fifth Control amount C22 are added.

[0164]

The differential chamber pressure responding to the control of the open-close degree of the Exhaust gas introduction valve 142 of the Exhaust gas treatment unit 140 and the number of rotations of the Exhaust gas blower 143 is detected by the Differential chamber pressure sensor 132 together with the disturbance element in the Exposure unit 120, the differential chamber pressure GF that is obtained from the Differential chamber pressure sensor 132 is fed back as the process value PV, and thereby the differential chamber pressure of the Exposure unit 120 is controlled to remain constant.

[0182]

In addition, the Control unit 150 controls the Exhaust gas treatment unit 140 as follows when biogas is generated by the Biogas generation unit 110.

[0183]

In other words, when biogas is generated, the Control unit 150 controls the rotation of the Exhaust gas blower 143 so that the chamber pressure is kept at negative pressure

at a lower level than the chamber pressure that is indicated by the chamber pressure information that is obtained from the Chamber pressure sensor 132 of the Exposure unit 120. In addition, based on the exhaust gas catalyst temperature information obtained from the Exhaust gas catalyst temperature sensor 147, the Exhaust gas catalyst heater 146 is controlled so that the exhaust gas catalyst heater temperature reaches a specified value (300°C).

[0196]

The Device for nucleolytic degradation 100 with the aforementioned structure can perform quantitative control of the temperature, humidity, and concentration in the exposure area of the Exposure unit 110 by feedback control and can define conditions to demonstrate high efficacy in a short period of time according to exposure target types.

[0198]

In the Device for nucleolytic degradation 100, the Biogas generation unit 110 contains at least the reaction components of methanol, formaldehyde, carbon monoxide, carbon dioxide, hydrogen, and oxygen, and generates free radical components (superoxide anion O_2・-, hydroxyl radical・OH, hydrogen radical H・, and superoxide (O_2-) at least) composite radical gas.

[0201]

The exposure target exposed in the Exposure unit 110 of the Device for nucleolytic degradation 100 may be an object having a slender tube (such as an endoscope, etc.), an object having a complicated shape, or a precision instrument, etc.

[0211]

In addition, the Device for nucleolytic degradation 100 can perform gas sampling during operation and halfway sampling of specimens (optional extraction). In addition, since the operation environment and status can be checked manually as well as automatically, it is a system where human operators can make a determination and take actions arbitrarily during automatic operation. In other words, by checking the chamber environment by sampling after exhaust gas treatment, it is possible to judge the chamber inlet and outlet conditions in the Exposed unit 120.

[Working examples]

[0216]

Hereinafter, specific examples using the Device for nucleolytic degradation 100 related to this invention are shown. The following examples and the details explained in detail by the examples are only workings of the invention. They do not limit this invention. The invention may be changed to the extent that it does not deviate from the scope of this invention.

[0217]

<1. Sample preparation>

The double strand DNA (dsDNA), RNA, and single strand DNA (ssDNA) were prepared from Human HeLa cell (human cervical cancer).

[0221]

<2. Biogas exposure test>

Exposure was conducted using the samples prepared in 1. above by the Device for nucleolytic degradation 100 related to this invention under the conditions as shown in Figure 17 where the parameters of the exposure time, exposure temperature, and sample capacity are changed, and the nucleolytic degradation ability of the biogas was evaluated. Each sample was prepared in a 0.2mL PCR tube and a biogas exposure test was conducted.

[0226]

<3. Results>

<3-1. Results of dsDNA>

Tables 1 through 3 show the Bioanalyzer results with sample amounts of 2μl, 20μl, and 100μl, respectively. "C" in each table indicates that the nucleic acid was completely degraded; "+++" indicates that a high degree of partial degradation occurred; "++" indicates a moderate partial degradation occurred; and "+" indicates that minor partial degradation occurred. In addition, Figure 18 indicates nucleolytic degradation ability criteria of dsDNA by Bioanalyzer and Figures 19 through 21 show spectrum diagrams indicating test results of the nucleolytic degradation ability by Bioanalyzer.

[0234]

Based on the above, it is found that nucleolytic degradation by biogas using the Device for nucleolytic degradation 100 can highly degrade nucleic acid under approximately normal temperatures and in a short period of time. In addition, it was suggested that the dsDNA degradation ability effects by biogas are temperature-dependent (effects increase at high temperature) and volume-dependent (wet conditions).

[0238]

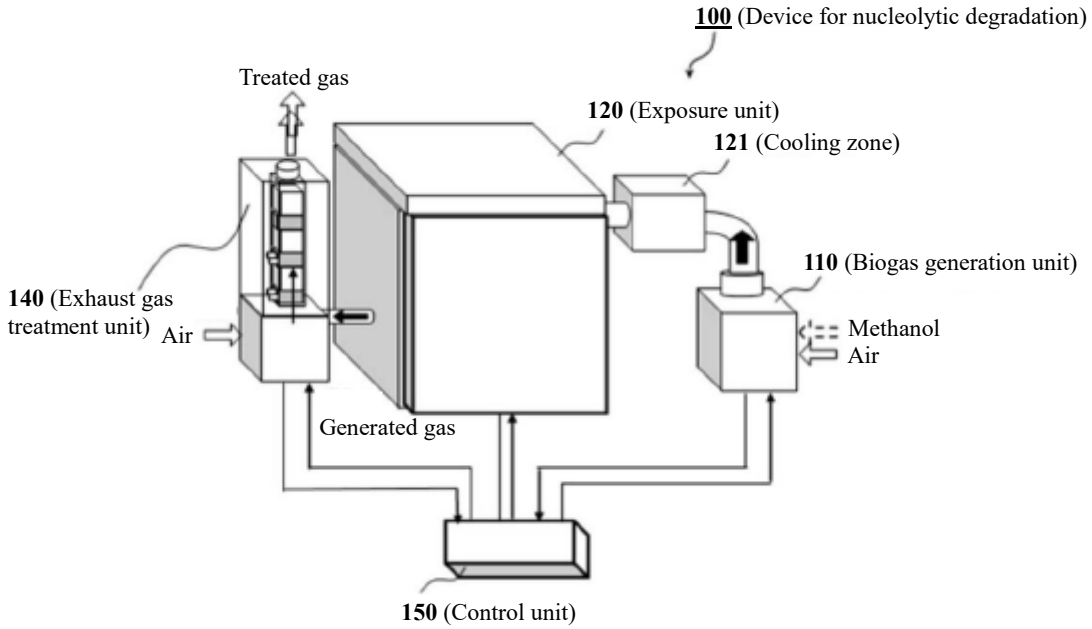
On the other hand, when nucleolytic degradation with biogas using the Device for nucleolytic degradation 100 is performed, nucleic acid amplification of GAPDH was not observed for the exposure for 15 min. under any temperature conditions of 37℃, 45℃, and 50℃ by the biogas exposure to 2μL of RNA samples, complete degradation effects of RNA were shown, and the same results were obtained for the exposure for 120 min.

[0241]

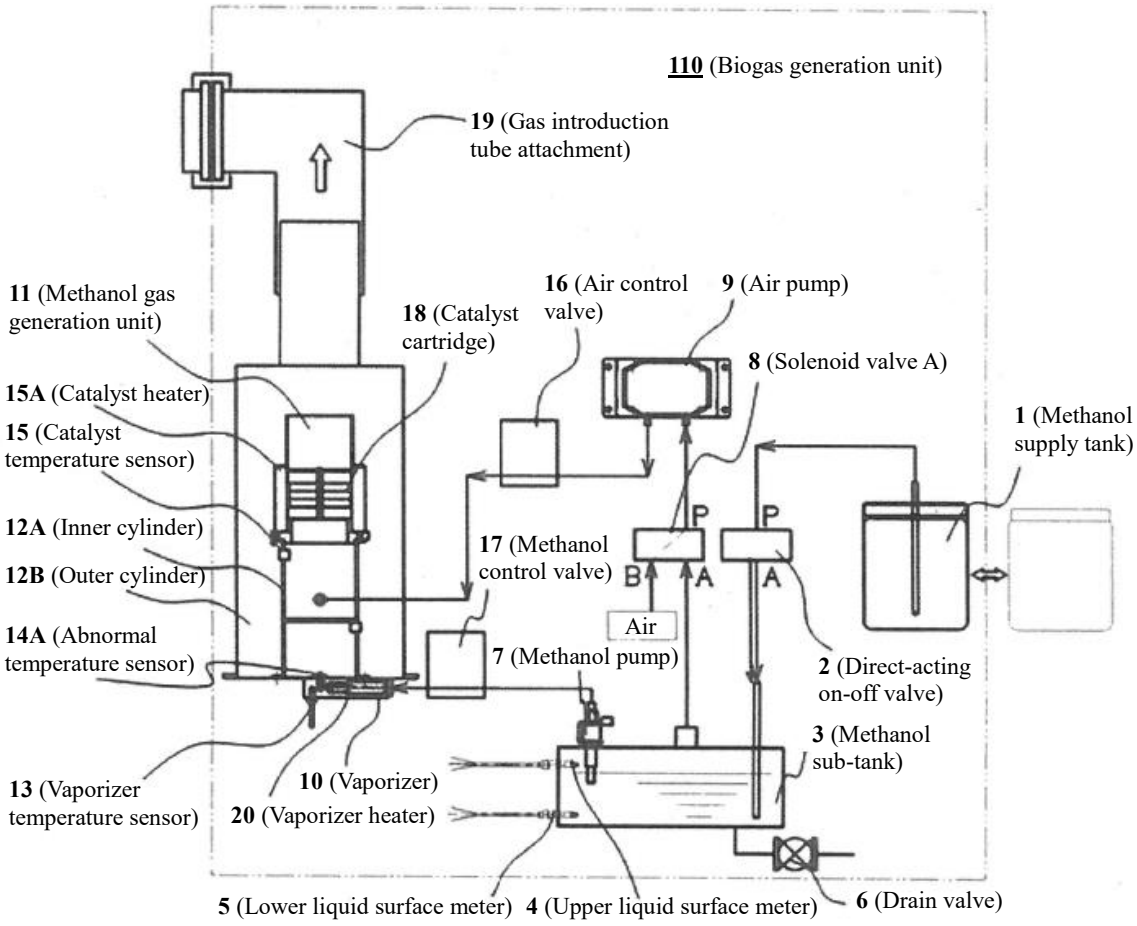
On the other hand, when nucleolytic degradation with biogas using the Device for nucleolytic degradation 100 is performed, nucleic acid amplification of GAPDH was not

observed for the exposure for 60 min. under any temperature conditions of 37℃, 45℃, and 50℃ by the biogas exposure to 2μL of ssDNA samples, complete degradation effects of ssDNA were shown, and the same results were obtained for the exposure for 120 min.

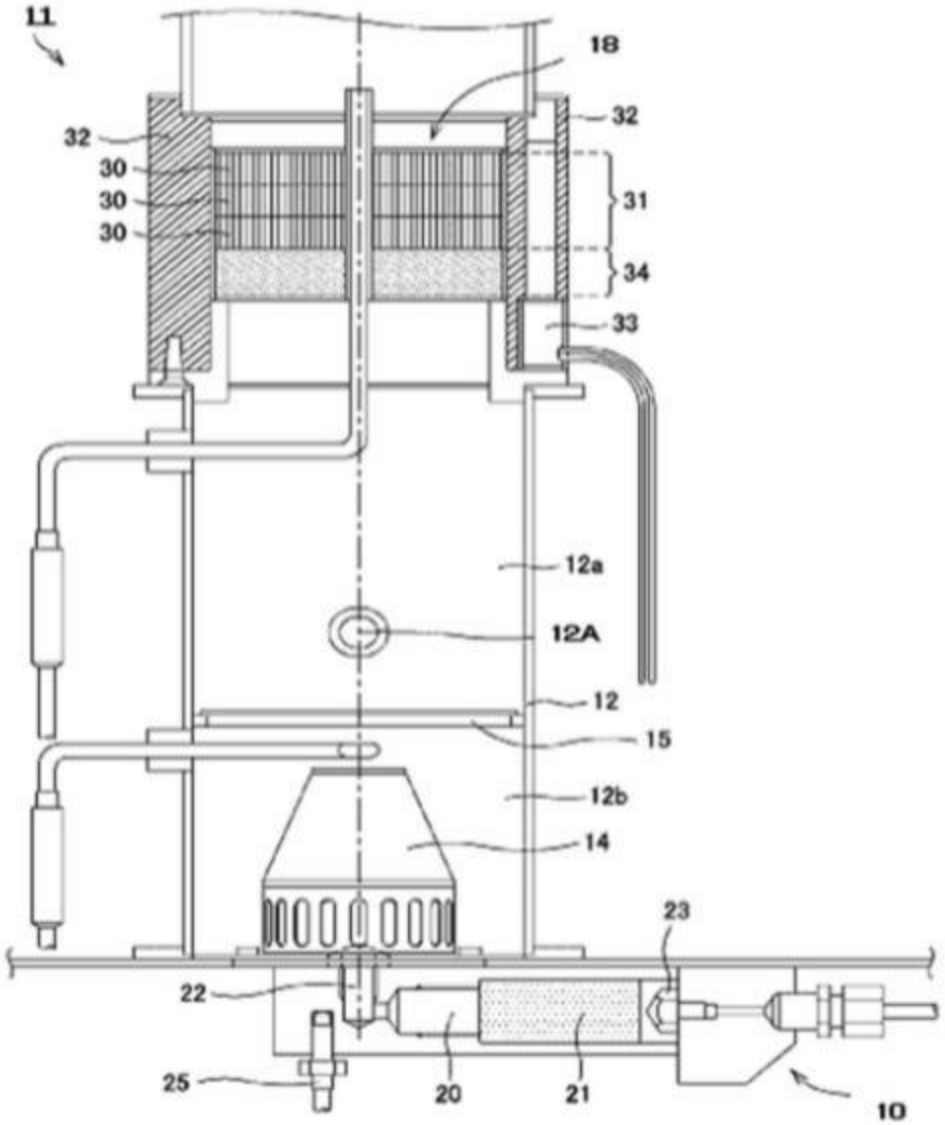
[Figure 1]


100 (Device for nucleolytic degradation)
Treated gas
120 (Exposure unit)
121 (Cooling zone)
110 (Biogas generation unit)
140 (Exhaust gas treatment unit)
Air
Methanol
Air
Generated gas
150 (Control unit)

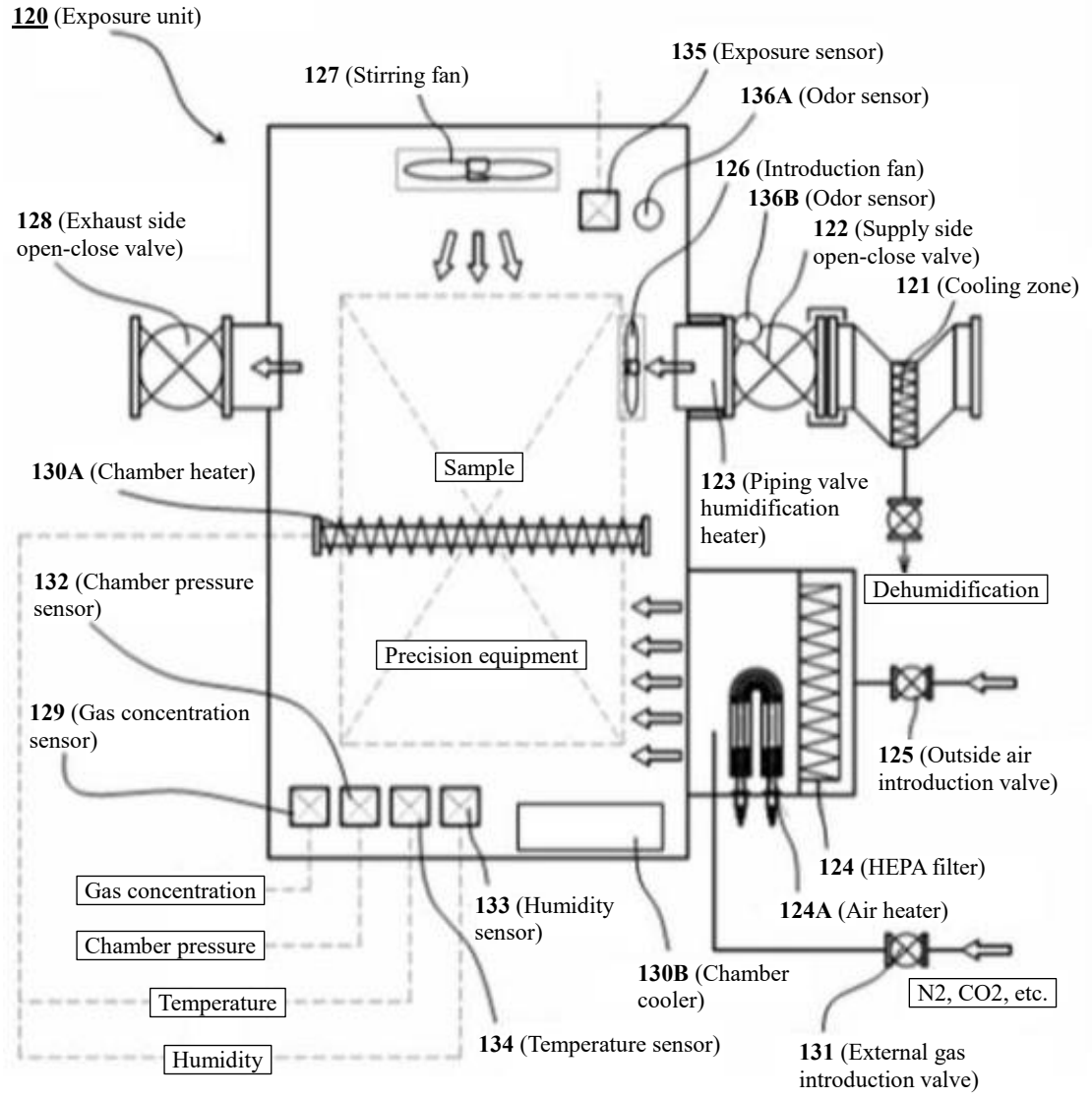
[Figure 2]


110 (Biogas generation unit)
19 (Gas introduction tube attachment)
11 (Methanol gas generation unit)
18 (Catalyst cartridge)
16 (Air control valve)
9 (Air pump)
8 (Solenoid valve A)
15A (Catalyst heater)
15 (Catalyst temperature sensor)
1 (Methanol supply tank)
12A (Inner cylinder)
12B (Outer cylinder)
17 (Methanol control valve)
P
P
B
A
A
Air
14A (Abnormal temperature sensor)
7 (Methanol pump)
2 (Direct-acting on-off valve)
3 (Methanol sub-tank)
13 (Vaporizer temperature sensor)
10 (Vaporizer)
20 (Vaporizer heater)
5 (Lower liquid surface meter)
4 (Upper liquid surface meter)
6 (Drain valve)

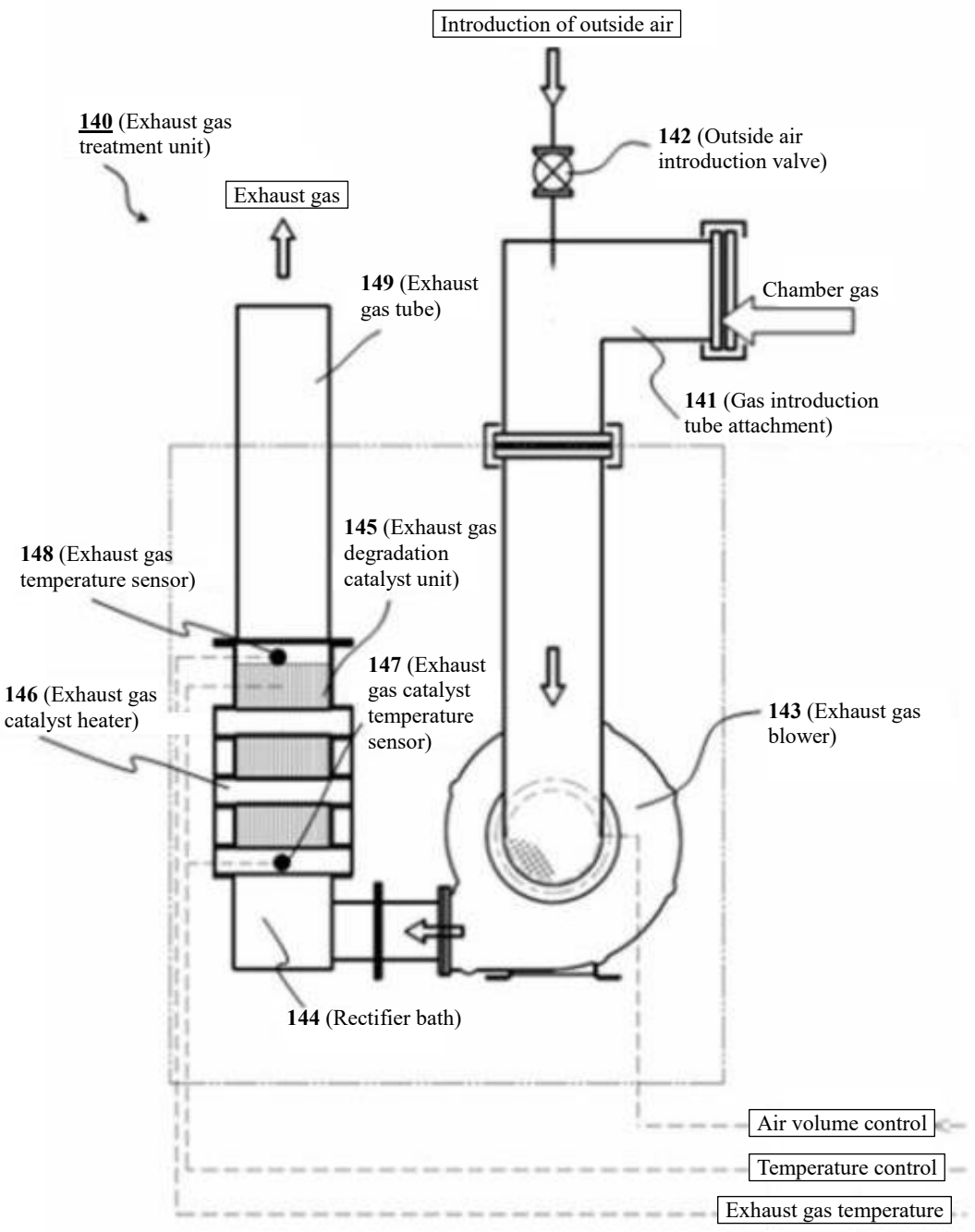
[Figure 3]



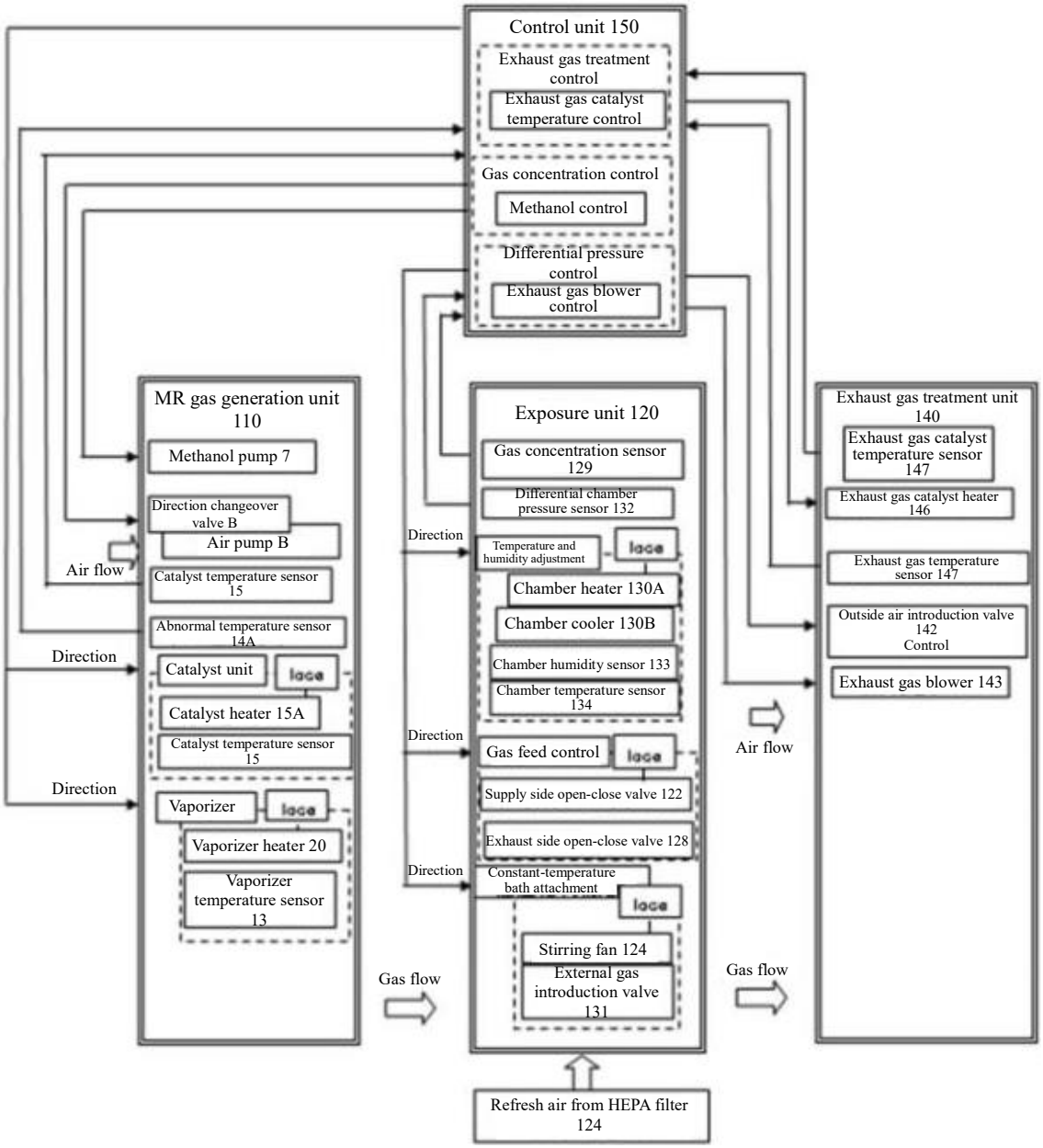
[Figure 8]


120 (Exposure unit)
127 (Stirring fan)
135 (Exposure sensor)
136A (Odor sensor)
126 (Introduction fan)
136B (Odor sensor)
122 (Supply side open-close valve)
121 (Cooling zone)
128 (Exhaust side open-close valve)
130A (Chamber heater)
Sample
123 (Piping valve humidification heater)
Dehumidification
132 (Chamber pressure sensor)
Precision equipment
129 (Gas concentration sensor)
125 (Outside air introduction valve)
124 (HEPA filter)
124A (Air heater)
Gas concentration
Chamber pressure
Temperature
Humidity
133 (Humidity sensor)
130B (Chamber cooler)
N2, CO2, etc.
134 (Temperature sensor)
131 (External gas introduction valve)

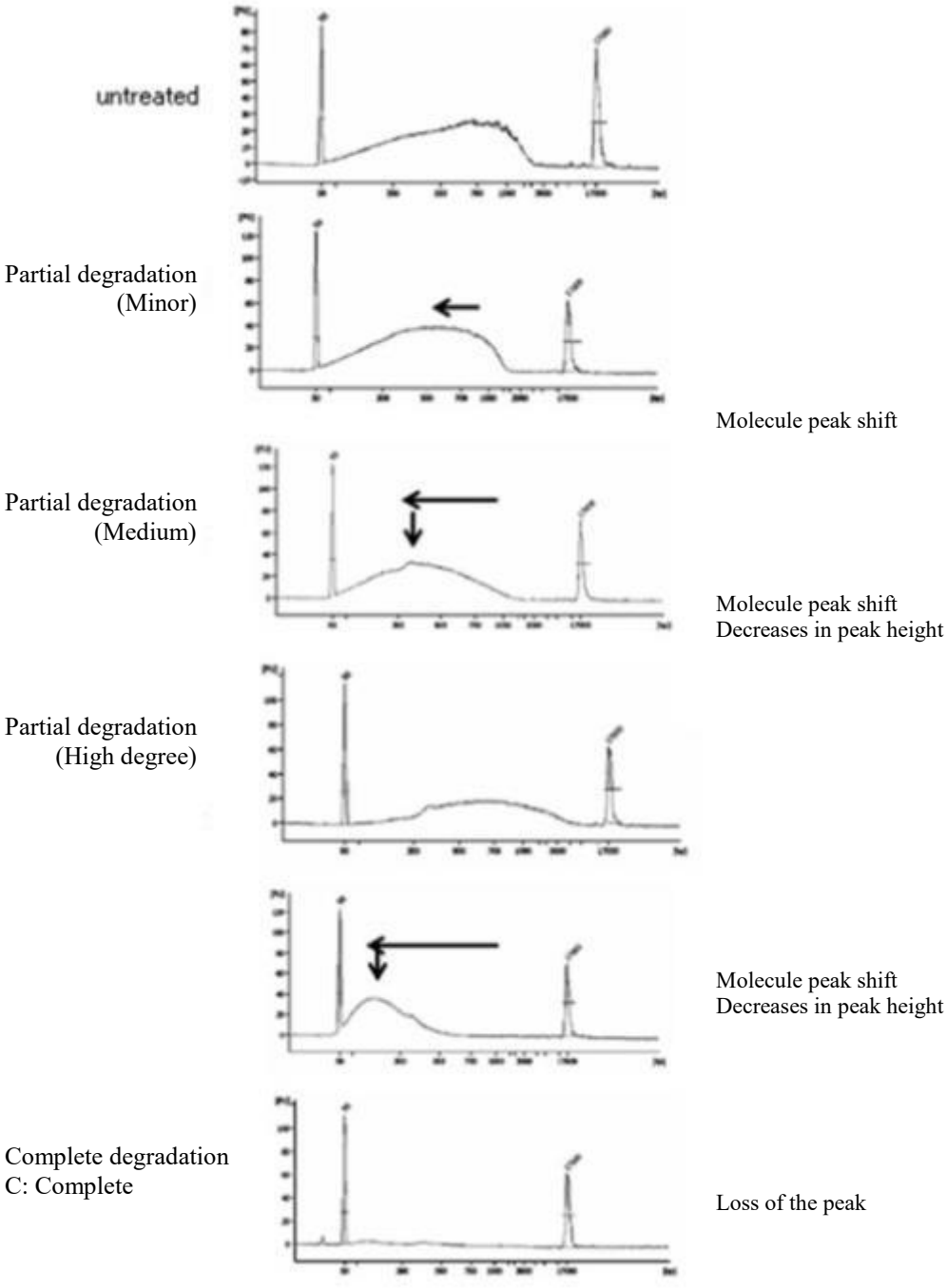
[Figure 9]


Introduction of outside air
140 (Exhaust gas treatment unit)
142 (Outside air introduction valve)
Exhaust gas
149 (Exhaust gas tube)
Chamber gas
141 (Gas introduction tube attachment)
145 (Exhaust gas degradation catalyst unit)
148 (Exhaust gas temperature sensor)
147 (Exhaust gas catalyst temperature sensor)
146 (Exhaust gas catalyst heater)
143 (Exhaust gas blower)
144 (Rectifier bath)
Air volume control
Temperature control
Exhaust gas temperature

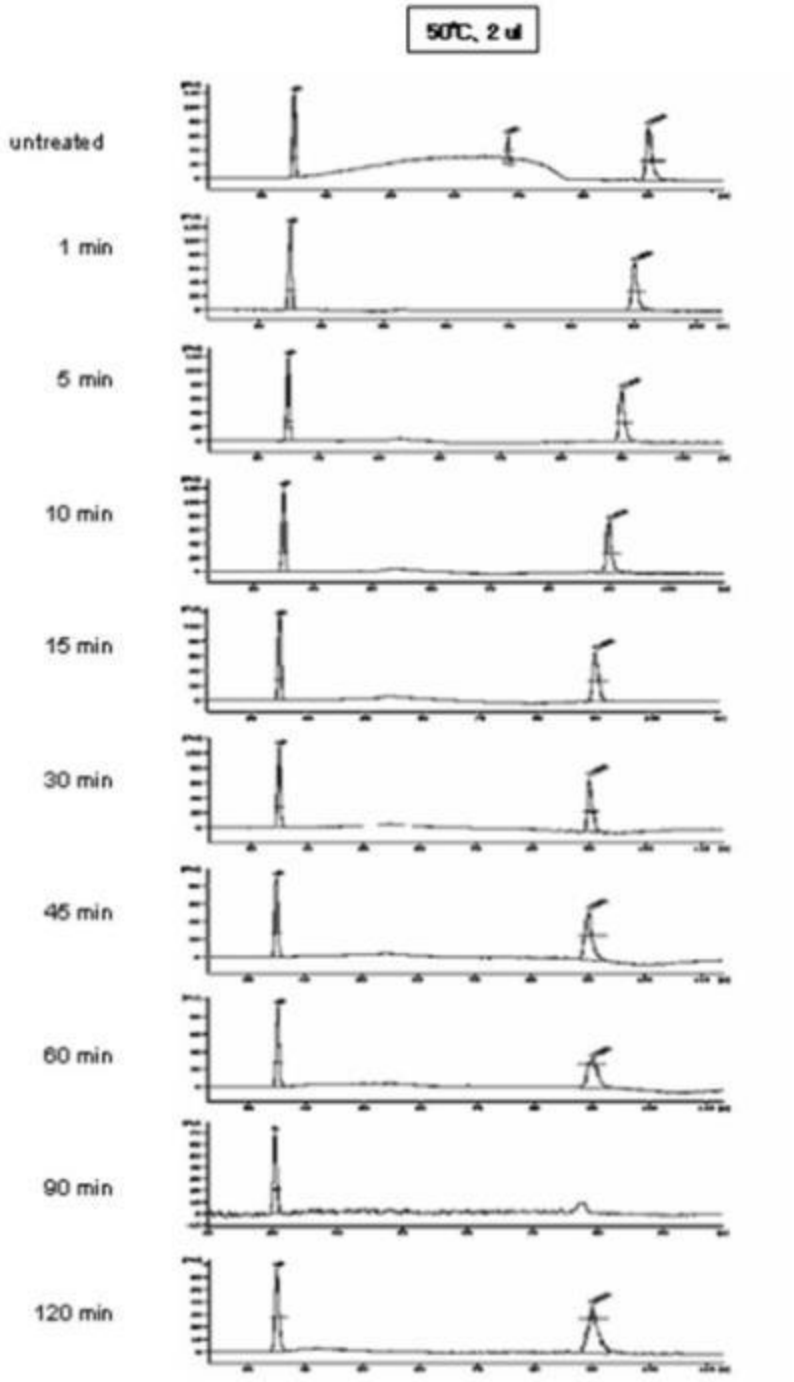
[Figure 10]


Control unit 150
Exhaust gas treatment control
Exhaust gas catalyst temperature control
Gas concentration control
Methanol control
Differential pressure control
Exhaust gas blower control
MR gas generation unit 110
Methanol pump 7
Direction changeover valve B
Air pump B
Air flow
Catalyst temperature sensor 15
Abnormal temperature sensor 14A
Direction
Catalyst unit
face
Catalyst heater 15A
Catalyst temperature sensor 15
Direction
Vaporizer
face
Vaporizer heater 20
Vaporizer temperature sensor 13
Exposure unit 120
Gas concentration sensor 129
Differential chamber pressure sensor 132
Direction
Temperature and humidity adjustment
face
Chamber heater 130A
Chamber cooler 130B
Chamber humidity sensor 133
Chamber temperature sensor 134
Direction
Gas feed control
face
Supply side open-close valve 122
Exhaust side open-close valve 128
Direction
Constant-temperature bath attachment
face
Stirring fan 124
External gas introduction valve 131
Gas flow
Refresh air from HEPA filter 124
Exhaust gas treatment unit 140
Exhaust gas catalyst temperature sensor 147
Exhaust gas catalyst heater 146
Exhaust gas temperature sensor 147
Outside air introduction valve 142 Control
Exhaust gas blower 143
Air flow
Gas flow

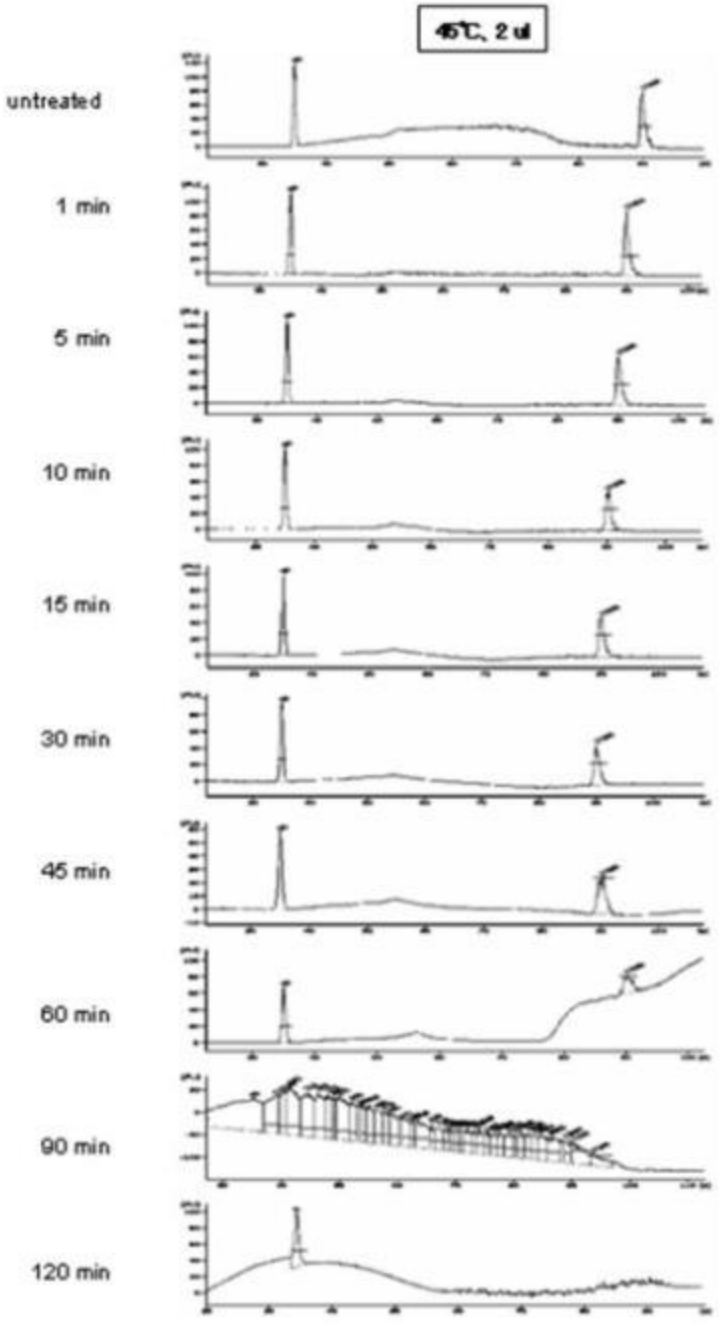
[Figure 18]


untreated
Partial degradation
(Minor)
Molecule peak shift
Partial degradation
(Medium)
Molecule peak shift
Decreases in peak height
Partial degradation
(High degree)
Molecule peak shift
Decreases in peak height
Complete degradation
C: Complete
Loss of the peak

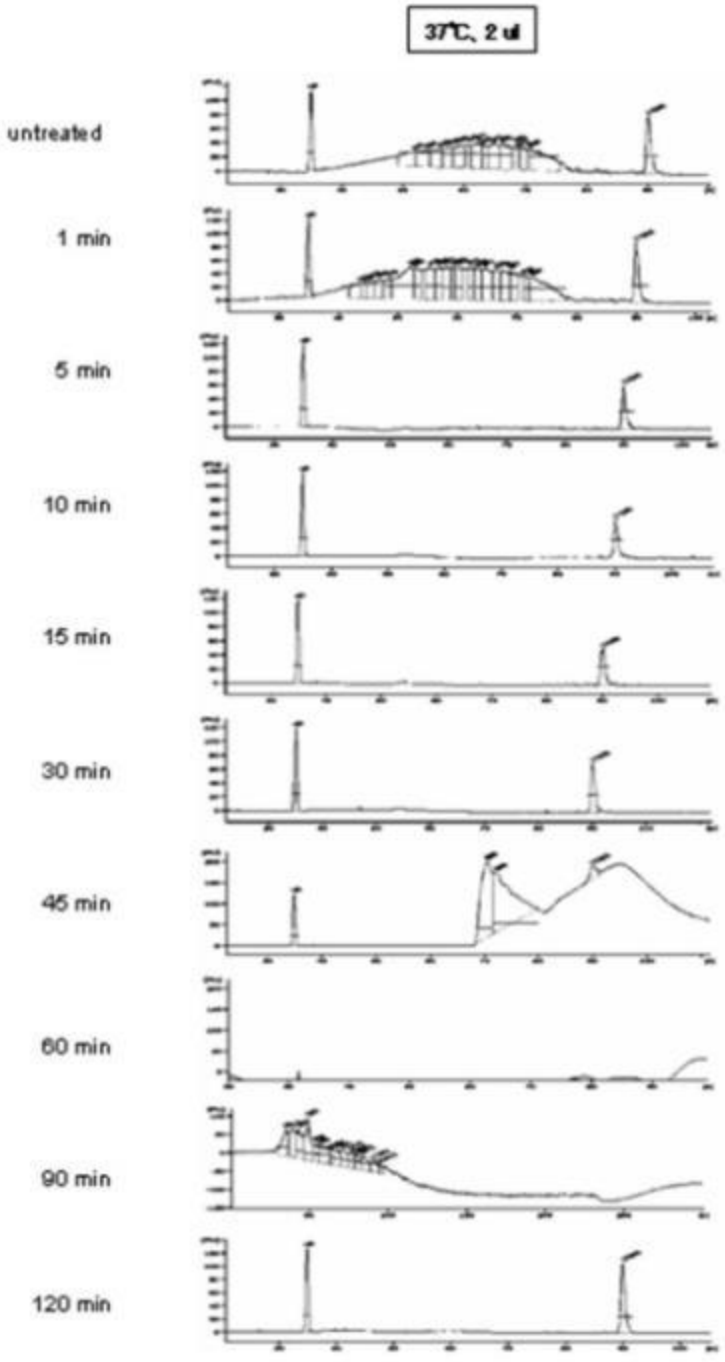
[Figure 19A]


50℃, 2 ul
untreated
1 min
5 min
10 min
15 min
30 min
45 min
60 min
90 min
120 min

[Figure 19B]


untreated
1 min
5 min
10 min
15 min
30 min
45 min
60 min
90 min
120 min

[Figure 19C]


37℃, 2 ul
untreated
1 min
5 min
10 min
15 min
30 min
45 min
60 min
90 min
120 min

(Attachment 2)

[Technical field]

[0001]

This invention is related to a sterilization gas generation device, a catalyst cartridge that is installed on the sterilization gas generation device in an exchangeable manner, and a sterilization treatment device that sterilizes targets with radical methanol radical gas (hereinafter referred to as "MR gas") generated from methanol by catalyst reaction.

[Background art]

[0002]

A sterilization system using radical (methanol radical: MR) gas generated from methanol by catalytic reaction has sterilizing power superior to ethylene oxide gas (EOG) or ozone, etc., which have been widely used as gases for sterilizing medical devices, etc. It has been confirmed that the system is free from persistence or corrosiveness, and it has been drawing attention from many fields today.

[0003]

MR gas is a radical gas with a strong sterilizing effect generated from methanol by a catalyst, has high permeability, and can sterilize the inside of a sterilization target even at atmospheric pressure. It has excellent features, such as being free from metal corrosion or plastic deterioration. It can also be used with non-sterile materials and does not remain in sterilization targets. It has a strong safety record.

[Problems to be solved by the invention]

[0006]

However, since a conventional MR gas generation device had a catalyst unit with a size of approximately 150mm to 180mm in diameter, for example, it was difficult to keep the temperature necessary for the radicalization reaction of methanol gas constant in the catalyst unit. Therefore, it was necessary to have an electric heater in the catalyst unit and to control temperature by heating as necessary in order to maintain the temperature necessary for the radicalization reaction.

[0007]

With the aforementioned conventional MR gas generation device, temperature fluctuated widely at the time of the catalyst reaction. As a result, it could not generate MR gas at a constant concentration. In addition, since it had a catalyst unit with a diameter of approximately 150mm to 180mm and it was necessary to have an electric heater for heating as mentioned above, the catalyst unit naturally became large and it was difficult to downsize the MR gas generation device to increase convenience.

[0008]

This invention was proposed in consideration of these conventional problems and it aims to keep the catalyst reaction temperature for radicalization constant, to generate sterilization gas at a stable concentration, and to provide a sterilization gas generation device that can be downsized, a catalyst cartridge that is used with the sterilization gas generation device, and a sterilization treatment device.

[Means of solving problems]

[0009]

The inventors of this invention found that using a catalyst that has a honeycomb structure makes it possible to keep catalyst reaction temperature for radicalization constant, as a result of conducting studies from various perspectives to resolve the aforementioned problems and completed this invention.

[0010]

In other words, the sterilization gas generation device related to this invention is composed of a methanol gas generation unit that vaporizes the methanol and generates methanol gas; a cylindrical unit that is positioned above the methanol gas generation unit, serves as a flow channel to transfer the methanol gas generated from the methanol gas generation unit to the upper part by natural convection and mixes air into the methanol gas at the predetermined ratio; and a catalyst unit that is located above the cylindrical unit and radicalizes the methanol gas into which air is mixed at the predetermined ratio in the cylindrical unit by catalytic reaction; and the catalyst unit is composed of radicalization reaction catalysts made from thin metal plates formed into a honeycomb structure.

[Effects of the invention]

[0013]

This invention uses radicalization reaction catalysts made from thin metal plates formed into a honeycomb structure and thereby the surface area of the catalyst unit is increased and reaction efficiency increased. It can therefore cause a self-reaction where the catalyst reaction temperature is kept constant and generate MR gas at a stable concentration. In addition, improvement of reaction efficiency at the catalyst unit makes it possible to downsize the catalyst unit and to downsize the sterilization treatment device itself, and thereby convenience can be increased.

[Best embodiment of the invention]

[0015]

Figure 1 is a frame format indicating an MR gas generation device related to this embodiment schematically. As shown in Figure 1, the MR gas generation device 10 related to this embodiment is composed of a Methanol gas generation device 11 that generates methanol gas by vaporizing methanol that is supplied from a methanol tank (not

shown in the Figure); a Cylinder 12 that is located above the Methanol gas generation device 11, mixes air with methanol gas that is generated from the Methanol gas generation device 11 and forms a flow channel to guide the generated methanol gas to the upper part by natural convection; and a Catalyst cartridge 13 that is installed successively on the Cylinder 12 at above the flow channel of methanol gas in a detachable manner and radicalizes methanol gas by catalyst reaction and generates MR gas. Each structure is explained concretely below.

[0016]

First, the Methanol gas generation device 11 that composes the MR gas generation device 10 related to this embodiment is explained. The Methanol gas generation device 11 generates methanol gas that is a reaction substance of radicalization reaction by vaporizing methanol and supplies it to the Cylinder 12.

[0017]

Figure 2 is a frame format indicating the Methanol gas generation device 11 schematically. As shown in Figure 2, the Methanol gas generation device 11 is composed of the Electric heater 20 that is connected to a methanol tank (not shown in the Figure) that holds raw materials, methanol and at least heats and vaporizes methanol; a Heat medium 21 that is made of temperature stabilization metal, such as sintered metal, etc., to control temperature when vaporizing methanol supplied from the methanol tank; a Vaporizing nozzle 22 that leads the vaporized methanol to the upper part of the MR gas generation device 10; and a Nozzle 23 that sprays methanol supplied from the methanol tank in mist form and transfers it to the Heat medium 21.

[0018]

In the Methanol gas generation device 11, methanol supplied from the methanol tank is heated and vaporized by the Electric heater 20 under the temperature control by the Heat medium 21 and the methanol gas that is generated by vaporization is emitted from the Vaporization nozzle 22. The generated methanol gas goes through the Vaporization cover 14 and spreads and transfers to the upper part of the MR gas generation device 10, which is the Catalyst cartridge 13 by natural convection.

[0023]

In addition, the Methanol gas generation device 11 has the Nozzle 23 that sprays the methanol that is supplied through a Methanol supply communication tube 24 from the methanol tank using a pump, etc. in mist form to the Heat medium 21. The methanol supplied from the methanol tank is sprayed from the Nozzle 23 in mist form and the mist methanol is heated by the Electric heater 20 as mentioned above via the Heat medium 21, and thereby the temperature is kept constant and methanol can be vaporized in stable

conditions.

[0024]

By generating methanol gas in stable conditions where the temperature remains constant in this manner, it prevents the temperature of the Methanol gas generation device 11 from fluctuating. As mentioned above, it effectively controls catalyst reaction temperature fluctuations in the Catalyst cartridge 13, which is explained in detail below, and enables the stable generation of MR gas.

[0026]

It is known that the sterilization environment needs to be kept at the predetermined humidity for sterilization. For example, in cases of preparing a DNA-free environment by the destruction of DNA, such as viruses, etc., sterilization must be conducted in the sterilization environment where humidity of approximately 75% is maintained. However, when conducting MR gas sterilization, in order to prepare the MR gas exposure environment in the predetermined humidity condition (for example, approximately 75%), a certain degree of time for adjustment of the environment is required and it is also necessary to keep the predetermined humidity environment constant, but it is extremely difficult to keep a constant humidity environment.

[0027]

Therefore, as mentioned above, in the step of generating methanol gas, the predetermined amount of water is mixed with the methanol supplied from the methanol tank to generate methanol that contains water at the predetermined ratio, thereby generating methanol gas from this methanol and generating MR gas. This enables effective sterilization without adjusting the humidity of the sterilization environment in advance. In this case, if a Methanol gas generation device 11 in the aforementioned other embodiment is used, since it has a Mixing nozzle 23' that can mix methanol and water and can supply methanol which contains water at the predetermined ratio in mist form, the optimal methanol gas that is maintained at the predetermined humidity can be generated efficiently and can be supplied to the Catalyst cartridge 13. In addition, if this MR gas that is generated from the methanol gas by catalyst reaction is used, effective sterilization can be performed and therefore it is not necessary to manage and keep the predetermined humidity environment constant.

[0028]

As mentioned above, the Methanol gas generation device 11 has the Nozzle 23. Therefore, it can spray methanol in mist form, can vaporize methanol at the temperature conditions in a constant range where there is no temperature fluctuation, and can cause a stable radicalization catalyst reaction in the Catalyst cartridge 13. The Nozzle 23, for

example, can also be composed as the Mixing nozzle 23' that mixes methanol and water and can supply the methanol that contains water at the predetermined ratio in mist form. Therefore, it can effectively generate methanol gas that is maintained at the predetermined humidity and can generate MR gas that can perform effective sterilization.

[0031]

Next, the Cylinder 12 that composes the MR gas generation device 10 related to this embodiment is explained. The Cylinder 12 serves as a flow channel that guides to the Catalyst cartridge 13 that serves as a radicalization catalyst reaction site of methanol gas supplied from the Methanol gas generation device 11 and mixes air into the methanol gas at the predetermined ratio.

[0037]

Air supply in the Cylinder upper part 12a is explained in detail here. The MR gas generation device 10 related to this embodiment changes the amount of supplied air in the Cylinder upper part 12a and thereby can control the radicalization catalyst reaction temperature by self-reaction in the Catalyst cartridge 13, which is explained later.

[0038]

The Catalyst cartridge 13 of the MR gas generation device 10, for which the details are explained later, is composed of the Radical reaction catalyst 30 made from thin metal plates formed into a honeycomb structure so that reaction efficiency is increased by increasing the surface area of contact with methanol gas. Just by heating to temperatures in the approximate range of 230℃ to 250℃ for about ten minutes immediately after the start of operation, the Catalyst cartridge 13 subsequently enables a stable self-reaction (catalyst burning reaction of methanol gas) that makes it possible to increase the temperature to the range of 450℃ to 500℃ as necessary for the radicalization reaction, and to maintain the reaction temperature. Therefore, differing from a conventional device, it is not necessary to continue heating in order to maintain the reaction temperature. As described above, the MR gas generation device 10 does not require continued heating to maintain the reaction temperature but can increase the temperature as necessary and keep it constant by stable self-reaction. Therefore, it can easily control the temperature necessary for the radicalization reaction by changing the amount of supplied air in the Cylinder upper part 12a.

[0039]

In addition, apart from a conventional MR gas generation device that has a catalyst formed by mixing metal pipe and diatomaceous earth, etc. randomly, the MR gas generation device 10 related to this embodiment causes a radicalization catalyst by passing methanol gas through the Catalyst cartridge 13 made from thin metal plates

formed into a honeycomb structure. Therefore, it does not cause a variation in the catalyst reaction of methanol gas and can easily control the catalyst reaction temperature by changing the amount of supplied air.

[0040]

In concrete terms, in cases of generating the temperature of 450℃ that is necessary for the radicalization catalyst reaction by self-reaction, as mentioned above, air is supplied in direct proportion to the amount of supplied methanol. In concrete terms, if the amount of supplied methanol is 3cc, air is to be supplied at a rate of approximately 3.5L/min.

[0041]

At the same time, in cases of generating the temperature of approximately 500°C, which is higher than the 450°C that is necessary for a radicalization catalyst reaction, by self-reaction, air is to be supplied at an amount more than the amount that is directly proportional to the amount of supplied methanol. This makes it possible to increase the burning temperature by self-reaction and to increase the temperature for a radicalization reaction close to 500°C. In concrete terms, air is supplied in an amount that exceeds the rate of the amount of supplied air for generating the temperature of approximately 450°C (the rate where the amount of supplied air is approximately 3.5L/min. when the amount of supplied methanol is 3cc).

[0042]

Figure 5 is a graph to explain that the MR gas generation device 10 related to this embodiment can control the radicalization catalyst reaction by changing the amount of supplied air. The reaction temperature range required for the radicalization catalyst reaction of methanol gas is approximately 450°C to 500°C. As shown in the graph of Figure 5, the MR gas generation unit 10 changes the amount of air supplied from the Cylinder upper part 12a in the range of approximately 3.5L/min to 6.0L/min. to an amount of supplied methanol of approximately 3.0cc. This makes it possible to change radicalization catalyst reaction temperature in the range of approximately 450°C to 500°C. Therefore, the temperature of the radicalization catalyst reaction can be easily controlled by changing the amount of air supplied from the air supply unit.

[0043]

As mentioned above, the MR gas generation unit 10 related to this embodiment does not require heating to maintain the temperature of the radicalization catalyst reaction and can cause a radicalization reaction by a stable self-reaction. Therefore, the radicalization reaction temperature can be controlled easily by changing the amount of supplied air alone. Since the concentration of the generated MR gas depends on the radicalization catalyst reaction temperature, the MR gas concentration can be easily controlled by

controlling the reaction temperature by changing the amount of supplied air as described above. This makes it possible for the MR gas concentration to be changed easily depending on the sterilization target, and sterilization can be performed on various targets.
[0056]

In the MR gas generation device 10 related to this embodiment, as mentioned above, the Catalyst cartridge 13 is composed of the Radicalization reaction catalyst 30 made from thin metal plates formed into a honeycomb structure, the surface area of contact between methanol gas and the Radical reaction catalyst 30 is increased, and methanol gas passes through a specified route.
[0057]

Increasing the surface area of contact with methanol gas by forming the Radical reaction catalyst 30 into a honeycomb structure makes it possible to increase catalyst reaction efficiency and to minimize the size of Catalyst cartridge 13 that is necessary for a radicalization reaction. In concrete terms, the size of Radical reaction catalyst 30 in the diameter direction in the Catalyst cartridge 13 can be set at a range of approximately 50mm to 70mm and a radicalization reaction with high reaction efficiency can be caused within this size range. By minimizing the size of Catalyst cartridge 13, it becomes possible to create a form that can be exchanged easily. In addition, by making methanol pass through a specific route, it becomes possible to reduce and keep variation in the radicalization reaction constant, and to control the fluctuations in reaction temperatures.
[0077]

In addition, as mentioned above, the Catalyst cartridge 13 enables a radicalization catalyst reaction by a stable self-reaction. Therefore, by arbitrarily controlling the amount of air supplied from the air supply unit that is connected to the Cylinder 12, it becomes possible to control the fluctuations in radicalization catalyst reaction temperatures easily and also change the concentration of MR gas to be generated easily. Thereby, by only changing the amount of supplied air to be mixed with methanol gas, MR gas at an appropriate concentration for sterilization targets can be generated easily and efficient sterilization can be performed on various targets. Additionally, since MR gas with an appropriate concentration can be generated arbitrarily in this way, it becomes possible to reduce the amount of supplied methanol to the minimum necessary, to use the device more safely, and to achieve sterilization that is suitable for the environment.
[0079]

Figure 13 is a frame format indicating schematically an example of the Sterilization device 40 to which MR gas generation device 10 related to this embodiment is applied. As shown in Figure 13, the Sterilization device 40 is composed of the Methanol tank 41,

an MR gas generation device 10', and a Sterilization tank 42 that serves as a place for maintaining the MR gas generation device 10' and sterilization targets and for sterilizing them with MR gas generated from the MR gas generation device 10'.

[0085]

In addition, by applying the aforementioned MR gas generation device 10 related to this embodiment, it is possible to make a sterilization device that does not require placing a Sterilization target 43 in the Sterilization device 40 for sterilization, as indicated in the Sterilization device 40 as shown in Figure 13. In other words, by placing in a closed area a sterilization device to which the MR gas generation device 10 related to this embodiment that enables downsizing is applied, and filling the closed area with the MR gas generated by the radicalization catalyst reaction, it is possible to sterilize that closed area. By doing this, sterilization becomes possible for areas that were impossible to sterilize with a sterilization device using a conventional MR gas generation device, such as hospital rooms, car interiors, etc.

[0088]

For example, by applying the MR gas generation device related to this embodiment, an ambulance car that transferred a patient with an infectious disease can be treated as a sterilization target. With a conventional sterilization device using MR gas, since the device itself was large, it was difficult to carry and took time for sterilization, and therefore only a limited number of ambulance cars, etc. could not to be sterilized quickly. However, when using a sterilization device to which the MR gas generation device related to this embodiment is applied and with which downsizing of the reaction catalyst is achieved by improving reaction efficiency, it is possible to carry the device easily and to implement sterilization easily.

[0089]

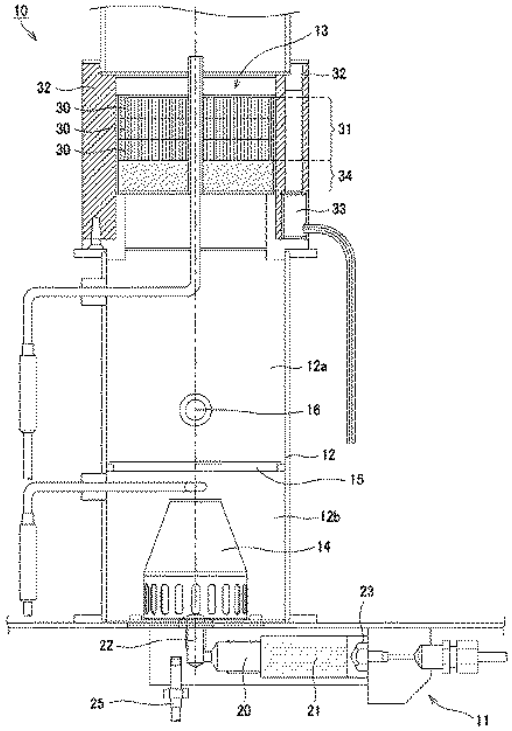
In addition, the MR gas generation device 10 related to this embodiment can control the radicalization reaction temperature by catalyst self-reaction easily by changing the amount of supplied air in the Cylinder upper part 12a, and thereby it can easily change the concentration of the generated MR gas. Therefore, for example, in cases of exposing MR gas for the purpose of destructing DNA, such as viruses, etc., the concentration of MR gas to be generated can be changed by changing the amount of supplied air depending on the sterilization target, such as, for example, increasing the radicalization reaction temperature by increasing the amount of supplied air to generate MR gas, etc. at a high concentration.

[0090]

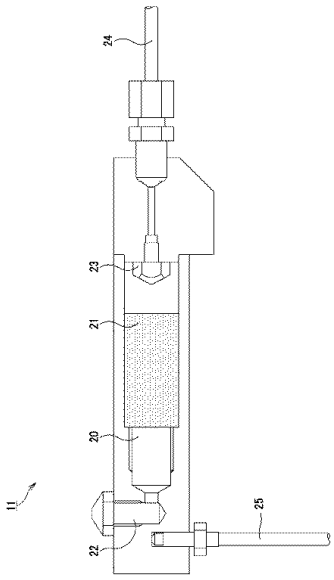
This invention is not limited to the aforementioned embodiment. Design changes, etc.

that do not deviate from the gist of the invention are also included in this invention.

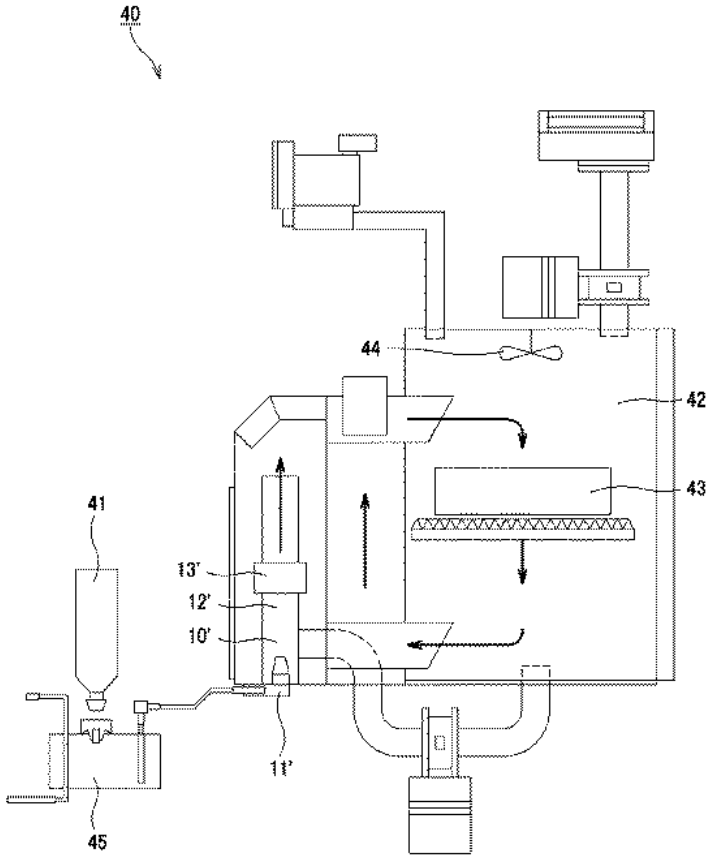
[Figure 1]



[Figure 2]



[Figure 13]



(Attachment 3)

1. [Claims]

[Claim 3]

A formaldehyde gas sterilization device with the following features: It is composed of a formaldehyde gas supply and exhaust device that supplies and exhausts formaldehyde gas in the sealed room and

a room pressure adjustment device that adjusts the pressure of the room;

wherein the formaldehyde gas supply and exhaust device is composed of a formaldehyde gas generator that generates the formaldehyde gas, a humidity adjuster that adjusts the humidity of the formaldehyde gas, a temperature adjuster that adjusts the temperature of the formaldehyde gas, a gas carrier that transfers and introduces the formaldehyde gas into the room, an exhaust gas processor that treats exhaust gas exhausted from the room, a gas ejector that exhausts the exhaust gas, and a control unit that controls the concentration, humidity, and temperature of the formaldehyde gas in the room to the predetermined concentration, humidity, and temperature;

wherein the room pressure adjustment device is composed of an air supply unit that supplies air from outside the room into the room, an exhaust air unit that exhausts the air in the room to outside the room, a means of detecting difference in pressures that detects differences in pressures between inside and outside the room, a means of controlling the air supply unit and the exhaust air unit based on the values detected by the means of detecting differences in pressures, and a means of outputting the control status of the room pressure based on the values detected by the means of detecting differences in pressures.

2. [Detailed explanation of the invention]

(1) "Technical field

This invention is related to a formaldehyde gas sterilization device that sterilizes the area subject to sterilization by formaldehyde gas." (Page 4, lines 2 through 4)

(2) "Technical background

The conventional method of using formaldehyde gas for the purpose of sterilizing the area, such as a bio-clean room, surgery room, etc., required the area subject to the sterilization to be a closed area and generated formaldehyde gas by placing a formaldehyde gas generator in the area.

However, sterilization (hereinafter it also means "disinfection" in these descriptions) effects by formaldehyde gas greatly depend on the concentration, humidity, and temperature of the formaldehyde gas in the area subject to sterilization. Therefore, in order to obtain fully certifiable sterilization effects, it is not enough to fill the area subject to sterilization with formaldehyde gas for a specified time.

...In addition, the area subject to sterilization is required to be a sealed area (room). Therefore, it is also necessary to control room pressure." (Page 4, lines 5 through 21)

(3) "Disclosure of invention

...In addition, the formaldehyde gas sterilization device of this invention is composed of a formaldehyde gas generator that generates formaldehyde gas; a humidity adjuster that adjusts the humidity of the formaldehyde gas; a temperature adjuster that adjusts the temperature of the formaldehyde gas; a gas carrier that transfers and introduces the formaldehyde gas into the area subject to sterilization; an exhaust gas processor that treats exhaust gas exhausted from the area subject to sterilization; a gas ejector that exhausts the exhaust gas; and a control unit that instructs the formaldehyde gas generator to generate formaldehyde gas at a concentration in the predetermined range, controls the humidity of the formaldehyde gas in the predetermined range by the humidity adjuster, controls the temperature of the formaldehyde gas in the predetermined range by the temperature adjuster, controls the gas transfer amount by the gas carrier in the predetermined range, controls the formaldehyde gas amount that is being exhausted by the exhaust gas treatment device in the predetermined range, and controls the exhaust gas emission amount by the gas ejector.

The formaldehyde gas sterilization device of this invention controls the concentration, humidity, and temperature of formaldehyde gas in the area subject to sterilization to the predetermined concentration, humidity, and temperature by the control unit and therefore fully certifiable sterilization effects can be obtained." (Page 4, line 22; Page 5, line 17 through page 6, line 3).

(4) "In addition, the formaldehyde gas sterilization device of this invention has the following features: it has a formaldehyde gas supply and exhaust device that supplies and exhausts formaldehyde gas into and from the sealed room and a room pressure adjustment device that adjusts room pressure; wherein the formaldehyde gas supply and exhaust device is composed of a formaldehyde gas generator that generates formaldehyde gas, a humidity adjuster that adjusts the humidity of formaldehyde gas, a temperature adjuster that adjusts formaldehyde gas temperature, a gas carrier that transfers and introduces formaldehyde gas into the room, an exhaust gas processor that treats exhausted gas from the room, a gas ejector that exhausts the exhaust gas, and a control unit that controls the concentration, humidity, and temperature of the formaldehyde gas in the room to the predetermined concentration, humidity, and temperature; wherein the room pressure adjustment device is composed of an air supply unit that supplies air outside the room into the room, an air exhaust unit that exhausts room air outside the room, a means of detecting differences in pressures between inside and outside the room, a means of

controlling the air supply unit and air exhaust unit based on the values detected by the means of detecting differences in pressures, and a means of outputting the control status of the aforementioned room pressure based on the values detected by the means of detecting differences in pressures.

...The formaldehyde gas sterilization device of this invention has a room pressure adjustment device and therefore room pressure can be kept constant even if the room air expands due to increases in room temperature.

In addition, the formaldehyde gas sterilization device of this invention has a treatment device that treats the air exhausted from the room by the air exhaust unit.

The formaldehyde gas sterilization device of this invention treats formaldehyde gas, etc. that is contained in the room air by the treatment device even if room air is exhausted in order to adjust room pressure, and therefore, formaldehyde gas can be exhausted outside the room after it is treated." (Page 6, line 4 through page 7, line 6).

(5) "Best embodiment of the invention

The first embodiment of this invention is explained hereinafter in reference to Figure 1. Figure 1 is a configuration diagram of the Formaldehyde gas sterilization device 2 related to the first embodiment. The Formaldehyde gas sterilization device 2 has a Housing 10 and can be attached outside the biohazard safety cabinet and can easily implement sterilization of the area in the cabinet (hereinafter referred to as "Area subject to sterilization 100"). In this case, the inside of the cabinet must be a closed area by closing dampers, etc. The cabinet has a Formaldehyde gas inlet 102 for supplying formaldehyde gas from the Formaldehyde gas sterilization device 2 and an Exhaust gas outlet 104 for exhausting formaldehyde gas.

The Area subject to sterilization 100 has a Formaldehyde gas concentration sensor 12, a Humidity sensor 14, and a Temperature sensor 16, and each monitored value is communicated to the Controller 24 via the Control lines 18, 20, and 22.

Outside air is introduced in the Area subject to sterilization 100 from the Formaldehyde gas inlet 102 by the Pump 26 and exhaust gas is exhausted outside from the Exhaust gas outlet 104 via the Pump 28. Or, the exhaust gas exhausted from the Pump 28 is introduced again to Pump 26 via a Reflux route 30 and thereby air in the Area subject to sterilization 100 is circulated." (Page 7, lines 7 through 23)

"...For this reason, the formaldehyde gas concentration, humidity, and temperature in the Area subject to sterilization 100 are monitored by the Concentration sensor 12, the Humidity sensor 14, and the Temperature sensor 16 respectively; necessary calculation is conducted by the Control device 24 based on the obtained values; and the Formaldehyde gas generator 36, the Temperature adjuster 34, the Humidity adjuster 32, and the Pump

26 are controlled through the Control lines 38, 40, 42, and 44. ...

After the predetermined time has elapsed, the Formaldehyde gas generator 36 is stopped and treatment by the Exhaust gas processor 46 is implemented until the formaldehyde gas concentration in the Area subject to sterilization 100 falls below the predetermined value. In other words, the gas released from the Pump 28 is introduced again into the Pump 26 via the Reflux route 30, air in the Area subject to sterilization 100 is circulated, and thereby the formaldehyde gas concentration is decreased gradually to below the predetermined concentration." (Page 8, lines 1 through 12)

(6) "A formaldehyde gas generator that can be used in this invention is not particularly limited as long as it can generate formaldehyde gas at a high concentration while controlling humidity and temperature." (Page 8, lines 19 through 21)

"Controlling the generation amount of formaldehyde depends on control of the catalyst temperature, and the amount of supplied methanol, or the vaporizing amount. Reaction conditions can be optimized by actually generating formaldehyde and measuring the appropriate formaldehyde gas concentration." (Page 9, lines 4 through 7)

"In this invention, it is preferable to adjust the temperature in the area subject to sterilization in order to maintain formaldehyde gas at an appropriate concentration within the appropriate temperature range for a long period of time. The means of controlling the temperature that is installed for this purpose is not particularly limited and a publicly-known heating or cooling device can usually be used." (Page 9, line 27 through page 10, line 1).

"In this invention, it is preferable to adjust humidity in the sealed area in order to maintain formaldehyde gas at an appropriate concentration within the appropriate humidity range for a long period of time. The means of controlling the humidity that is installed for this purpose is not particularly limited and a publicly-known humidification or dehumidification device can usually be used." (Page 10, lines 6 through 9)

"In this invention, it is necessary to maintain the temperature, humidity, and formaldehyde gas concentration in the area subject to sterilization in the predetermined range for the predetermined time. The concentration of formaldehyde gas in the area subject to sterilization is decreased by various reactions, such as the sterilization reaction, etc., in the area subject to sterilization. Therefore, in order to keep the concentration of formaldehyde gas constant, it is necessary to import the temperature, humidity, and formaldehyde gas concentration data within the set period and to control the means of generating formaldehyde so that the concentration is within the specified range. The control method and control device for this purpose are not particularly limited; however, a manual method or a control device using a computer program may be considered. In

this invention, it is necessary to maintain formaldehyde at a high concentration for a long period of time. Therefore, it is preferable to have functions to send signals to the formaldehyde generation device, pump, temperature adjuster, and humidity adjuster, while optimizing them on a timely basis, and to control the concentration. (Page 11, line 19 through the last line)

(7) "Next, by referring to Figure 2 and Figure 3, a formaldehyde gas sterilization device related to the second embodiment of this invention is explained. The formaldehyde gas sterilization device related to the second embodiment is a Formaldehyde gas supply and exhaust device 4 that has the same structure as the Formaldehyde gas sterilization device 2 related to the first embodiment and that is equipped with the Room pressure adjustment device 6 that adjusts pressure in the area subject to sterilization, which is formed as a sealed room.

Figure 2 is a configuration diagram of the Formaldehyde gas sterilization device 4 related to the second embodiment and the formaldehyde gas sterilization device that includes the Room pressure adjustment device 6. The Room pressure adjustment device 6 is installed by connecting it to the Room wall 50 and it adjusts pressure of the room sealed by the Room wall 50. The Room pressure adjustment device 6 is composed of an Air supply unit 52 that supplies air from outside the room into the room, an Air exhaust unit 54 that exhausts the air inside the room to outside the room, a Minor differential pressure detector 56 that detects differences in pressures between inside and outside the room, and the Control unit 58 that controls the Air supply unit 52 and Air exhaust unit 54 based on the values detected by the Minor differential pressure detector 56.

The Air supply unit 52 has an Air supply grill 60 for intaking air from outside the room. Three Air supply adjustment solenoid valves 62 that adjust the amount of air supplied from outside to inside the room are installed downstream from the Air supply grill 60. In addition, an Air blower 66 and HEPA (high efficiency particulate air) filter 68 are installed sequentially in the Air route 64 downstream from the Air supply amount adjustment solenoid valve 62.

The Air exhaust unit 54 has a HEPA filter 72 in an Air supply route 70 and three Exhaust gas amount adjustment solenoid valves 74 that adjust the amount of air exhausted from inside to outside the room are installed downstream from the HEPA filter 72. In addition, downstream from the Exhaust air amount adjustment solenoid valve 74, an Air treatment device 76 including a platinum catalyst and a heater, is installed. Air outside the room is supplied to the Air treatment device 76 via a Solenoid valve 78. The catalyst temperature can be kept constant by supplying air from outside the room.

In addition, downstream from the Exhaust air amount adjustment solenoid valve 74,

an Air blower 82 is installed in order to exhaust the air that went through the Air treatment device 76 and air that is taken in from the Air supply grill 80 to the outside the Room pressure adjustment device 6." (Page 13, the last line through page 14, the last line).

(8) "The Minor differential pressure detector 56 is installed on the Room wall 50 and is connected to the Control unit 58 via a signal line. The differences in pressures between inside and outside the room that are detected by the Minor differential pressure detector 56 are input into the Control unit 58.

The Control unit 58 is connected to the Air supply amount adjustment solenoid valve 62 and the Air blower 66 of the Air supply unit 52 via a signal line and it is also connected to the Exhaust air amount adjustment solenoid valve 74, the Solenoid valve 78, and the Air blower 82 of the Exhaust air unit 54. The Control unit 58 controls the Air supply amount adjustment solenoid valve 62, the Air blower 66, the Exhaust air amount adjustment solenoid valve 74, and the Air blower 82, etc. based on the values detected by the Minor differential pressure detector 56. The Control unit 58 is connected to a Memory device 84 that always saves the values detected by the Minor differential pressure detector 56 and is connected to an Output device 86, such as a printer, etc., that outputs detected values that are saved in the Memory device 84." (Page 15, lines 1 through 11)

"The Formaldehyde gas sterilization device introduces outside air from the Pump 26 of the Formaldehyde gas supply and exhaust device 4 into the room from the Formaldehyde gas inlet 102 and exhausts air from the Exhaust gas outlet 104 to the outside air through the Pump 28. Room temperature and humidity that are obtained from the Humidity sensor 14 and the Temperature sensor 16 are controlled by the Humidity adjuster 32 and the Temperature adjuster 34 of the Control device 24 so that they are within the range of the predetermined temperature of 20°C to 40°C and the range of the predetermined humidity of 50% to 90% (relative humidity). In addition, the Formaldehyde gas generator 36 and the Pump 26 adjust the formaldehyde gas concentration so that it maintains the predetermined formaldehyde gas concentration of 160ppm and higher for the predetermined time. For this reason, the formaldehyde gas concentration, humidity, and temperature are monitored by the Concentration sensor 12, the Humidity sensor 14, and the Temperature sensor 16 respectively, the necessary calculations are conducted by the Control device 24 based on the obtained values, and the Formaldehyde gas generator 36, the Temperature adjuster 34, the Humidity adjuster 32, and the Pump 26 are controlled through the Control lines 38, 40, 42, and 44." (Page 15, lines 12 through 23)

(9) "Room pressure is maintained at positive pressure by the room pressure adjustment device while the predetermined time, room temperature, humidity, and formaldehyde gas

concentration are respectively maintained in the temperature range of 20°C to 40°C, in the humidity range of 50% to 90% (relative humidity) and in the formaldehyde gas concentration range of 160ppm or higher respectively. In other words, room pressure is maintained at positive pressure (10Pa to 20Pa) by the treatment shown in the flowchart of Figure 3. Control based on the flowchart is implemented repeatedly by the Control unit 58 with minor time intervals." (Page 15, line 26 through page 16, line 3)

"First, the Control unit 58 obtains differences in pressures between inside and outside the room that is detected by the Minor differential pressure detector 56 (Step S10) and saves it in the Memory device 84 (Step S11). Next, if the differences in pressures are 10Pa to 20Pa (Step S12), the pressure is normal and therefore the Control unit 58 returns to the treatment in Step S10 and continues processes, such as detecting differences in pressures (Step S10), saving detected values (Step S11), etc.

At the same time, if the difference in pressures between inside and outside the room that is detected by the Minor differential pressure detector 56 is 10Pa or lower (Step S12), the room pressure is too low. Therefore, air is to be supplied into the room (Step S14). In other words, control signals are sent to the Air supply amount adjustment solenoid valve 62 and Air blower 66 to open the Air supply amount adjustment solenoid valve 62 for the predetermined time and operate the Air blower 66. Through this, the outside air is supplied...into the room and room pressure increases by the value corresponding to the time when the Air supply amount adjustment solenoid valve 62 is opened.

If the difference in pressures between inside and outside the room that is detected by the Minor differential pressure detector 56 is 20Pa or higher (Step S12), the room pressure is too high. Therefore, air is to be exhausted outside the room (Step S13). In other words, control signals are sent to the Exhaust air amount adjustment solenoid valve 74 and the Air blower 82 to open the Exhaust air amount adjustment solenoid valve 74 for the predetermined time and operate the Air blower 82. Through this, the room air is exhausted to outside the room via the HEPA filter 72, the Exhaust air amount adjustment solenoid valve 74, and the Air treatment device 76 and the room pressure will decrease by the value corresponding to the time when the Exhaust air amount adjustment solenoid valve 74 is opened." (Page 16, lines 4 through 24)

"The Room pressure control device 6 can always maintain the differences in pressures between inside and outside the room at 10Pa to 20Pa. Therefore, in cases of sterilizing the room using formaldehyde gas, even if room air volume increases due to increases in room temperature, formaldehyde gas is exhausted after it is treated by the Air treatment device 76. Therefore, it can prevent formaldehyde gas from leaking outside the room without being treated. In addition, since the differences in pressures between inside and

outside the room are saved in the Memory device 84 in chronological order, the detected values that were saved in the Memory device 84 are output from the Output device 86 and thereby it can guarantee that the room pressure is always maintained at the predetermined positive pressure based on the output results. Consequently, it is possible to guarantee that formaldehyde gas has not been released outside the room without being treated." (Page 16, line 27 through page 17, line 7).

(10) In the aforementioned second embodiment, the Air treatment device 76 is installed on the Room pressure adjustment device 6. Formaldehyde gas can be treated by using the Exhaust gas processor 46 of the Formaldehyde gas supply and exhaust device 4." (Page 17, lines 13 through 15)

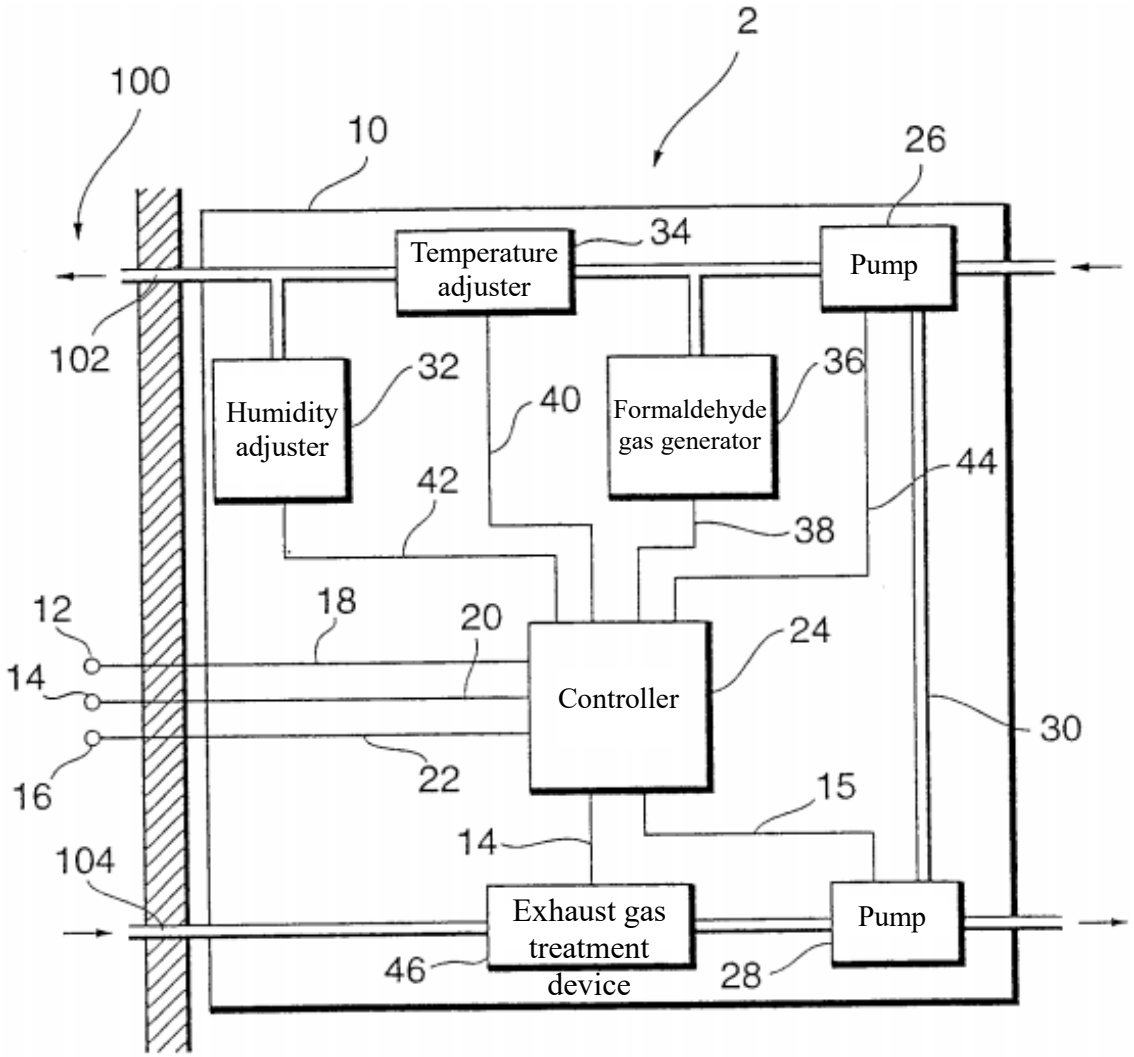
"The device of this invention has an integrated type housing structure and can be installed outside the area subject to sterilization. Therefore, clean emissions can be achieved by introducing formaldehyde gas into the area subject to sterilization and treating exhaust gas from the area subject to sterilization before emissions. In addition, the device can be detached easily. Furthermore, the device related to this invention can be easily moved to the place where the area subject to sterilization is located. Fully certifiable sterilization can be implemented easily in an ambulance, mobile surgery room (including tent), or bio-clean room." (Page 17, lines 16 through 21)

(11) "In addition, the device related to this invention can prevent formaldehyde gas from leaking outside the room before treatment even in cases where the room air volume increases due to increases in the room temperature, and fully certifiable sterilization effects can be obtained." (Page 17, line 28 through page 18, line 2).

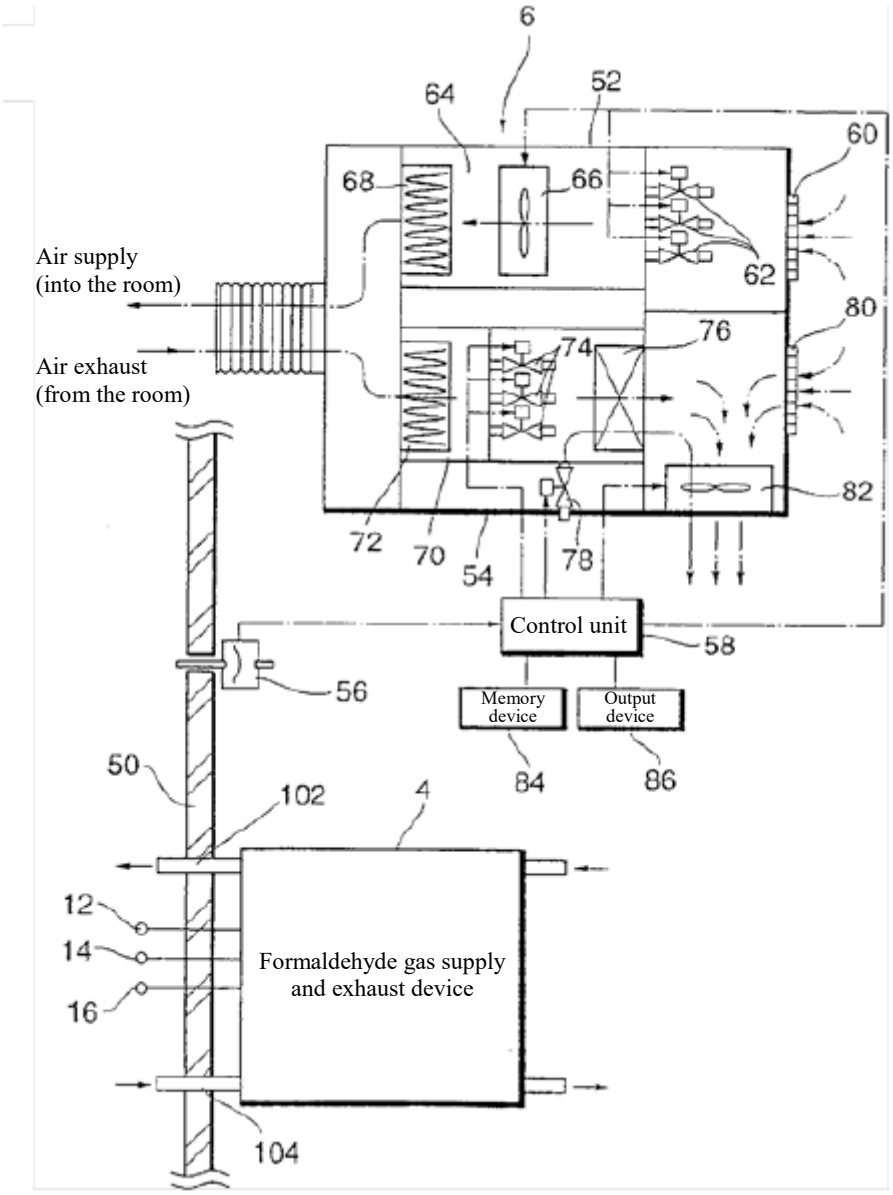
(12) "Industrial availability

Based on the above, the formaldehyde gas sterilization device of this invention is suitable for sterilizing the area subject to sterilization to an extent that is fully certifiable." (Page 18, lines 3 through 5)

[Figure 1]


2
100
10
26
34
Temperature adjuster
Pump
102
32
Humidity adjuster
40
36
Formaldehyde gas generator
44
42
38
12
18
20
24
14
Controller
30
16
22
15
14
104
Exhaust gas treatment device
Pump
46
28

[Figure 2]


6
64
52
60
68
66
62
Air supply
(into the room)
Air exhaust
(from the room)
74
76
80
82
72
70
54
78
Control unit
58
56
Memory device
Output device
84
86
50
102
4
12
14
16
Formaldehyde gas supply and exhaust device
104

(Attachment 4)

1. Exhibit Ko 23 (Unexamined Patent Application Publication No. 2001-349586; Publication date: December 21, 2001)

[Claim 1] A Room pressure adjustment device with the following features: It is a room pressure adjustment device that adjusts pressure of the sealed room; and
it is composed of an air supply unit that supplies outside air into the room,
an exhaust air unit that exhausts the air in the room to outside the room,
a means of detecting differences in pressures between inside and outside the room,
a means of controlling the air supply unit and the air exhaust unit based on the values detected by the means of detecting differences in pressures,
a means of outputting the control status of the room pressure based on the values detected by the means of detecting differences in pressures.

[Claim 2] The control device is a room pressure adjustment device that is stated in Claim 1 and is featured by the function to control the room pressure at positive pressure against the pressure outside the room.

[Claim 3] The control device is a room pressure adjustment device that is stated in Claim 1 and is characterized by the function to control the room pressure at negative pressure against the pressure outside the room.

[0002]

[Conventional art] ...In addition, it is preferred for biohazard rooms, etc. that room pressure is maintained at a lower pressure than outside the room so that air that may be contaminated does not leak outside the room.

[0007] The room pressure adjustment device that is stated in Claim 3 has the feature that the control device that controls the room pressure at negative pressure against the pressure outside the room. The room pressure adjustment device stated in Claim 3 can prevent room air that may be contaminated from being exhausted outside the room by always maintaining the room at negative pressure in cases where the inside of the room may be contaminated.

[0019] Since the HEPA filter 28 is installed in the Air route 24 of the Air supply unit 12, in cases of sterilizing a room, etc., even if it is necessary to supply air into the room, such as the situation where the room pressure becomes too low, etc., it can prevent very fine particles that exist outside the room from entering the room. In this embodiment, room pressure is controlled to maintain positive pressure; however, it is also possible to control the room pressure to maintain negative pressure. Negative pressure refers to the case where (Room pressure) - (Pressure outside the room) is negative.

[0020] In the biohazard room, chemical hazard room, etc., room air may be contaminated.

Therefore, it is necessary to prevent room air from leaking outside the room. The Room pressure control device 2 can always maintain the differences in pressures between inside and outside the room at 10Pa to 20Pa (maintaining room pressure at -10Pa to -20Pa from the pressure outside the room) and the detected differences in pressures are saved in the Memory device 44 in chronological order. Therefore, it can be guaranteed that the room pressure is always maintained at negative pressure based on the output results by outputting the detected values that are saved in the Memory device 44 by the Output device 46. Consequently, it can be guaranteed that there is no contamination outside the room by guaranteeing that the air in the biohazard room, etc. has not leaked outside the room.

2. Exhibit Ko 82 (Unexamined Patent Application Publication No. 1998-132346; Publication date: May 22, 1998)

[0004] ...Biohazard countermeasure facilities handle microbes that cannot be guaranteed to be unharmful to the human body, such as general pathogens, tumor viruses, and recombinant DNA. In biohazard countermeasure facilities, countermeasures have been taken to prevent disasters that human beings would suffer directly or indirectly from biohazard or microbe infections. The room pressure of a laboratory, etc. that is subject to biohazards is maintained at negative pressure so that air flow, including leakage from clearances, is kept in one direction from outside to inside the room, thereby preventing the leakage of biohazard sources to the outside. In addition, in chemical hazard countermeasure facilities, chemical substances that contaminate the environment and are harmful to the human body are handled. Therefore, in the same way that in biohazard countermeasure facilities, the room pressure of laboratories, etc. are set at negative pressure, air flow, including leakage from the clearance, is maintained in one direction from outside to inside the room, and thereby preventing the leakage of chemical hazard sources from inside to outside the room.

3. Exhibit Ko 83 (Unexamined Patent Application Publication No. 1999-347106; Publication date: December 21, 1999)

[0008]

[Means of solving problems] The method of the invention is to conduct the depressurization and introduction of ozone gas alternately regarding the sterilization chamber where sterilization targets are stored, and to conduct the sterilization of the sterilization targets.

[0064] In other words, maintaining sterilization chamber 5 at a pressure lower than the atmospheric pressure even during the supply of Ozone gas 4 can prevent Ozone gas 4 from leaking outside the Sterilization chamber 5.

4. Exhibit Ko 84 (Unexamined Patent Application Publication No. 1992-64846; Publication date: December 17, 1992)

[Claim 1] An aseptic bed device with the following features: It is roughly a rectangular solid; it has a bed storage area to store a bed, including a bedroom unit that has an opening end that connects with the bed storage area at least on two side walls, a clean air supply source that can be detachable to at least one of the opening ends of the bedroom unit and supplies clean air to the opening end, and an auxiliary unit that is detachable with at least one of the opening ends of the bedroom unit, has an open-close door, or forms an area that connects to the bed storage area; wherein the bedroom unit has a sterilization gas supply port and inner pressure adjustment exhaust port, and supplies the sterilization gas from the first port to sterilize inside the bedroom, while adjusting, through the second port, the exhaust gas amount so that the inside of the bedroom is always kept at a negative pressure, and [that] exhausts the sterilization gas to the air exhaust line via the means of detoxifying the sterilization gas, and thereby eliminates the leakage of sterilization gas to the outside of the aseptic bed device.

[0013] The bedroom unit and the auxiliary unit have a port to supply ozone gas or other sterilization gases and an inner pressure adjustment exhaust port. Inside the bedroom unit and the auxiliary unit, etc. can be disinfected by supplying ozone or other sterilization gases through the supply port. The exhaust air amount is adjusted through the inner pressure adjustment exhaust port so that inside the bedroom unit and the auxiliary unit are always kept at a negative pressure, and thereby preventing ozone from leaking outside. A deozonizer that is a means of detoxifying is installed on the exhaust line of the gas exhausted from the inner pressure adjustment exhaust port, thereby detoxifying some of the sterilization gas, such as ozone, etc., by changing it to oxygen, and then diffusing and exhausting the detoxified gas into the air. …

[0030] Figure 10 is a system chart for one entire working example of this invention. In the Bedroom unit 2 or the working example in Figure 10, a Supply port 71 that supplies ozone, which is a sterilization gas, is installed on the Door unit 4 and the Inner pressure adjustment exhaust port 72 is installed on the Bedroom unit 2. Air from outside or oxygen through the Ozonizer 73, or ozone that is obtained from the circulation gas from the Pipeline 79 are supplied to the Supply port 71 via the Pipeline 74 and the Variable orifice 75 that is a flow rate control valve. This makes it possible to sterilize inside the Bedroom unit 2 and the Door unit 4. Part of the gas from the Exhaust port 72 is led to the Deozonizer 77 via the Attracting fan 76, and ozone is detoxified into oxygen and diffused into the air. Using the Attracting fan 76 always keeps the inside of the Bedroom unit 2 and the Door unit 4 at a negative pressure and thereby prevents ozone from being leaked outside. The

pressure in the Bedroom unit 2 is detected by the Pressure detector 78. The opening degree of the Variable orifice 75 is changed by the Adjustment meter 79 so that the pressure in the Bedroom unit 2 can be maintained at the predetermined constant negative pressure. …In this way, inside the Bedroom unit 2 and the Door unit 4 are sterilized when there is no patient and thereby it can prevent leakage of ozone to the outside during disinfection and the disinfection can be implemented easily. …

(Attachment 5)

1. Exhibit Ko 81 ("Kagaku Daijiten (Chemical Dictionary)" (1st edition) (Edited by Ohki Michinori, et al.; Tokyo Kagaku Dojin; Issued on October 20, 1989)

"Formaldehyde: ...A combustible colorless gas with a strong pungent odor. It exists in the smoke when coal and wood are burnt. It is very irritating to mucosa and is a carcinogen." (P. 2261, right column, lines 23 through 28)

2. Exhibit Ko 85 (JIS T 7328: 2005 Formaldehyde gas disinfectors for medical use) (Japanese Standards Association/Japan Association of Medical Equipment Industries; 2005)

"Formaldehyde gas disinfectors for medical use...

1. Scope of application: This standard stipulates the requirements for the safety, performance, testing, and labeling of a disinfector for which the use pressure is normal pressure and atmospheric pressure or lower out of formaldehyde gas disinfectors that are used for the disinfection of medical devices (disinfection targets) (hereinafter simply referred to as a "disinfector"). (Page 3, lines 3 through 7)

"4. 2. Disinfector safety

4. 2. 1. The interlock of a door or a cover: A disinfector must have an automatic interlock structure where it is designed so that gas is not supplied in the chamber when the chamber door or cover is not locked under normal operating conditions.

4. 2. 2. Prevention of exposure of operators to formaldehyde: A disinfector must conform to 13.1.101 of IEC61010-2-042:1997 in order to prevent exposure of operators.

If a gas leakage occurs, a disinfector should have a structure to stop gas supply, reduce pressure in the chamber, and display a warning automatically by interlocking with the gas leakage alarm that is installed separately. However, a disinfector where gas is supplied at negative pressure compared to the atmospheric pressure is excluded." (Page 5, lines 20 through 31)

3. Exhibit Ko 88 (Patent No. 2690518; Publication date: August 29. 1997)

"Figures 1 and 2 are for explaining this invention, ...Figure 2 is a line map that shows the relationship between the changes in pressures in the sterilization container in association with the progress of the sterilization and the status of constituent features along with the passage of time." (Page 2, left column, lines 36 through 39)

"When sterilizing, first close the Cover 2 of the Sterilization container 1 after placing the sterilization target in the Sterilization container 1, operate the Vacuum pump 3 to maintain the inside of the Sterilization container 1 at negative pressure, implement vacuum procedures to exhaust air in the sterilization target, and thereby make conditions where sterilization gas can easily enter the sterilization target. After the vacuuming procedures,

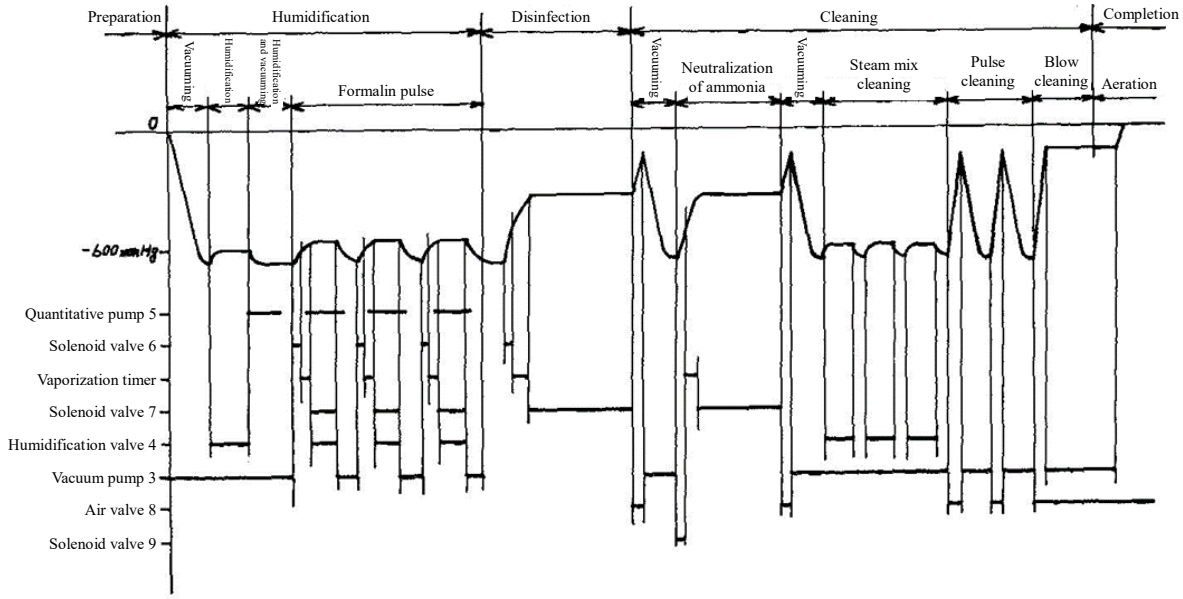
open the Humidification valve 4 only for an appropriate time, conduct humidification procedures to humidify the sterilization target to make a better fit between the sterilization gas that is supplied subsequently into the Sterilization container 1 and the sterilization targets.

After the humidification procedure and humidification vacuum procedure, implement formalin pulse procedures where the operation of the Quantitative pump 5 for transferring formalin, the release of Solenoid valve 6, turning ON of a vaporization timer to heat and vaporize formalin, and the release of Solenoid valve 7 to send the formaldehyde generated from vaporization into the Sterilization container 1 are repeated as necessary and where generating formaldehyde for sterilization and sending a rather small amount of formaldehyde into the Sterilization container 1 are implemented repeatedly so that there is a better fit between the large amount of formaldehyde that is sent subsequently and sterilization targets.

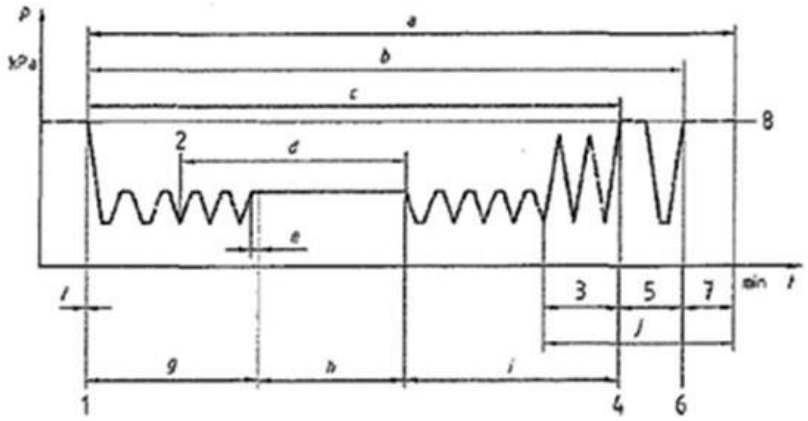
After completing this vacuuming, humidification, humidification and vacuuming, and formalin pulse procedures, send a rather large amount of formaldehyde into the Sterilization container 1 and sterilize (disinfect) the sterilization targets stored in the Sterilization container 1. (Page 2, left column, line 42 through right column, line 13 in the same page).

"Figure 2 is a line map that shows the relationship between the changes in pressures in the sterilization container in association with the progress of the sterilization and the status of constituent features along with the passage of time." (Page 3, left column, line 4 through right column, line 1 on the same page)

[Figure 2]



4. Exhibit Ko 94 ("Healthcare Seihin no Mekkin oyobi Mekkin Hosho" (Sterilization of Healthcare Products and Guarantee of Sterilization) (Issued on April 25, 2011)



1. Cycle start
2. Start of injecting sterilization materials
3. Cycle flashing
4. Display of cycle completion
5. Post-cycle
6. Display of cycle completion when door opening and ejection were delayed
7. Taking out sterilization targets (conduct aeration outside the sterilization device as necessary)
8. Atmospheric pressure

a. Sterilization process
b. Operating cycle
c. Sterilization cycle
d. Exposure time
e. Balance time
f. Pre-heating
g. Degassing and conditioning
h. Retention time
i. Desorption
j. Aeration

Figure 7.3 LTSF Sterilization Process

"7.6.1.2. Characteristic of the process

Low Temperature Steam and Formaldehyde (LTSF) sterilizer must include the

following processes. They are shown along with the changes in pressures in the sterilizer in Figure 7.3.

(1) Air removal

(2) Conditioning

(3) Injection of sterilizer

(4) Balancing time and retention time

(5) Desorption

(6) Pressure restoration to atmospheric pressure by injecting air.

In order to achieve the sterilization process of LTSF, it is necessary to select the formaldehyde concentration to be used in the range between 2% to 38% and to define the sterilization process based on the concentration. The parameter setting that forms the sterilization process varies by the formaldehyde concentration to be used and there are differences in the sterilization performance and drying performance." (Page 308, right column)

"(2) Sterilization operation

After supplying 12% formaldehyde solution at -10kPa, depressurize to -80kPa, heat and vaporize. After maintaining the conditions for 10 minutes, supply filtered air into the chamber and restore pressure to -10kPa.

Due to increases in the pressure, sterilization agents are exposed to the inner cavities that are difficult to sterilize in the sterilization target. After maintaining the pressure for 5 min., repeat the operation to supply 12% formaldehyde solution and the subsequent series of depressurization, heating and vaporizing, and pressure restoration by introducing air 12 times.

Operation time: 180 min.

Use amount of 12% formaldehyde solution: 90mL" (page 317, left column)

5. Exhibit Ko 95. "Formaldehyde Gasu Mekkin no Tokusei to Jitsukizai no Gaiyou" (Characteristics of Sterilization with Formaldehyde and Outline of Equipment" (Kansen-Seigyo Vol. 7, No. 2; Issued on April 25, 2011)

"Formaldehyde is... Its steam is an irritant to mucosa and the respiratory tract when it exceeds the predetermined concentration. It has been determined to be one of causes of sick house syndrome. In Japan, the Order for Enforcement of the Industrial Safety and Health Act and the Regulation on Prevention of Hazards due to Specified Chemical Substances, etc. are partially enforced and the category of formaldehyde was changed from Group 3 substances to Group 2 substances of the specified chemical substance. …In addition, WHO's International Agency for Research on Cancer (IRAC) classifies formaldehyde into Group 1, which is 'carcinogenic to the human body.'" (Page 119, line

5 from the bottom of the left column through line 7 from the bottom of the right column)

"The treatment method of HS6610 TURBO LTSF is low-temperature steam formaldehyde sterilization. In other words, inject steam and formalin through a mounted vaporizer several times so that they disseminate uniformly to the sterilization target in the chamber that is kept at negative pressure. On the other hand, PS140R adopts a pre-vacuum method to keep the chamber at negative pressure using a pump, vaporize the formalin solution, and have it act on sterilization targets." (Page 120, 13 lines through line 6 from the bottom of the right column)