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Boucher

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[54] METHOD FOR CONTINUOUS STERILIZATION AT LOW TEMPERATURE

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[52] **U.S. Cl.** .....**21/54 A,** 21/54 R, 21/58, 21/102 R, 21/102 A, 21/DIG. 2

[51] **Int. Cl.** **A61l 13/00,** A61l 1/00, A61l 3/00

[58] **Field of Search**..21/102 R, 54 A, DIG. 2, 102 A, 21/58, 54 R; 134/1

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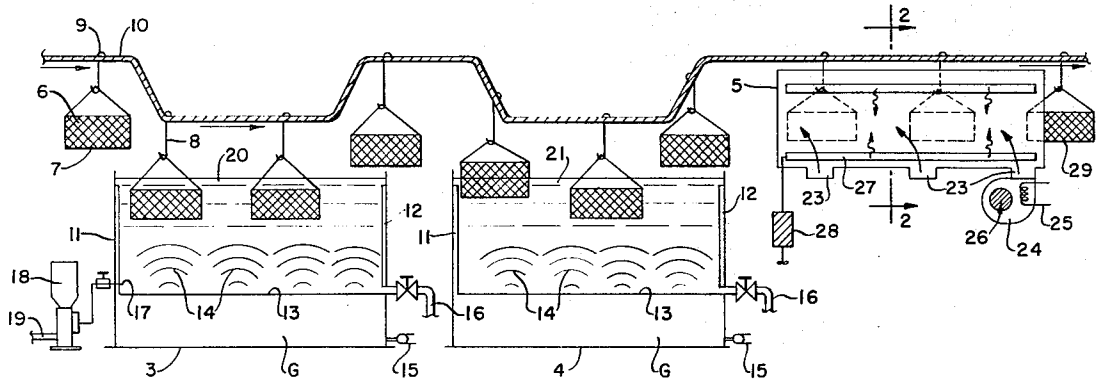
[57] **ABSTRACT**

An automatic method and apparatus to continuously surface sterilize at temperatures below 75° C any objects, parts or components made of metal or heat sensitive materials. Said method consists of treating materials first in a synergistically active chemical solution in an ultrasonic tank, then of rinsing in a second ultrasonic tank. The final step consists of drying the processed material in a sterile atmosphere. The three different processing steps take place in a matter of minutes inside a laminar flow positive pressure clean or white room. The apparatus continuously delivers sterile parts or instruments ready for packaging and sealing. Sterilized parts or instruments are not physically or chemically affected by the process and do not contain dissolved corrosive or toxic compounds.

19 Claims, 2 Drawing Figures



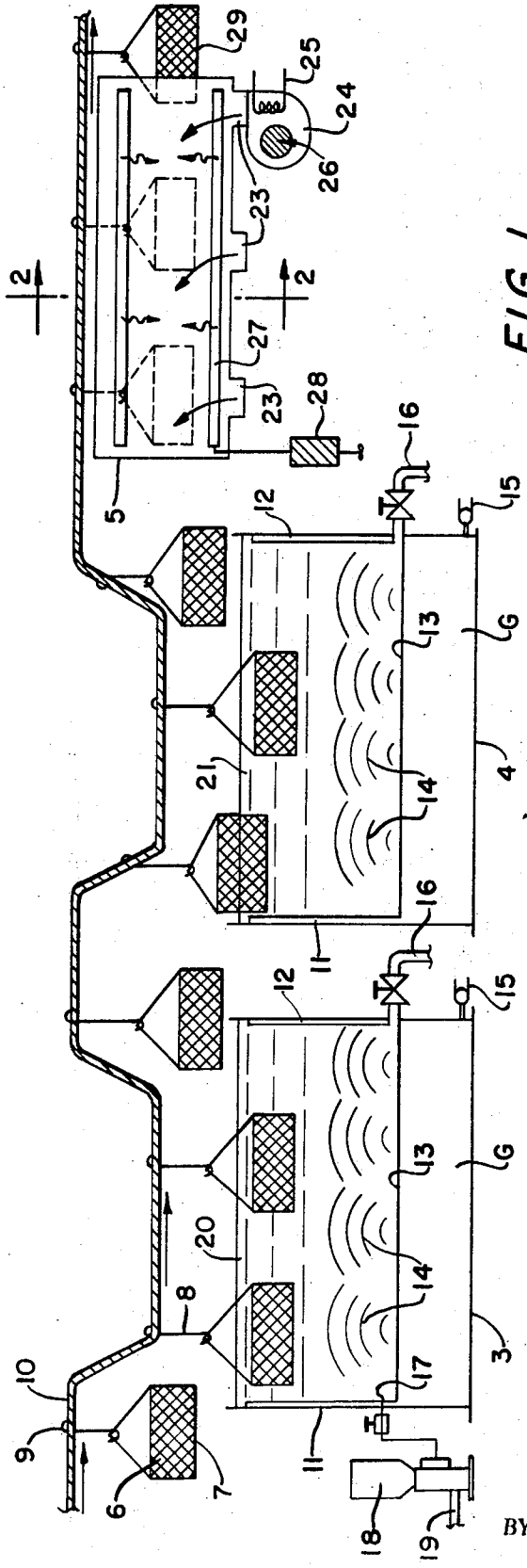


FIG. 1.

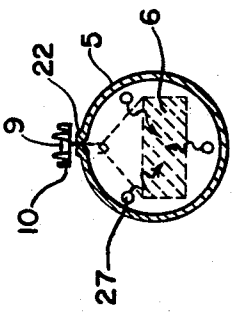


FIG. 2.

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METHOD FOR CONTINUOUS STERILIZATION AT LOW TEMPERATURE

This invention relates to a continuous sterilization method at low and medium temperatures to process heat sensitive materials such as hospital and medical plastic made disposables or delicate electro-optical devices such as bronchoscopes or cytoscopes which cannot be autoclaved. Today hospitals, clinics and practitioner offices use a large number of disposables made of heat sensitive materials. Among these items are syringes, suction catheters, feeding and urinary drainage tubes, sutures, masks, nebulizer tubes, surgical gloves, etc. To sterilize these heat sensitive materials before, during or after packaging, most of today's manufacturers use low temperature gas sterilization. This is at the moment the only practical method to handle low softening point plastics, but, as well known, this method has numerous drawbacks and limitations. Although several aerosols, vapours and gases (see C. R. Philipps, Disinfection, Sterilization and Preservation, pg. 669 Lea and Febiger, Philadelphia, 1968) have been suggested in the past for gaseous sterilization, ethylene-oxide is the only chemical used on a large scale for industrial and medical applications. The advantages of ethylene-oxide sterilization lie not in the speed, simplicity, or economy of the treatment but rather in the fact that many types of materials are sterilized with least damage to the material itself when this technique is used. Among the drawbacks of this method is the acute inhalation toxicity of this gas. Cases of acute human exposures with nausea, vomiting, and mental disorientation have been reported in the technical literature (R. E. Joyner, Archiv. Environ Health, vol. 8, 700–710, May 2, 1964). As little as 3 percent of ethylene-oxide vapor in the air will support combustion and will have explosive violence if confined. When mixed with carbon dioxide (90% CO^2) or various fluorinated hydrocarbons the resulting mixture can in turn be mixed with air in all proportions without any risk of explosion. However, these mixtures are very slow acting compared to pure ethylene oxide. The humidity of the air or gas mixture is another important factor to take into consideration. Ethylene oxide sterilization is most rapid at about 30 to 40 percent relative humidity and decreases as the relative humidity approaches 100 percent. Highly desiccated micro-organisms are slow to respond to ethylene oxide sterilization. Ethylene oxide is a very active chemical (alkylating agent) and it sometimes alters the characteristics of the processed material. A note of warning has been sounded, for instance, in the sterilization of foodstuffs. It has been shown (E. A. Hawk and O. Mickelsen, Science, vol. 121, no. 3143, 442–444, Mar. 1955) that various vitamins and amino acids were attacked by ethylene oxide. More recently a food additive amendment to the Food, Drug and Cosmetic Act discouraged the use of ethylene oxide due to the presence of traces of toxic ethylene glycol which is one of the by-products of the hydrolyzation of this chemical.

When processing certain organic materials (such as plastics) it has been found that ethylene oxide is often soluble and may remain in large amount after sterilization. Up to 4 percent ethylene oxide has been detected by C. R. Philipps after gas sterilization of rubber. Laboratory personnel have received chemical burns by donning rubber shoes only 1 hour or so after they were sterilized. More recently R. B. Roberts (MSR Fourth Quarter, page 3, 1968) warned that ethylene oxide residues on surgical supplies could harm medical personnel as well as patients. On rubber gloves, they can burn the hands; and on tubes carrying blood, they will damage red blood cells. Endotracheal tubes which are not properly aerated can cause tracheitis or tissue necrosis. As a result of these observations it was recommended that surgical plastic devices stand at least 5 days at room temperature or 8 hours at 120° F before use. Since already the time requested for ethylene oxide sterilization is not negligible (for instance a 180 minute cycle at 30°C) an additional long deaeration period often renders this method very expensive. It precludes anyway the development of a continuous process for sterile packaging.

Special problems (see D. A. Gunther, J. R. Nelson, G. W. Smith, Contam. Contr. vol. VIII, No. 8, 9–12, Aug. 1969) are also encountered in ethylene oxide bulk sterilization of disposable articles such as catheters, irrigation sets, intravenous kits, syringes etc. Most of these items are being packaged in clear plastic film, such as hermetically sealed polyethylene. When a sealed polyethylene package is placed in the environment of a permeable sterilizing gas mixture, the gases will permeate the polyethylene unit they reach an equilibrium. This occurs when the concentrations of the permeating gases become equal on the inside and on the outside of the package. Since the residual air within the package is trapped it also contributes to increase the pressure inside the package. Thus, when the permeating gases reach equilibrium, the total pressure in the package may become greater than the outside pressure. This often results in package "swelling" or even rupture. To cope with this problem various pressure cycles are imposed upon the processed load. The pressure decrease is also programmed to coincide with the pressure decrease within the package as the permeable gases permeate out during the final stage (post-diffusion period). This means a lengthy operation which can last up to 8 hours when including water vaporization time, ethylene oxide exposure and gas evacuation.

Despite all the above mentioned drawbacks, ethylene oxide sterilization is the only technique used today at industrial scale to "batch process" medical and hospital disposables. Other non-thermal techniques of surface sterilization have been tried at laboratory scale (particles radiation, electro-magnetic radiations) but they always were too inefficient (long contact time required), expensive or delicate to handle for industrial scale processing. For instance ultraviolet (at 2,650 A, 2,350 A and 2,537 A for instance) irradiation can be under certain conditions quite effective to destroy bacteria, vegetative cells or spores. The energy level required to kill *Bacillus Subtilis* spores for instance is said to be around 22,000 microwatt/sec/cm^2. The difficulty with ultraviolet radiation as a sterilizing agent is that it has a very low penetrating power and micro-organisms are easily shielded from it by soil or other materials through which it cannot penetrate. The presence of agglomerates or "shadow zones" greatly limits the use of this technique for surface sterilization of odd shaped devices. In addition certain organic materials and plastics are quite susceptible

(polymerization or molecular degradation) to high intensity UV irradiation. The same disadvantage exists when one uses radioactive sources, such as cobalt 60 (gamma radiation) or Xrays. The energy imparted by electrons, Xrays and gamma rays results in ionizations (Compton effect) within the absorbed material. This has a lethal effect on the majority of spores according to dosage rate, presence of oxygen or protective compounds, physiological state of the micro organisms, water content and temperature. To achieve complete sterilization for instance of *Bacillus megaterium* spores (A Tallentire, and E. L. Powers, Rad Res, 20, 270–287, 1963) large doses of energy (5.10^5 Rad) are needed and this means potential damage to the irradiated material. More recently the synergistic effect produced by combining heat and radiation (Contamination Control, 20–22, Feb. 1970) gave some hope of improving operational conditions. Unfortunately, if the method provides a reduction in irradiation time requirements (from 40 to 12 hours) at 105° C it does not seem to give encouraging results at temperatures below 105° C.

It is therefore an object of the present invention to provide a method to surface sterilize laboratory, medical, dental devices and heat sensitive disposables in a matter of minutes rather than hours.

It is also an object of the present invention to surface sterilize within a short time period at low and medium temperatures within the 15° to 70° C temperature range.

It is a further object of this invention to quickly "surface sterilize" heat sensitive instruments and components in a continuous process, which includes dipping the load of contaminated objects in an ultrasonic bath synergistically activated by a sporicidal agent, rinsing it in a second bath with sterile water, drying it at a temperature below 75°C inside an ultraviolet tunnel and conveying the sterile material directly to the packaging machine. All said automatic operations taking place in a germs- and particles-free "white" room atmosphere.

It is a further object of this invention to continuously surface-sterilize heat sensitive materials, tools, instruments or components without leaving an amount of absorbed or dissolved chemical which could create a toxicity problem when the processed part is in contact with the human body.

It is a further object of this invention to continuously sterilize heat sensitive materials in a manner such that none of the physical, chemical, mechanical or structural characteristics of the sterilized products will be altered during processing.

Other objects, advantages, features and uses of our invention will be apparent during the course of the following discussion. To aid in the understanding of the present invention, the potential contribution of large amplitude sonic and ultrasonic waves to the mechanism of sterilization in liquid phase when used alone or in combination with chemicals such as glutaraldehyde or alkalynized glutaraldehyde will first be reviewed briefly.

Although a little complex at first sight, the physical action of sonic or ultrasonic waves can be brought into play in four major ways; namely, through large variations of pressure, motion, heat degradation or electrical phenomena. The acoustic energy is transmitted through the liquid by the back and forth motion of the molecules along the direction of propagation. This produces alternate adiabatic compressions and rarefactions, together with corresponding changes in density and temperature.

In the case of a planar acoustic wave transmitted through a liquid like water at an intensity of 10 watt/cm^2, one can calculate that the water molecules will oscillate with a motion amplitude of the order of 3 microns (assume the emission frequency equal to 20 kHz). The molecular accelerations at the end of the molecular excursions will be 5,000 times greater than the acceleration due to gravity and considerable pressure changes (a few atmospheres) will occur at any given point in the liquid twenty thousand times each second. Since the pressure is increased and decreased alternately, it is understandable that during the negative pressure phase a point may be reached at which the natural cohesive forces of the liquid will be overcome. Then a new phenomenon known as "cavitation" takes place. It corresponds to the formation and rapid collapse of small cavities through the entire liquid. According to the energy density level the cavities are filled with gas or vapor. In the latter case, their collapse produces very large amplitude shock waves (up to several hundred atmospheres) with local temperature up to a few hundred degrees centigrade or more. Electrical discharges are also believed to occur during the collapsing phase, this is called the sonoluminescence effect.

Due primarily to the effects of electrical discharges (ionization), "hot" points in the liquid, and sharp pressure waves gradients, the molecular bonds of water will be severed and free radicals OH and H will then be produced.

Chemically active hydroxyl radicals and hydrogen atoms will be available in the water solution to trigger several types of chemical reactions which may lead to bactericidal compounds such as water peroxide. (See I.E. Elpiner, Ultrasound, pg. 20, Chapter 2, Consult. Bur. ed. New York 1964). If other chemicals are present in the water such as glutaraldehyde, other molecular bond breakages could take place which would favor for instance the combination of aldehyde radicals with cells amino groups. With carbontetrachloride one will observe, for instance, the production of free chlorine (S.P. Liu, Chlorine Release Test for Caviation Activity Measurements, Journal of Acoustical Society of America, Vol. 38, No. 5, 817–826, Nov. 1965) and with potassium iodide the liberation of iodine (D. E. Goldman and G. R. Ringe, Determination of Pressure Nodes in Liquids, J. Acous. Soc. Am., Vol. 21, 270, 1949). It is known that alkyl and aryl halides in aqueous suspension, irradiated at low frequency, are hydrolysed to produce a halide ion and the corresponding hydroxyl compound or ether (A. E. Crawford, Ultrasonic Engineering, pg. 212, Chapter 9, London, Butterworths Sci. Publ. 1955). The production of highly bactericidal compounds such as ozone can also be the result of low frequency sonic irradiation of oxygen saturated water. (M. Haissinsky and A. Mangeot, Nuovo Cimento, 4:5, 1086, 1956). Nitrous acid, nitric acid and nitrogen oxides can also be detected in small amounts during the insonation of water saturated with air or nitrogen.

It can be said that low frequency (8 to 300 kHz) high energy density (higher than 10 watts/liter) acoustic emissions may alone produce free radicals, atoms, ions or new chemicals with strong bactericidal or sporicidal powers. Beside the production of new chemicals or active radicals which could be toxic to most pathogens, viruses or spores it is important to consider in detail the other physical mechanisms which may affect the life of unicellular or multicellular micro-organisms under ultrasonic irradiation.

Large amplitude sonic and ultrasonic waves, inside the frequency range previously stated, will considerably modify the ion exchange processes through the cell membranes. This modification of the diffusional process through inert or living membranes is well known in the art. Along these lines there is, for instance, the early work of J. H. Rees (Mast. Thesis, Mass. Inst. Techn., 1948) on the influence of low frequency insonation (10 to 30 kHz) on the dialysis constant. The enhanced membrane diffusion observed during insonation can be interpreted as the complex result of the radiation pressure, the acoustic pressure and cavitation on the motion of individual ions or molecules. Each ion or molecule receives a supplementary amount of energy in a high intensity acoustic field, and it "boosts" its level of activity. This could be, for instance, an extra "push" due to the passage of fast travelling cavitation shock waves resulting from the collapse of a resonant bubble. (I. Schmid, Acustica, 9:4, 321–326, 1959). But the effect of acoustic waves on the membrane structure must also be carefully considered. The enormous localized pressure waves which can rip apart metal particles during intense vapourous cavitation can indeed loosen macromolecular structures, such as the cell walls of water-borne micro-organisms. By so doing, pressure waves associated with the acoustic field can change the permeability of the walls and membranes of living cells. This would explain, for instance, why low frequency (8 – 300 kHz) high energy density (above 10 watts/liter) ultrasound waves increase the sensitivity of micro-organisms to disinfectants. It has been shown, for instance, a few years ago (I. E. Elpiner, Gigiena I Sanit, USSR, 7:26, 1958) that the sterilization of aqueous suspensions of E. Coli previously irradiated at 20–25 kHz requires much lower concentration of bactericides than the treatment of the same type of unirradiated suspensions.

One can conclude that ultrasonic irradiation of contaminated liquids at low frequency, high intensity, and with reasonable contact time may lead either to the production of compounds which would be toxic to the micro-organisms in contact with the liquid phase (through reaction at the active sites) or to cells structure modifications which will be lethal to the same micro-organisms.

Whatever the micro-organisms destruction mechanism is, ultrasonic irradiation alone would rarely achieve a hundred percent kill. This is understandable when one remembers that positive results can be observed in practice only with huge amount of acoustic energy and long exposure times (often several days).

It has been found in accordance with one aspect of the present invention that a combination of liquid borne ultrasonic energy with the chemical action of a glutaraldehyde solution provides an extremely fast kill of pathogen bacteria, viruses, vegetative cells, bacterial spores and spores. Such fast bactericidal and sporicidal action takes place in a matter of minutes (1 to 30 minutes) thus enabling the continuous treatment of contaminated parts when they are submerged during the right time period in the ultrasonically activated solution of glutaraldehyde.

When using batches of hundred disposable syringes artifically contaminated with *Bacillus Subtilis* (ATCC 6051) or Clostridium sporogenes (ATCC 7955) it was found that a 6 minutes contact time in a 1 percent solution of glutaraldehyde (pH5) at a temperature of 54° C would give 100 percent kill. The ultrasonic bath was operated at a nominal frequency of 20 kHz while the density of acoustic energy corresponded to approximately 15 watts per liter. The average number of micro-organisms per syringe was one million before treatment. All other things being equal, a higher bath temperature (70° C) would reduce treatment time to less than 4 minutes.

It was also found that the sporicidal effect remained the same when pH varied between 2 and 7 at the above mentioned temperatures, all other experimental conditions being identical.

It was also found that the same bactericidal and sporicidal activity was displayed for ultrasonically irradiated solutions (1 and 2 percent) buffered by suitable alkalinating agents to a pH of 7.5 to 8.5. In this latter case it was discovered that under the experimental conditions hereabove defined it was possible to decrease the 100 percent kill contact time down to 8 minutes at a temperature as low as 25° C.

It was also found that higher ultrasonic frequencies (250 kHz for instance) could also provide total destruction of spores on the contaminated syringes with a slightly longer exposure (30 minutes at 25° C) time in a 2 percent solution of alkalinized glutaraldehyde. In all cases the bactericidal and sporicidal mechanisms seem to be the result of a synergistic phenomenon between the chemical and ultrasonic energy since the killing effect of the combined agents is always greater than the sum of the two agents acting separately.

It was also found that the synergistic bactericidal and sporicidal activity can be accelerated by adding traces of dimethyl sulfoxide to the glutaraldehyde solution in the ultrasonic tank. For instance, as previously mentioned, a batch of 100 disposable syringes artifically contaminated with *Bacillus Subtilis* (ATCC 6051) were sterilized after a 6 minutes contact in a 1 percent solution of glutaraldehyde (pH5) at 54° C. The same batch of syringes under identical conditions were sterilized in only 3 minutes when adding between 1 and 10 parts per million of dimethylsulfoxide to the activated solution in the ultrasonic tank.

This important time reduction could be due to a faster penetration of activated chemical molecules or radicals through the spores cortex. The above described experiments took place at a nominal frequency of 20 kHz while the average density of acoustic energy in the tank oscillated between 15 and 20 watts per litter.

It was also found that the concentration of glutaraldehyde could be greatly decreased when operating at higher temperatures in the 60° to 70° C range. For in-

stance, at 70°C a 0.1 percent concentration of glutaraldehyde (pH 4.7) enables the complete sterilization of contaminated disposable syringes in 5 to 6 minutes, thus providing results equal to those obtained with a 1 percent glutaraldehyde solution at 54°C. In all these experiments, the acoustic energy density in the tank remained constant (around 15 to 20 watts/liter). The nominal frequency was kept at 20 kHz.

The method of surface sterilization, object of the present invention, consists of a three step system. The first step consists of dipping the contaminated objects in an ultrasonic bath heated at a temperature comprised between 25° and 70°C and filled with a glutaraldehyde solution (maximum concentration 5 percent). The objects to be sterilized are contained in a tray (or trays) made of perforated metal or plastic. Said tray is submerged in the activated ultrasonic solution and moves slowly under the influence of a "carrier-conveyor" system. The contact time into the activated ultrasonic solution varies according to the nature of the contaminant and the bath temperature, but it is in general comprised between 2 and 30 minutes.

When the irradiated tray leaves the ultrasonic tank which contains the glutaraldehyde solution traces of this chemical may remain absorbed on the wet processed parts. From analytical data (spectroscopy) the glutaraldehyde content of the sterilized parts is always less than one thousandth (1/1,000) of the original amount present in the processing tank. This means a quantity far below any potentially dangerous toxicity level. However, to decrease this content down to a few gammas (parts per million) a second ultrasonic tank is used with sterile water into which the tray is dipped during a few minutes at a temperature comprised between 54° and 70°C. This second ultrasonic tank which performs a thorough washing operation of any remaining traces of glutaraldehyde is the second step of the continuous sterilization process object of the present invention. The last step consists of a drying operation (a few minutes) into a medium temperature tunnel. Said tunnel contains several powerful ultraviolet lamps (intensity 10 watts/square foot) to maintain sterile surface conditions while the warm stream of filtered air is injected in the tunnel countercurrent to the direction of the moving tray (or trays). The filtered air temperature is calculated to maintain at all times a maximum temperature in the 54° to 70° C range inside the processed solid parts. Residence time (a few minutes) in the tunnel is the same as the exposure time in the ultrasonically activated solution tank and in the following washing tank.

FIG. 1 is a vertical cross-sectional side view of the three apparatuses (synergistic bath, cleaning tank and dryer) which are needed to apply the method object of the invention.

FIG. 2 is a vertical cross-sectional front view of the dryer-oven taken along the line 2—2 as seen in FIG. 1.

As can be seen in FIG. 1, the system to continuously sterilize heat sensitive parts consists of an ultrasonic tank 3 which contains the sterilizing agents, said ultrasonic tank being followed by a second ultrasonic tank 4 which rinses and eliminates most of the chemicals absorbed on the processed material, said ultrasonic rinsing tank being followed by a drying tunnel or oven 5 equipped with a sporicidal source (ultraviolet lamps, microwave source, radianty or X rays source).

The heat sensitive material 6 to be processed is placed into trays of perforated metal or plastic baskets 7 which are suspended through a hook 8 to a standard moving chain-wheel device 9 guided by a rail support 10. The latter is designed in such a way that the basket will be submerged at a few inches distance of the liquid/air interface when the basket enters the areas above the ultrasonic tanks 3 and 4.

The ultrasonic tanks 3 and 4 are in general of the same type and they have the same dimensions to insure identical contact time for the processed material in the liquid phases. The ultrasonic tank will consist for instance of a stainless steel parallel-epipedic tank 11 whose lateral walls (one or several of them according to the type of operation) contain a heating element 12 (electrical resistance, infrared, microwave, or dielectric, for instance. To the bottom of the tank are fastened one or several standard electroacoustic transducers 13 (piezo ceramic, ferrite or magnetostrictive types) which irradiate in and upward manner and create a high intensity ultrasonic field 14. To successfully apply the process object of the present invention, the acoustic energy density in the two tanks 3 and 4 must be greater than ten watts of irradiated acoustic energy per liter.

The frequency of emission of the transducer elements in the first tank 3 must also be comprised between 8 kHz and 900 kHz while the frequency range in the rinsing tank 4 is restricted to the 8 kHz to 300 kHz region. Also located in the lower section below each tank bottom is a power-generator G to drive the transducers array with associated cooling and automatic frequency tuning or impedance matching devices. The standard power generator could be packaged separately and placed at a remote location since this will not affect the proper functioning of the transducers. As shown in FIG. 1, the ultrasonic generator is activated from the main line alternative current (120 or 220 volts, 60 cycles) through an electrical connector 15. Each ultrasonic tank is equipped with a draining-valve system arrangement 16. The first ultrasonic tank 3 is provided with an opening 17 which enables introducing fresh sporicidal agent into the tank. An electric pump 18 introduces automatically the active chemicals at the right dosage and concentration into the filtered water main line 19. In the first tank 3, the active cavitating solution will contain, for instance, a solution 20 of glutaraldehyde whose concentration will be comprised between 0.05 and 5 percent volume. Optionally and according to the type of micro-organisms to be destroyed, a certain amount of dimethylsulfoxide could be added (concentration lower than 2 percent in volume). The temperature in the first tank 3 could vary between 15° and 70° C according to solution pH and to the type of irradiated micro-organisms. In most current applications for spores destruction, the first tank is operated around 54° C. The speed of the basket conveyor system is adjusted to allow an average contact time in the sterilizing solution comprised between 2 and 30 minutes according to the type of application. The second ultrasonic tank 4 whose function is to rinse away most of the chemicals absorbed on the sterilized parts or components originally contains germ free water 21 with small amount of (less that 0.1 percent) surface active agents such as cationic surface active agents or quaternary ammonium salts. The second

ultrasonic tank is always operated at a temperature comprised between 45° and 70° C which corresponds to maximum cavitation activity (L. D. Rosenberg, Ultrasonic News, 16–20, 4th quarter 1960).

After the sterilizing and rinsing operations, the baskets which contain the sterile equipment enter into the drying tunnel **5**. The length of the drying tunnel is the same as the length of each one of the two ultrasonic tanks **3** and **4**, thus providing the same contact time in the liquids and the dryer. The dryer tunnel **5**, as shown in FIG. **1**, is only one of the possible embodiments of the type of dryer apparatus to be used in our invention. As shown in FIG. **2**, the dryer tunnel in this example is of circular shape with a slit longitudinal opening **22** at the top to allow the continuous motion of the hooks **8** to which the basket **7** are attached. Three openings **23** at the bottom of the tunnel are provided to introduce warm filtered air into the tunnel. Warm air could be conveyed through a piping system communicating with a central source of warm filtered air, or it could be provided by means of individual blowers **24** equipped with an internal heating element **25**. The air could be drawn directly from the processing room and filtered at the blower inlet **26**. The temperature inside the dryer tunnel is adjusted for each application (taking into account convection, conduction and radiation thermal effects) in such a manner that the maximum temperature of the parts at the time they leave the tunnel is always below 70° to 75° C. This objective can be achieved through the use of various forms of thermal energy such as infrared, dielectric or electromagnetic (microwaves) heating. Since the baskets which enter the dryer-tunnel **5** are sterile and contain sterile material, it is necessary to sterilize the tunnel atmosphere to avoid the deposition of airborne bacteria or spores. To insure such a protection during the final drying phase we already mentioned that we use warm filtered air. As a supplementary protection, the dryer tunnel is equipped with powerful ultraviolet lamps. In FIGS. **1** and **2**, three such ultraviolet lamps **27** are shown spaced each at 120° from the other. These ultraviolet lamps could, for instance, be of the Hanovia type 94A–1 which emits 7.3 watts of UV energy at the 2,537 A wave length. They will insure complete destruction of airborne bacteria and spores during processing time in the tunnel. A transformer **28** is shown connected to one of the ultraviolet lamps. The basket **29** which leaves the tunnel, contains dry, sterilized parts or components with traces of chemicals far below toxicity level. At no time does the temperature of parts reach a level higher than 70° – 75° C. Such parts and components are ready to be fed manually or automatically to a packaging machine under sterile conditions.

Also not shown in FIGS. **1** and **2**, but obvious to a person skilled in the art, the entire system described in FIGS. **1** and **2** is enclosed inside a positive pressure clean or white room equipped with high retention ULTRA HEPA filter modules. Horizontal laminar flow clean rooms (class 100) of the type manufactured by Agnew-Higgins could be used to operate the continuous sterilization system hereabove described. With a view to increasing the efficiency of the white room for bacteria and spores control, additional mobile LETHERAY high intensity UV air sterilizers could be added inside the white room specially in the vicinity of transfer points i.e., between tank **4** and tunnel **5**, or between tunnel **5** exit and the packaging sealing machine).

Without departing from the frame work of the present invention, it must be well understood that, according to the desired results, the present invention can be applied to variable load sizes of heat sensitive materials at different temperatures within the specified 15° – 70° C range or at multiple gas pressures above the irradiated liquid, and that, still without departing from the scope of the invention, the structural details of the described apparatuses, the dimensions and the shapes of their members (such as the ultrasonic tank configuration) and their arrangement (the position of ultraviolet tubes inside the dryer tunnel, for instance) may be modified, and that certain members may be replaced by other equivalent means (electrical heating elements replaced, for instance by infrared radiant panels).

The teachings of the invention may be practiced within the following parameters:

First Step:
- contact time in the sterilizing solution: 2 to 30 minutes
- Glutaraldehyde concentration: 0.05 to 5 percent in volume
- Glutaraldehyde solution pH: 2 to 8.5
- Dimethylsulfoxide concentration: less than 2 percent in volume
- Acoustic energy density in liquid: higher than 10 watts/liter
- Emission Frequency: 8 to 900 kHz
- Temperature range in liquid: 15° to 70° C

Second Step:
- Contact time in rinsing solution: 2 to 30 minutes
- Concentration of surface active agents less than 0.1 percent in volume
- Acoustic energy density in liquid: higher than 10 watts/liter
- Emission Frequency: 8 to 300 kHz
- Temperature range in liquid: 45° to 70° C

Third Step:
- Contact time in dryer tunnel: 2 to 30 minutes
- Temperature inside tunnel: adjusted to a maximum of 70° to 75° C in the processed material leaving the dryer

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. The process of sterilizing sensitive materials such as plastic or the like comprising contacting the material to be treated with a chemical solution comprising an aqueous solution of from 0.05 to 5 percent by volume glutaraldehyde and from 1 part per million to 2 percent by volume of dimethyl-sulfoxide and ultrasonic waves simultaneously at temperatures below 75° C.

2. A continuous process of synergistically destroying all surface micro-organisms including pathogens, viruses and spores on metal or heat sensitive materials such as plastic or the like, comprising contacting the material to be treated with a chemical solution comprising an aqueous solution of from 0.05 to 5 percent by volume glutaraldehyde and from 1 part per million to 2 percent by volume dimethylsulfoxide and ultrasonic waves simultaneously at temperatures below

75° C, subsequently treating the material with a rinsing solution and ultrasonic waves simultaneously at temperatures below 75° C and finally drying the material at temperatures below 75° C.

3. The process of claim 2, wherein the material to be treated is first submerged in said chemical solution while said material to be treated and said chemical solution is being treated with ultrasonic waves, subsequently said material to be treated is submerged in a rinsing solution while said material to be treated and said rinsing solution is being treated with ultrasonic waves and finally drying said material to be treated.

4. The process of claim 2, wherein the rinsing solution is sterile water.

5. The process of claim 2, wherein all the steps take place in a sterile atmosphere.

6. The process of claim 2, wherein the chemical solution has a pH of between 2 to 8.5.

7. The process of claim 2, wherein the chemical solution contains a buffer to adjust the pH from between 7 and 8.5.

8. The process of claim 2, wherein the chemical solution is submitted to a high intensity ultrasonic field whose normal frequency is from between 8 kHz and 900 kHz.

9. The process of claim 2, wherein the chemical solution is submitted to an ultrasonic field having an intensity of at least 10 watts per liter.

10. The process of claim 2, wherein the material is treated in the chemical solution at a temperature of between 15° and 70° C.

11. The process of claim 2, wherein the rinsing solution is submitted to a high intensity ultrasonic field whose normal frequency is from between 8 kHz and 300 kHz.

12. The process of claim 2, wherein the intensity of the ultrasonic field on the rinsing solution is greater than 10 watts per liter.

13. The process of claim 2, wherein the temperature of the rinsing solution is between 45° and 70° C.

14. The process of claim 2, wherein the material to be treated is dried at a temperature at between 70° and 75° C.

15. The process of claim 2, wherein the material is treated with the chemical solution and ultrasonic waves, the rinsing solution and ultrasonic waves and the drying operation for from 2 to 30 minutes each, respectively.

16. The process of claim 2, wherein the material being treated is exposed to ultraviolet light while being dried.

17. The process of claim 2, wherein the rinsing solution also contains up to 0.1 percent by volume of a surface active agent.

18. The process of claim 17, wherein the surface active agent is a cationic surface active agent.

19. The process of claim 18, wherein the cationic surface active agent is a quaternary ammonium salt.

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