

United States Patent

[11] 3,561,444

[72] Inventor **Raymond Marcel Gut Boucher**
Metuchen, N.J.
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[73] Assignee **Bio-Logics, Inc.**
Salt Lake City, Utah
a corporation of Delaware
Continuation-in-part of application Ser. No.
510,537, Nov. 30, 1965, now abandoned.

807,544 1/1959 Great Britain..... 324/51
Primary Examiner—Richard A. Gaudet
Assistant Examiner—J. B. Mitchell
Attorney—Lynn G. Foster

[54] ULTRASONIC DRUG NEBULIZER 15 Claims, 23 Drawing Figs.

[52] U.S. Cl..... 128/194,
128/24
[51] Int. Cl..... A61h 1/00,
A61m 15/00
[50] Field of Search..... 128/194,
24.05, 172, 173, 186, 193, 419, 421, 424;
310/(Inquired); 324/51; 128/24 (A), (Ultrasonic
Nob Digest), 194

[56] References Cited UNITED STATES PATENTS

2,267,547	12/1941	Zimmerman.....	128/256
2,863,075	12/1958	Fry.....	310/8.1
3,137,836	6/1964	Glover.....	340/10
3,285,242	11/1966	Wallace.....	128/23
3,360,664	12/1967	Stroube.....	310/8.2

FOREIGN PATENTS

962,296	9/1957	Germany.....	310/9.1
1,056,065	4/1959	Germany.....	128/194
1,103,522	3/1961	Germany.....	128/186

ABSTRACT: An ultrasonic drug nebulizer for forming droplets from a medicated solution and emitting the same into the surrounding atmosphere having a receptacle with a base and walls to form a liquid containing chamber. a truncated conical cup for containing the medicated solution removably mounted in the upper portion of the receptacle so that its smaller base is below its larger base, the smaller base being closed and the larger base being open, a dome containing an inner, vertically disposed, column and an outer, vertically disposed, column surrounding the inner, vertically disposed, column removably mounted to the receptacle above the truncated conical cup, the inner, vertically disposed, column and the outer, vertically disposed, column both being open at the bottoms thereof, the outer, vertically disposed, column having an opening therein adjacent the top thereof, a transducer mounted in the base of the receptacle, gas flow regulating means in the top of the inner, vertically disposed, column, means for exciting the transducer at an ultrasonic rate such that a geyser is formed from the medicated solution in the truncated conical cup, and means for introducing gas into the inner, vertically disposed, column through the gas flow regulating means in the top thereof so that there is a pressure difference between the gas in the column and the ambient atmosphere to thereby sweep the mist of the geyser into the outer, vertically disposed, column to be discharged through the opening therein, the flow rate of the gas introduced into the inner column controlling the size of the liquid droplets which are so discharged from the column.

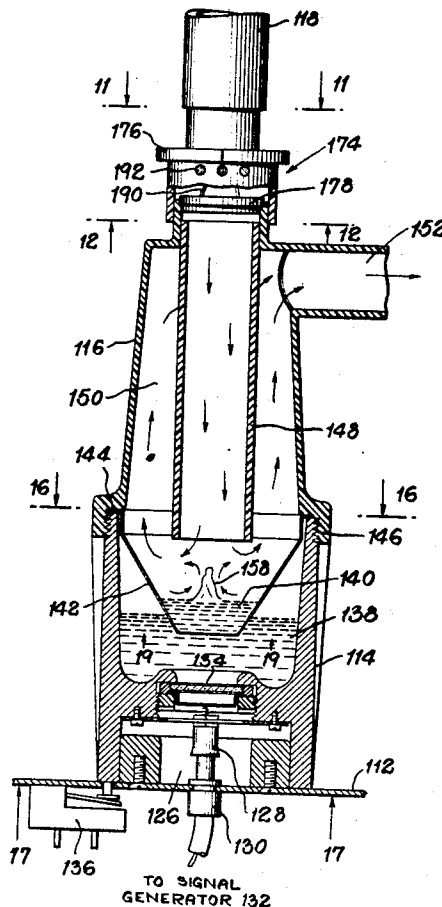


Fig. 1.

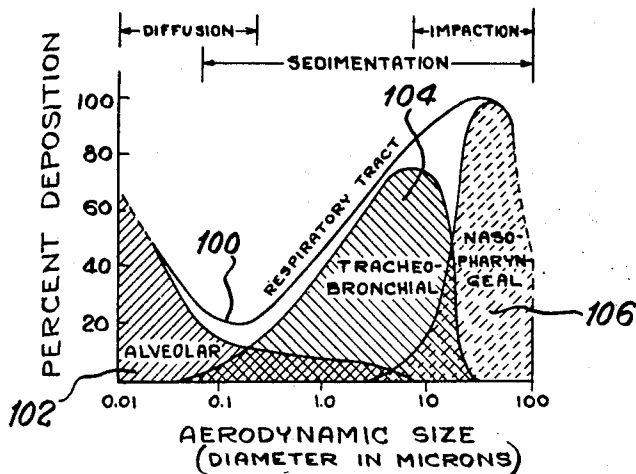


Fig. 10.

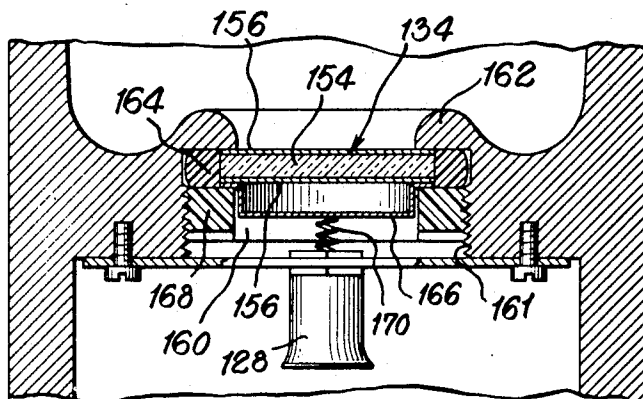


Fig. 21.

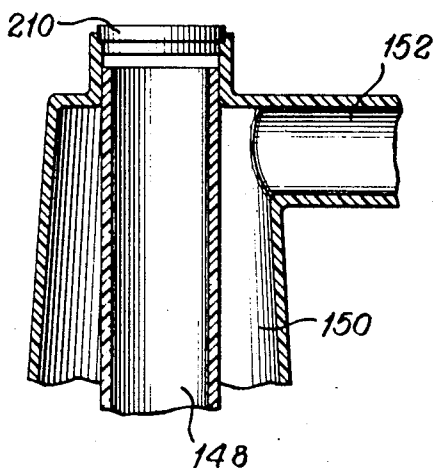
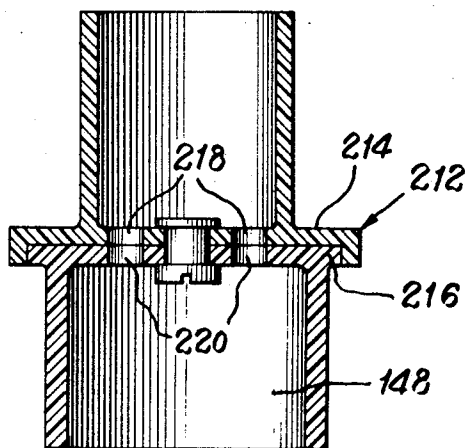


Fig. 22.



INVENTOR
RAYMOND M. G. BOUCHER
BY
Samuelson & Jacob
ATTORNEYS

Fig. 2.

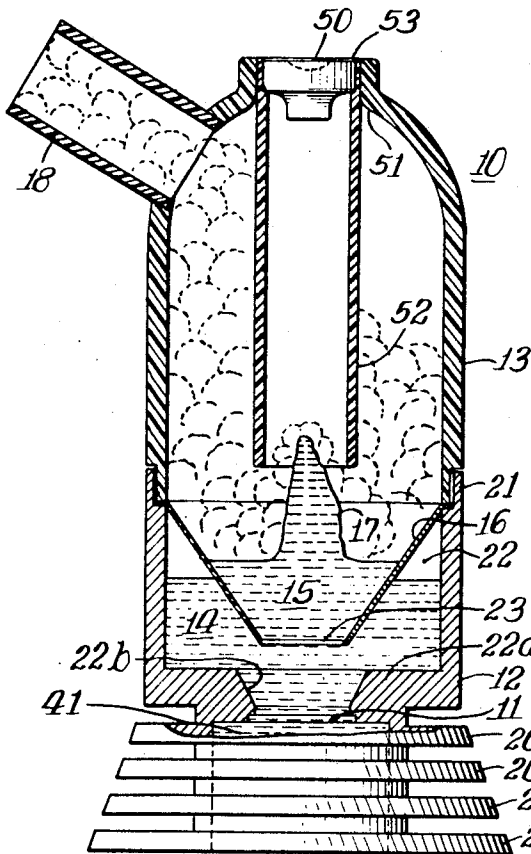


Fig. 3.

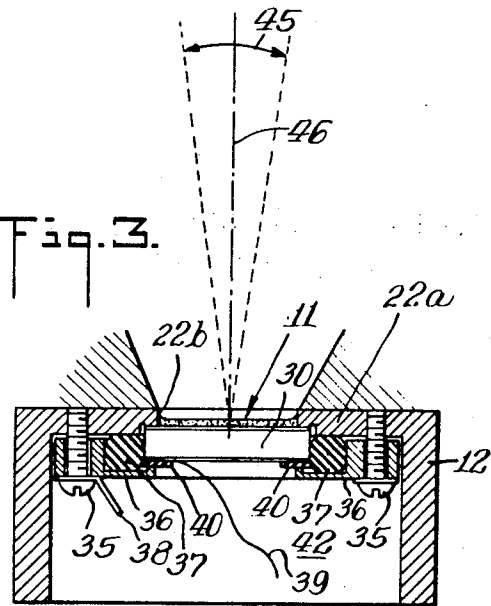


Fig. 4.

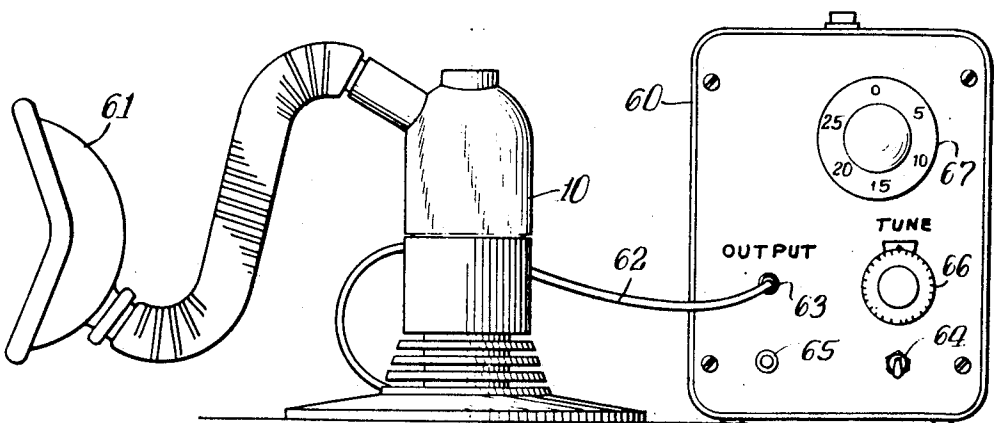
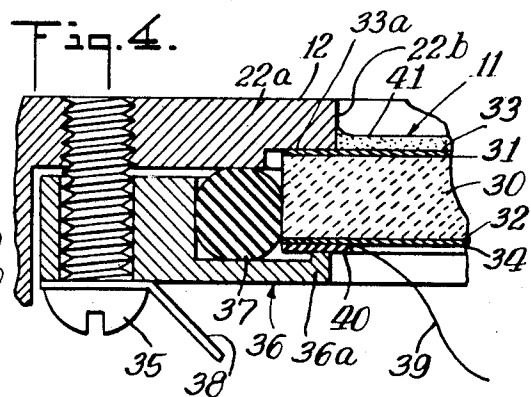


Fig. 5.

INVENTOR
RAYMOND M. G. BOUCHER

BY

Samuelson & Jacob
ATTORNEYS

Fig. 6.

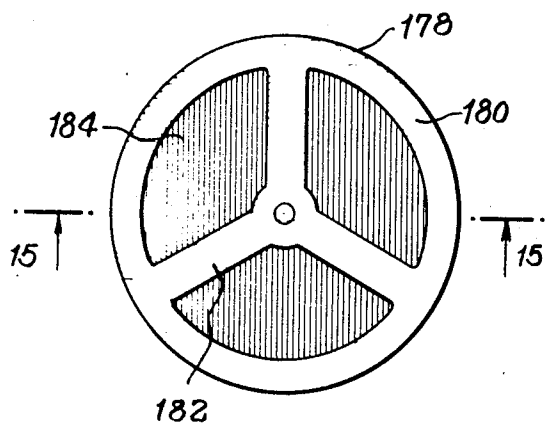
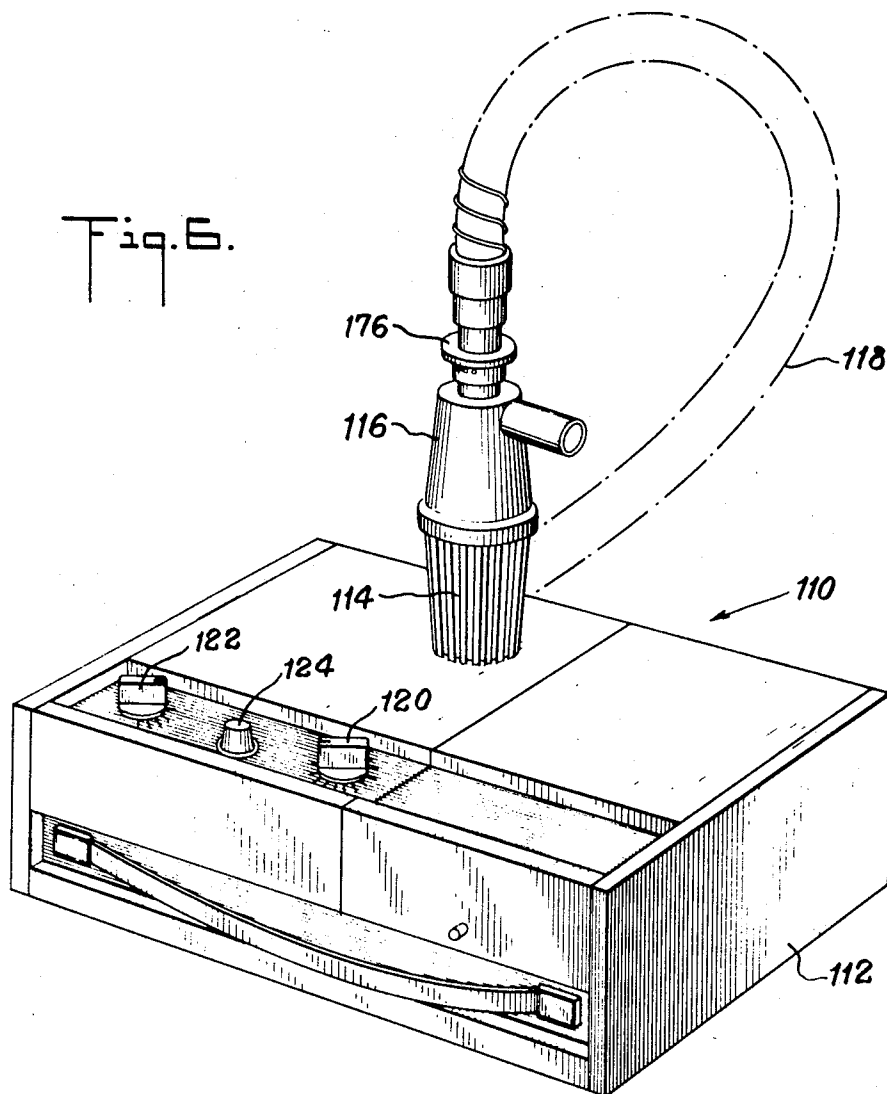


Fig. 14.

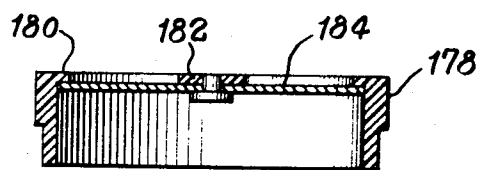


Fig. 15.

INVENTOR
RAYMOND M G BOUCHER
BY *Samuelson & Jacob*
ATTORNEYS

Fig. 7.

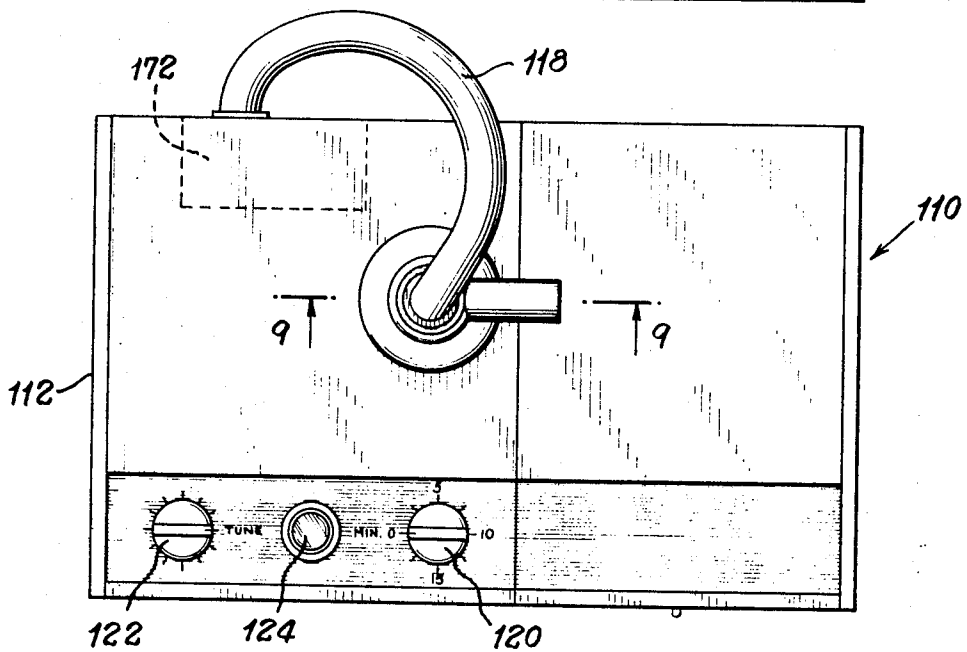
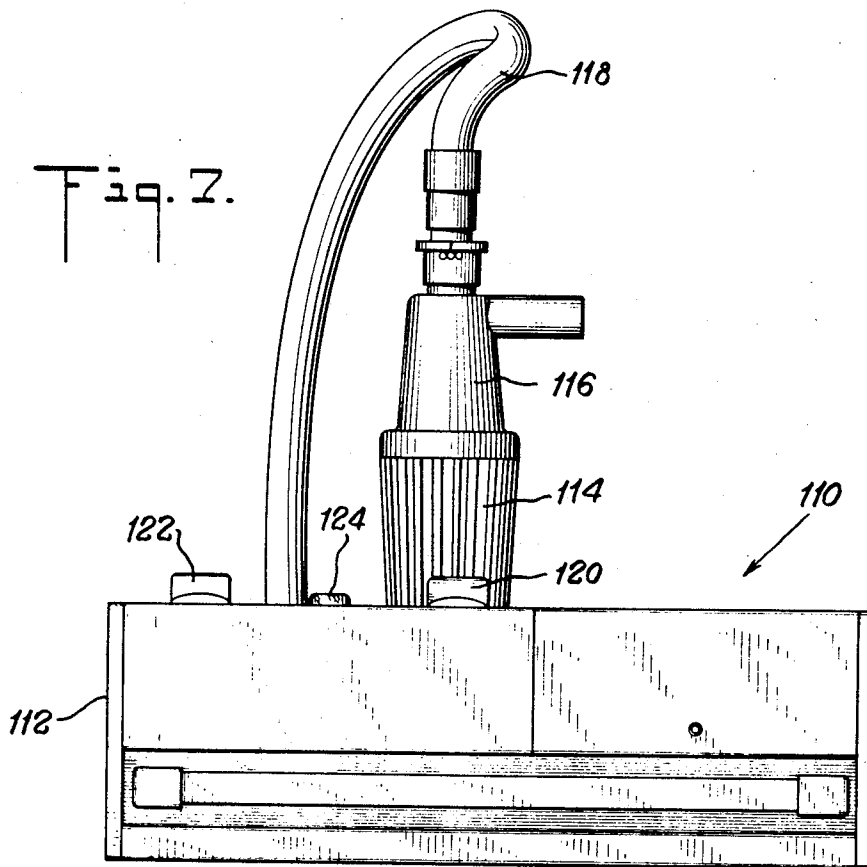
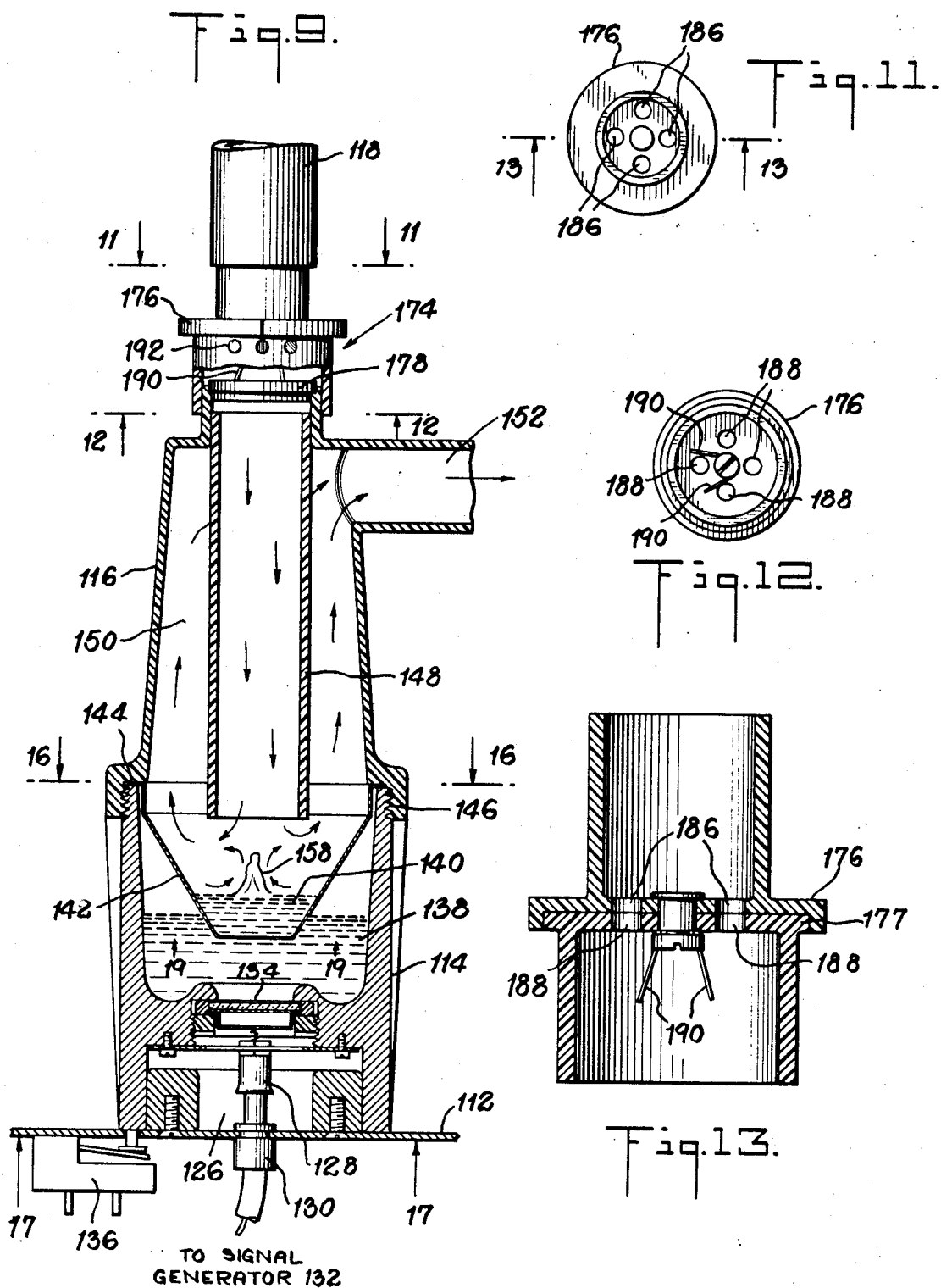


Fig. 8.

INVENTOR
RAYMOND M. G. BOUCHER
BY

Samuelson & Jacob
ATTORNEYS



INVENTOR
 RAYMOND M. G. BOUCHER
 BY *Samuelson & Jacob*
 ATTORNEYS

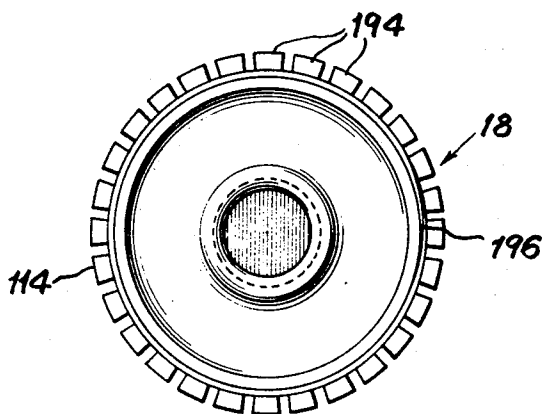


Fig. 16.

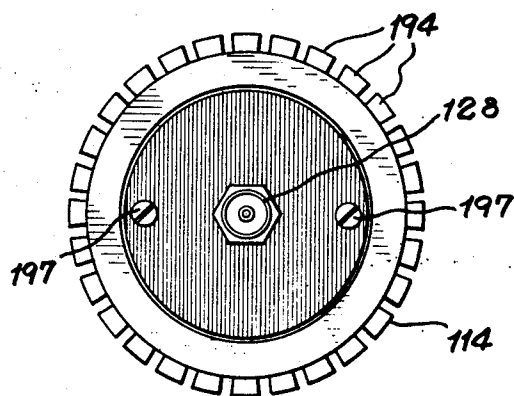


Fig. 17.

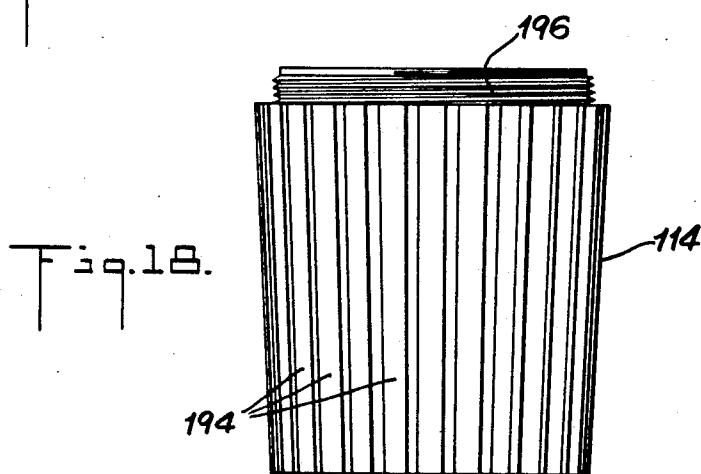


Fig. 18.

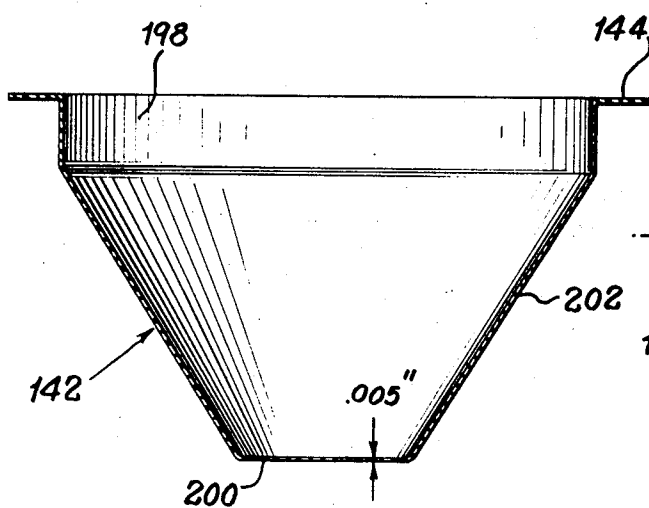


Fig. 20.

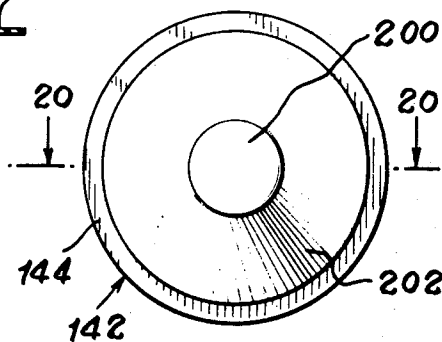


Fig. 19.

INVENTOR
RAYMOND M. G. BOUCHER
BY
Samuelson & Jacob
ATTORNEYS

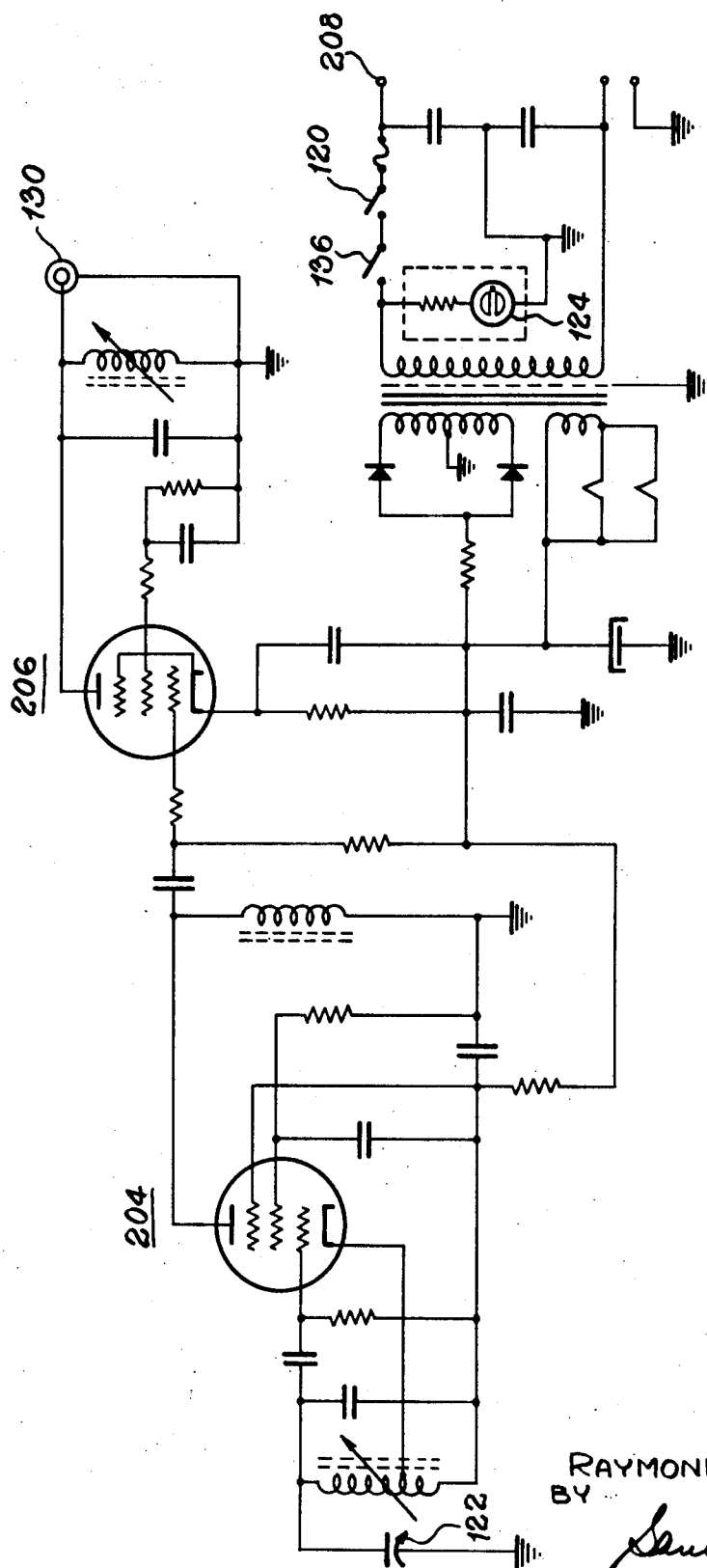


Fig. 23.

INVENTOR
RAYMOND M. G. BOUCHER
BY

Samuelson & Jacob
ATTORNEYS

ULTRASONIC DRUG NEBULIZER

This is a continuation-in-part of my application, Ser. No. 510,537, filed Nov. 30, 1965, now abandoned.

This invention relates to ultrasonic nebulizers and more particularly to devices for producing fine liquid aerosols, as for medicinal use, through the disintegration of the liquid geyser produced by radiation pressure effect of ultrasonic vibrations of a flat ceramic crystal transducer at a relatively high frequency. In particular, the invention is directed to such devices heel holding may be used to deliver either a steady supply of medicated solution or a pulsed supply thereof.

The creation of ultrafine droplets by means of ultrasonic energy is not new. Devices to accomplish this have been constructed but in most instances the objective lay outside the area of medicinal nebulization and have depended on surface wave disintegration at a relatively low frequency. The problems associated with the development of an ultrasonic nebulizer specifically for medicinal nebulization include the production of uniformly small particles, preferably with a high percentage less than 10 microns in diameter and of the order of 80 to 90 percent, by weight, less than 10 microns. The nebulizer should have a reliable particle formation rate (for example, 0.1 to 1.5 cc. per minute), and electrical requirements at reasonable voltage and power levels.

Most of the prior art drug nebulizers, which have been used to dispense nebulized medicated solutions into the atmosphere surrounding the patient or directly into the respiratory tract of the patient through a face mask or device, have been of the mechanical type wherein it was not possible to control the size of the nebulized droplets without using screens or obstacles in the aerosol path.

There is no universal agreement on the exact meaning the terms: aerosol, fog and However, there has been a recommendation that e.g., word "aerosol" be limited to airborne made up of particles less than 1 micron in diameter (Conference on Aerosols, Nov. 1959, Denver, Col.). For one could say that the word "fog" is used for droplets the 5 to 50 microns range and the word "mist" is used for droplets in the 50 to 500 microns range. The word "micromist" is often used to describe liquid dispersoids in the 5 to 25 microns range. The definitions set forth above may be used, in the specification, to describe the various dispersoids of the medicated solution.

The drug nebulizer of the the invention, utilizes high frequency ultrasonic energy to disperse fine liquid particles of the medicated solution into a It comprises a small plastic cup which contains the medicated solution and a polarized, piezoelectric ceramic (crystal) transducer which beams the ultrasonic energy to the medicated solution through the bottom of the cup. A liquid such as distilled or tap water, which is used to couple the ultrasonic energy between the ceramic transducer and the cup which contains the medicated solution, also serves as a cooling liquid to prevent the transducer from overheating and becoming ineffective.

When the is energized at the proper frequency, say, between 500 kHz. and 2 MHz., mechanical vibrations are set up in the coupling liquid. These mechanical vibrations occur at the frequency of the excitation signal. The mechanical vibrations are coupled through the coupling liquid to the bottom of the cup and thence to the medicated solution contained in the cup. The internal turbulence in the medicated solution is so great that the surface tension of the liquid and the cohesive forces at the gas-liquid interface are overcome and a geyser is produced due to the disintegration of the liquid into a fine mist or aerosol.

The aerosol produced at the surface of the heel-holding solution is carried out of the drug nebulizer to the atmosphere surrounding the patient or directly into the patient's respiratory tract by the gas flow produced by a small blower or by the pressure difference caused by the patient's respiration.

Drug nebulizers are intended and used for the purpose of carrying finely atomized therapeutic solutions through the lungs in order to deposit the therapeutic agent at selective sites in the pulmonary tree. This makes it possible to reach the blood circulatory system without physical infraction. For a

number of years, aerosol therapy has been recognized as having many curative advantages. However, its use has been limited by the disadvantages inherent in mechanical nebulizers. There are drastic physical limitations on the size of the droplets which may be produced by mechanical means such as high-speed jets, centrifugation, impingement, etc. In order to generate aerosol and fog particles of the size required for maximum deposition of the drug in the lungs (0.4 to 10 microns), it was necessary to develop sophisticated, complex, mechanical nebulizing devices. Simple mechanical generators could not be used satisfactorily because they always produced a certain amount of drops which were too large or the drug reconcentrated through filtration or the refluxing of the large particles.

Another object is to provide a richer, more abundant nebula without the waste of the compressed-air-driven nebulizer which is noisy and often entrains noxious oil vapors. The aerosol produced by the generator is very uniform, providing optimum particle size for deposition in the lung. The nebula can be generated continuously, stored and made available to the patient only during inspiration.

Still another object is to provide a system by which the crystal transmits its sonic energy through a liquid medium to the medicament which is held in a removable cup. Liquids placed in direct contact with the crystal would penetrate into the crystal and react chemically with it causing depolarization and resultant crystal failure. Accordingly, the crystal is sealed with a suitable covering, as an epoxy resin or a thin gold layer. The liquid medium, medicament or transfer liquid aids in dissipating heat generated in the crystal.

Yet another object is to provide compression mounting for the piezoelectric crystal transducer. The mounting of the crystal provides proper support to the electrodes, seals the crystal from the coolant fluid, and eliminates damping of the sonic output.

A further object is to provide the apparatus with a replaceable cup for the material to be nebulized so that various materials can be used without great difficulty.

It is a further object of the invention to provide such a device wherein the droplet size is controlled so that the large bulk of the droplets of the drug delivered to the patient's respiratory tract are of the proper size.

It is a still further object of the invention to provide such a device wherein the output of the device is maintained at a steady rate.

It is a still further object of the invention to provide such a device wherein the output of the device is pulsed at a respiratory or similar rate.

It is a still further object of the invention to provide a source of aerosols which may be used for therapeutic or other purposes.

One feature of this invention is the provision of a nebulizing apparatus including a base, a ceramic crystal having conductive electrodes, compression clamping means holding the crystal against the base, and a seal, sealing the joint between the crystal and base.

Another feature is the provision of a removable medication cup mounted upon the base so that the ultrasonic energy is transmitted to the medicament thereby producing fine liquid aerosols through the disintegration of a liquid geyser due to the radiation pressure force field.

More particularly, the mounting for the crystal which has upper and lower conductive electrodes comprises compression clamping means holding the crystal against a base and holding a circular seal so as to close off the joint between the base and crystal, the clamping means also holding a lead between a circular washer and the lower metallized electrode. The epoxy or thin gold layer may be used to protect the upper crystal surface.

These and other objects, advantages, features and uses will be apparent during the course of the following description, when taken in conjunction with the accompanying drawings, wherein:

FIG. 1 is a plot showing the percentage of particles deposited in the respiratory tracts;

FIG. 2 is a vertical sectional view of an embodiment of ultrasonic drug nebulizer embodying the invention;

FIG. 3 is an enlarged is section of the transducer mounting used in the ultrasonic drug nebulizer of FIG. 2;

FIG. 4 is an enlarged detail of the transducer mounting of FIG. 3;

FIG. 5 is an illustration of the ultrasonic nebulizer system of the invention utilizing the embodiment of FIGS. 2-4;

FIG. 6 is a view, in perspective, of another form of ultrasonic drug nebulizer of the invention;

FIG. 7 is a front elevational view of the ultrasonic drug nebulizer of FIG. 6;

FIG. 8 is a horizontal, plan view of the ultrasonic drug nebulizer of FIG. 6;

FIG. 9 is an enlarged, sectional view, taken along the lines 9-9 of FIG. 8, viewed in the direction of the arrows;

FIG. 10 is an enlarged view similar to and of a portion of FIG. 9 showing the transducer and its mounting;

diameter through the pulmonary tree is by inertial impingement in the tracheobronchial portion. Droplets in the sub-micron range reach the pulmonary tree in the alveolar region mainly by diffusion under the influence of Brownian motion.

In addition to the droplet size, one must also consider the mass of the droplets when attempting to deposit a drug inside the pulmonary tree. This is quite obvious when one considers that, since the volume varies as the cube of the diameter, one drop 10 microns in diameter will contain as much of the therapeutic agent as 1000 droplets, each of which is 1 micron in diameter. Since one wishes to arrive at a size range which will deliver the maximum therapeutic benefit with the most readily usable droplet size, it is desirable to be able to tailor the droplet size delivered to the patient in the ideal range. This range appears to be from about 0.4 to about 10 microns in diameter.

The following table, based on 1 milliliter of liquid, taken in conjunction with FIG. 1, will serve to illustrate the advantage of ultrasonic nebulizers over mechanical nebulizers for the production of therapeutic aerosols.

Particle diameter (microns)	Number of particles (billions)	Total surface of disperse (square centimeters)	Brownian movement in 1 second (microns)	Sedimentation rate in still air in 1 second (microns)	Overall retention in respiratory tract (percent)
10-----	2	6,280	1.75	6,096	89
5-----	15	12,000	2.5	1,550	80
2-----	240	30,000	3.8	400	56
1-----	2,000	63,000	5.9	70	44
0.1-----	2,000,000	630,000	29.4	1.7	21
0.05-----	10,000,000	1,260,000	60.0	0.7	30

NOTE.—Particles are of density 1 and are assumed to be spherical.

FIG. 11 is a top, horizontal, plan view, viewed in the direction of the arrows 11-11 of FIG. 9;

FIG. 12 is a bottom, horizontal, plan view, viewed in the direction of the arrows 12-12 of FIG. 9;

FIG. 13 is a sectional view, taken along the lines 13-13 of FIG. 11, viewed in the direction of the arrows;

FIG. 14 is an enlarged, top, plan view of the check valve used in the ultrasonic drug nebulizer of FIG. 6;

FIG. 15 is a sectional view, taken along the lines 15-15 of FIG. 14, viewed in the direction of the arrows;

FIG. 16 is a top, plan view of the liquid containing chamber, viewed in the direction of the arrows 16-16 of FIG. 9;

FIG. 17 is a bottom, plan view of the liquid containing chamber, viewed in the direction of the arrows 17-17 of FIG. 9;

FIG. 18 is an elevational view of the liquid containing chamber, viewed in the direction of the arrow 18 of FIG. 16;

FIG. 19 is a bottom, plan view of the truncated, conical cup, viewed in the direction of the arrows 19-19 of FIG. 9;

FIG. 20 is an enlarged, sectional view, taken on the lines 20-20 of FIG. 19, viewed in the direction of the arrows;

FIG. 21 is an enlarged, vertical sectional view, similar to that of FIG. 13, of a further embodiment of the invention;

FIG. 22 is a view, similar to that of FIG. 21 of a modification thereof; and

FIG. 23 is a schematic diagram of the circuit of the generator used with the ultrasonic drug nebulizers of FIGS. 2 and 6.

FIG. 1 is a plot showing the percent of retention of droplets in the respiratory tract against droplet size. Curve 100 illustrates the overall droplet retention in the respiratory tract against droplet size. The outline of area 102 designates the plot of percent of retention of droplets in the alveolar portion of the pulmonary tree against droplet size. The outline of area 104 designates the plot of percent of retention of droplets in the tracheobronchial portion of the pulmonary tree against droplet size and the outline of area 106 is the plot of percent of retention of droplets in the nasopharyngeal portion of the pulmonary tree against droplet size.

From FIG. 1, it can be seen that the predominant mechanism for collecting droplets larger than 1 micron in

The average droplet size of a therapeutic aerosol and fog is given as the mass median diameter (MMD) which is defined as the droplet size such that one-half the mass of the aerosol is in droplets smaller in size than said droplet size. The mass median diameter is related to the mean particle diameter as shown by the following formula: $\log D = \log MMD - 6.9 \log^2 \sigma$; where D = mean particle diameter; MMD = mass median diameter; σ = standard deviation

FIG. 1 shows that a droplet size of 10 microns is collected in the tracheobronchial and nasopharyngeal regions and the overall retention in the respiratory tract (from the table) is 89 percent. A droplet, which is 0.4 micron in diameter, would be collected in the alveolar and tracheobronchial regions and the overall retention in the respiratory tract is about 30 percent.

Thus, it can be seen that the ideal droplet size for therapeutic use is in the aerosol and fog range from 0.4 micron to 10 microns in diameter. Since these size droplets cannot be produced readily by mechanical means, other means must be found.

While illustrative embodiments of the invention are shown in the drawings and will be described in detail herein, the invention is susceptible of embodiment in many different forms and it should be understood that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the embodiment illustrated. The scope of the invention will be pointed out in the appended claims.

Referring not to FIG. 2, the nebulizing unit 10 consists of a flat-surfaced piezoelectric crystal 11 housed in an aluminum transducer base 12 and an aerosol chamber 13 mounted upon the base. The crystal 11 transmits its acoustic energy through a cooling (coupling) liquid 14 to the medicament 15 which is held in a removable cup 16 thereby creating a turbulent fountain 17. Nebulization occurs around the outer surface of the fountain producing a mist which is held in the aerosol chamber 13. This mist can be withdrawn from the chamber through an outlet 18 as needed. The radiation pressure fountain or geyser occurs only at relatively high sonic frequencies as of the order of at least 500 kilocycles and may be generated with presently available transducers operating at frequencies

up to the order of 2 megacycles. The details of the crystal and mounting will be described below.

The transducer base 12 is cylindrical with cooling fins 20 on its lower portion and a shoulder 21 along its top. A fluid cavity 22 is formed within the base 12 and has a transverse lower wall 22a with an opening 22b therethrough. A plastic medication cup 16 fits into the open top of the fluid cavity 22 with its outer portion resting on the shoulder 21. The cup is tapered, having a truncated conical form with the bottom portion 23 approximately the same diameter as the face of crystal 11. The cup may be of a suitable material as a plastic, a metal foil or the like.

A cooling (coupling) liquid 14 such as water or oil is contained within a fluid cavity 22 between the cup and the base 12. This liquid transmits the acoustic energy from the crystal 11 to the medicament 15 which is held in the cup thereby causing a radiation pressure fountain 17 and nebulization as will be described in detail later.

Referring now to FIGS. 3 and 4, the transducer mounting is shown in detail. The piezoelectric ceramic crystal body 30 may be made of materials such as lead zirconate, lead titanate zirconate, or calcium titanate with or without traces of salts of yttrium, lanthanum, strontium, or cobalt. The flat ceramic crystal can have various configurations, as circular, rectangular, square, etc. In one specific embodiment of the invention, the crystal is a circular flat disc with a diameter of 0.75 inch, a thickness of 0.1 inch, and a nominal resonant frequency of approximately 750 kilocycles. To establish good electrical contact with the crystal body, the upper 31 and lower 32 faces are coated with electrically conductive layers, 33 and 34, respectively, of metal such as gold, platinum, iridium or silver.

The crystal 11 closes opening 22b at the bottom of cavity 22 and is mounted under compression in the transducer base 12 by means of a series of clamp screws 35 which squeeze a circular shaped metal clamp ring 36 against a neoprene or synthetic rubber O-ring seal 37. Clamp ring 36 has an L-shaped cross section defining a generally rectangular space with the undersurface of wall 22a and the periphery of the crystal. Sealing ring 37 engages four surfaces.

The electrical connection to the upper face 31 of the crystal is achieved by direct contact of the base 12 with the upper metallized surface 33. A tin or copper ground lug 38 is provided on one of the clamp screws 35 to permit the base to be grounded.

The electrical connection to the lower face 32 of the crystal is achieved by direct contact of a copper foil lead 39 compressed between a circular neoprene washer 40 and the metal-coated bottom face 34 by an extending leg 36a of the metal clamp 36.

The upper face 31 of the crystal is in contact either with a liquid 14 (water, oil, etc.) or with the solution to be dispersed. Where liquid 14 is used, it serves the dual function of cooling the crystal and coupling sonic energy to the material to be dispersed. To protect the metallized surface 33 from corrosion, chemical reaction with the liquid or mechanical projections in the liquid phase during irradiation, it is covered with a sealing coating as a layer of epoxy resin 41. This design permits a satisfactory electrical contact along the circular edge 33a of the upper crystal surface and at the same time gives maximum protection to the upper vibrating face.

The sealing coating for the upper surface of the crystal must accommodate deflection of the crystal and the high accelerations which occur. For the crystal described above, driven with a voltage of the order of 150 volts (RMS), there will be a deflection of the order of 0.25 micron and accelerations as high as 500,000 G. Furthermore, the material must have good adhesive qualities, permit the dissipation of heat from the crystal and transfer the sonic energy with little attenuation. A suitable material is an epoxy resin sold under the trademark E. POX. E. by The Woodhill Chemical Corp., Cleveland, Ohio. A layer with a thickness on the order of 0.015 inch on the crystal discussed provides adequate protection without excessive heating or attenuation of the sonic energy.

In the present mounting the lower face of the ceramic crystal vibrates freely into air space 42 thus allowing near perfect reflection of the acoustic energy in the upward direction. More than 80 percent of the acoustic energy is contained inside the solid cone angle 45 on the axis 46 of the transducer. The solid cone angle 45 is equal to $2 \sin^{-1} .61 x/R$ where x is the wave length of the emission and R the radius of the vibrating disc. From experimental results the maximum value of angle 45 is 12° .

As shown in FIG. 2, the acoustic energy is transmitted through the cooling liquid 14 to the medicament 15 held in the cup 16 thereby creating a turbulent fountain 17. The high degree of internal turbulence achieved inside the fountain produced by the upward radiation pressure of the crystal causes nebulization to occur around the outer surface of the fountain 17.

A wide variation in the liquid level does not affect the fog production since the ceramic crystal has an excellent electroacoustic output sufficient to disintegrate the liquid geyser regardless of liquid level. A focusing (curved) transducer is not used since it would not produce a geyser as stable as the one erected by the flat transducer.

Aerosol chamber 13 is fitted on transducer base 12, above the medication cup. Chamber 13 is a clear plastic canopy to contain the nebula generated by the device. The chamber 13 has an outlet 18 that permits the aerosol to be directly inhaled or to which accessory devices such as mouth pieces and face masks can be attached.

The air inlet 50 to the chamber is through the top 51 by means of a plastic tube 52 that extends downward to the fountain 17 produced in the medicament 15. This tube not only provides a means of allowing air to be drawn into the chamber but also contains the fountain 17 so that it does not splash up into the upper surfaces of the aerosol chamber. The larger particles impinge on the tube wall and drain back into the body of medicament 15, leaving only the smaller particles suspended. The tube also brings the inlet air into the bottom of the chamber at a velocity sufficient to push the nebula upward allowing complete utilization of the generated aerosol. The velocity of the air in the outer chamber is much lower and the larger, more dense particles fall back into the cup. A one-way valve 53 in the top of the tube allows air to enter during inhalation but then closes so that it is impossible to exhale through the chamber. In the absence of air flow, the nebula remains in the chamber and provides for an "on demand" delivery to the user. All of the nebula formed is drawn out by the user or falls back into the cup, resulting in complete utilization of the medicament.

FIG. 5 shows the nebulizer system which consists of a generator 60, nebulizer 10, and mask 61. The generator 60 contains an oscillator circuit which provides power which is transmitted to the transducer by a coaxial cable 62. The cable 62 is connected between an output terminal 63 at one end and copper foil lead 39 and ground lug 38 at the other end. The generator may have an on-off switch 64 and indicator light 65. Furthermore, a vernier tuning control 66 is provided for balancing the system to various medicaments. A timer 67 is provided to control the amount of time the system operates for different dosages.

To operate the nebulizer, the transducer base is filled with cold tap water to the proper level. The medication cup is then placed into the transducer base and medication is added to the cup. The plastic aerosol chamber is placed on the shoulders of the base. After throwing the On-off switch to the "on" position and allowing a short period for the generator to warm up, the "timer" is set to the prescribed interval. Using the vernier tuning control, the system is tuned for the desired amount of nebulization activity.

A mask 51 or other means may be placed on the nebulizer outlet 18 of the mist chamber, and the patient may breathe the aerosol medicament.

In FIGS. 6 through 21, there are shown a further embodiment of ultrasonic drug nebulizer of the invention and some modifications thereof.

Nebulizer 110 is seen to comprise (FIGS. 6—8), cabinet 112, receptacle housing 114, transparent dome 116 and air pipe 118. The electronic signal generator is contained in cabinet 112, is actuated by timer switch 120 and is tuned by means of tuning control 122. Pilot light 124 is used to indicate that power has been applied to the signal generator and to indicate safe connection to the power mains as will appear further on in this description.

FIG. 9 is an enlarged sectional view of the receptacle and transparent dome used in the ultrasonic drug nebulizer 110. Receptacle 114 is preferably formed of a metal such as aluminum and is finned as shown in FIGS. 16 and 17 to facilitate the transfer to heat from the receptacle to the surrounding atmosphere. Receptacle 126 is provided on cabinet 112 to receive receptacle 114.

When receptacle 114 is placed on receptacle 126, connector 128 on the receptacle 114 mates with connector 130 which is mounted in cabinet 112 and thereby makes electrical connection between the output of the signal generator and transducer 134 which is mounted in the base of receptacle 114. In a preferred form of the invention, the insertion of receptacle 114 on receptacle 126 also closes limit switch 136, as shown in FIG. 9. This serves as a safety feature and prevents the user from turning the generator on with its output unloaded.

Alternatively, switch 136 can be omitted or locked closed so that receptacle 114 may be removed from the cabinet and connection made between connectors 128 and 130 by means of a suitable jumper cable (not shown). In such circumstances, the receptacle and dome assembly may be held by the patient at a distance (depending upon the jumper length) from the cabinet. However, since it is necessary that the dome 116 be held in a vertical attitude, it is not advisable to have weak patients use the nebulizer in this manner.

Receptacle 114 is filled with water 138 or a similar liquid to a suitable level such that the vibrations of transducer 134 are coupled to medicated solution 140. Medicated solution 140 is contained in truncated conical cup 142 which is preferably formed of a transparent polycarbonate resin such as is marketed under the trademark LEXAN by the General Electric Co. Truncated conical cup 142 is provided with a circumferential lip 144 surrounding its open, larger base to facilitate its installation in receptacle 114. Lip 144 rests on the top of receptacle 114 and the truncated conical cup 142 is held in place by dome 116 which is threaded to receptacle 114 as shown at 146.

Dome 116 is formed of a transparent material, preferably a polycarbonate resin such as LEXAN, and comprises inner, vertically disposed, column 148 and outer, vertically disposed, column 150 surrounding column 148. The aerosol is emitted to the surrounding atmosphere through exit 152 which is connected to column 150.

Transducer 134 is formed of flat circular disc 154 to which suitable electrodes 156 have been applied in a manner well known in the transducer art (FIG. 10). Disc 154 is preferably formed of a polarized, piezoelectric ceramic such as barium titanate, lead titanate, barium-lead titanate or any other suitable material with or additives. Transducer 134, upon excitation at a frequency in the range from about 450 kHz. to about 2 MHz., vibrates in its thickness mode and transmits mechanical vibrations to coupling liquid 138. The vibrations are transmitted, in turn, to medicated solution 140 and are of sufficient intensity to form geyser 158 therefrom.

Receptacle 114 is provided with opening 160 in the bottom thereof which is threaded as shown at 161 and with lip 162 overlying the threaded opening. O-ring 164 surrounds transducer 134 to keep it in position against lip 162 and to prevent any liquid leak around the transducer and its mounting. The upper electrode 154 is in intimate contact with lip 162 and thereby makes electrical contact with receptacle 114 (equipment ground).

Cup 166 is formed of a metal such as brass with its open base facing the lower electrode 156 and is held in position against the electrode by means of insulating ring 168 which

threads into threads 161. Ring 168 serves to insulate cup 166 from receptacle 114. The circumference of the open base of cup 166 is in intimate, electrical contact with the lower electrode 156 of transducer 134. Spring 170 makes the electrical connection between cup 166 and the hot lead of connector 128.

A gas, such as air, is introduced at a pressure above ambient pressure into column 148 through pipe 118 which is connected to an air blower in cabinet 112. The air blower is of a type well known in the art and the structural details are not shown. The gas enters column 148 and impinges against geyser 158 and causes the mist droplets to enter column 150 and to be emitted through exit 152 as the gas sweeps past geyser 158 and up into column 150.

Since different ailments require different droplet sizes for ideal therapeutic benefit, the gas flow past geyser 158 can be modulated to select the desired droplet size to be emitted through exit 152. The blower is run at constant velocity and the airflow is controlled by means of valve assembly 174. Valve assembly 174 comprises rotating control 176 and flap-type, check valve 178.

Check valve 178 (FIGS. 14 and 15) is normally a part of dome 116 and is in the gas stream input to column 148. It comprises an outer support 180 to which spider 182 is attached. Membrane 184 of material such as neoprene is fixed to the center of spider 182 with its periphery free. It is biased upward so that it is normally closed. When the membrane is pushed down by gas pressure or otherwise, the valve opens and the gas enters the column. This membrane is principally useful when the nebulizer is used without the blower. However, for the sake of simplicity of manufacture, the same valve assembly is used when the nebulizer is operated both with and without the blower.

Rotating control 176 is a part of pipe 118 and is provided with openings 186 which cooperate with openings 188 in fixed element 177 to control the gas flow. When the openings are aligned as shown in FIG. 13, the maximum flow of gas is delivered to the column 148. To ensure that check valve 178 is open when used with the blower, control 176 is provided with a pair of stiff wires 190. These wires 190 open the valve mechanically when pipe 118 is connected to dome 116.

The embodiment illustrated is provided with three control positions, as shown by indicia 192 of FIG. 9. By way of example, in the maximum position, the gas flow from a blower running at 3,250 r.p.m. is 12 li./min. which will produce an aerosol with the droplets having a mass median diameter between 1½ to 3 microns. At the same blower velocity in the middle position a gas flow of 6 li./min. is obtained and produces a light fog with the droplets having a mass median diameter between 3 and 6 microns. At the same blower velocity, the minimum position delivers a gas flow of 3 li./min. and a fog in which the mass median diameter of the droplets is between 7 and 10 microns. The foregoing is by way of example and is not intended to limit the scope of the invention.

FIGS. 16 through 18 are enlarged views of receptacle 114. It is preferably formed of aluminum or some other electrically and thermally conductive material. The outer periphery is provided with fins 194 to accelerate the transmission of heat away from the receptacle. Threads 196 at the top are used to connect dome 116 to receptacle 114. Screws 197 are utilized to hold the transducer assembly in place at the bottom of receptacle 114.

FIGS. 19 and 20 are views of the truncated conical cup 142 which is preferably formed of polycarbonate resin such as LEXAN. This material is transparent so that the action in the interior may be observed and is stable at sterilization temperatures so that it may be treated in an autoclave without harm or damage. Its large base 198 is open and its small base 200 is closed so that, in use, its small base is down. To facilitate the maximum transfer of acoustical energy from the transducer through the coupling liquid to the medicated solution in the cup, it is desirable to make base 200 as thin as possible. Generally, the thickness of base 200 should be about one-

quarter of that of the wall 202. By way of example but not by way of limitation of the scope of the invention, a wall thickness of 0.02 inch and a base thickness of 0.005 inch have produced excellent results.

In FIG. 23, there is shown the schematic diagram of signal generator 132. It delivers a power output of approximately 30 watts at a nominal frequency of 800 kHz. It comprises tuned grid electron coupled oscillator 204 which feeds power amplifier 206. The output of power amplifier 206 is delivered to connector 130. Tuning control 122 is adjustable by the operator and is used to adjust the geyser to maximum height.

Since ultrasonic drug nebulizers of the invention are intended to be used by persons who are not technically trained in the electronic and electroacoustical arts, it has been found advisable to utilize pilot light 124 as a warning light to indicate correct or incorrect connection to the AC mains.

The generator is provided with a standard, three-prong, 115 volt AC connector. When it is properly connected to the AC mains, pilot light 124 remains out when either interlock switch 136, or timer switch 120, or both are open. It goes on when both switches are closed.

However, if the ground connection is not made to the AC mains or if the hot terminal 208 is connected to the grounded terminal of the AC mains, pilot light 124 will light when either or both switches 120 and 136 are open. The light will go out when both switches are closed. This gives an immediate indication to the patient or technician that the connection should be corrected and will prevent possible electric shocks.

Operation of the ultrasonic drug nebulizer 110 proceeds as follows: the receptacle 114 is filled with water to the marked level and the cup 142 is placed on top of the receptacle 114. Medicated solution is now added to the cup to the desired level. Dome 116 is screwed in place on receptacle 114 thereby locking cup 142 in position. The assembly is now placed in position in receptacle 126 so that connection is made between connectors 128 and 130 and limit switch 136 is closed. Next, pipe 118 is connected to dome 116 and the nebulizer is ready for operation. The timer is turned to the desired time, which turns on the generator and blower, and the geyser after 15 seconds forms in the medicated solution. The tuning control is adjusted to produce maximum geyser height and is left there. The valve control is set for the desired droplet size and therapeutic treatment commences and continues until the set time expires and the generator and blower turn off.

FIG. 21 is an enlarged sectional view of an alternative form of valve which may be used with the ultrasonic nebulizer of FIG. 6. Pipe 118 is disconnected from dome 116 and flap-type, check valve 210, which is similar to check valve 178, is inserted at the top of column 148. A respiratory mask such as mask 61 of FIG. 5 is suitably connected to exit 152. Then, air is drawn into column 148 when the patient inhales and valve 210 is closed when the patient stops inhaling or exhales.

FIG. 22 is a view similar to FIG. 13 showing another form of valve used with the ultrasonic nebulizer of FIG. 6. Valve assembly 212 is similar to valve assembly 174 and is in the forced gas stream between pipe 118 and column 148. It is provided with rotating control 214 and fixed element 216. Element 216 is provided with openings 220 and rotating control 214 is provided with openings 218. The construction of flap valve 210 is the same as that of valve 178 and the amount of gas (air) received by column 148 is controlled by the position of rotating control 214 and the relationship of the positions of openings 218 with the positions of openings 220. Check valve 210 is constructed so that it opens under the pressure of the gas delivered by blower 172 and closes when there is insufficient pressure. This prevents the gas from escaping from column 148 back into pipe 118.

Ultrasonic drug nebulizers of the invention may be used for all types of treatment as well as for aerosol studies in flame spectroscopy and similar scientific investigations. In addition, a pulsed valve may be substituted for the valve illustrated and described to produce a pulsed output emission instead of the constant output delivered by the device described heretofore.

The output of the device may be emitted in a room, in a tent or through the typical respirator mask directly to the respiratory tract of the patient.

The invention is not limited to the particular arrangements of the apparatus described, but may be variously modified without departing from the spirit and scope of the invention.

I claim:

1. An ultrasonic drug nebulizer for forming a mist from a medicated solution and emitting the same into the surrounding atmosphere comprising:

a receptacle having a base with a sealed opening therein and walls to form a liquid containing chamber;

a truncated conical cup for containing the medicated solution in isolated relation to any source of solution, the cup being removably mounted to the walls intermediate the length thereof substantially in sealed relation so that the base of the receptacle is below the base of the cup, the base of the cup being closed;

a dome containing an inner, vertically disposed, unobstructed influent column and an outer, vertically disposed, effluent column surrounding the inner column, the dome being removably mounted to the receptacle above the truncated conical cup, the sealed opening, the base of the cup and the inner column being in vertical alignment;

the inner column and the outer column both being fully open at the bottom, thereof, the outer column having an effluent opening therein adjacent the top thereof;

gas flow regulating means in the top of the inner column;

a transducer mounted at the base of the receptacle so as to cover the opening in sealed relation;

means for exciting the transducer at an ultrasonic rate such that a geyser is formed from the medicated solution in the truncated conical cup, said means for exciting being arranged such that, the geyser extends upward in alignment with the inner influent column; and

means for introducing gas at a pressure above ambient pressure into the inner column through the gas flow regulating means in the top thereof to impinge directly on the geyser and thereby force the mist of the geyser into the outer column to be discharged through the effluent opening therein.

2. The invention of claim 1 wherein the dome is formed of transparent material such as a polycarbonate resin which is stable at sterilization temperatures and through which the geyser formed from the medicated solution may be observed.

3. The invention of claim 2 wherein the truncated conical cup is formed of a material such as a polycarbonate resin which is stable at sterilization temperatures.

4. The invention of claim 3 wherein the base of the truncated conical cup is thinner than the walls thereof so that maximum ultrasonic energy is transmitted from the transducer through the liquid to the medicated solution.

5. The invention of claim 4 wherein:

the gas flow regulating means is a valve; and

the means for introducing gas into the inner column comprises:

a blower; and

a pipe connecting the blower to the top of the inner column such that the valve is open when the pipe is connected thereto and is closed when the pipe is disconnected therefrom.

6. The invention of claim 5 wherein the valve comprises an opening, the size of which may be varied to thereby control the flow rate of the gas entering the inner column to thereby control the size of the liquid droplets which are emitted from the outer column.

7. The invention of claim 6 wherein the means for exciting the transducer at an ultrasonic rate comprises:

an electronic signal generator having a transformer with a primary and a secondary;

the primary being connected to a source of three wire, AC voltage and the secondary being connected to a rectifier power supply;

a switch connected in series with the primary; and
 a pilot light connected from one side of the primary to ground such that if the connection to the source of AC voltage is improper, the pilot light is lit with the switch open and is extinguished with the switch closed.

8. The invention of claim 7 wherein the transducer comprises:

- a polarized ceramic disc having an upper electrode and a lower electrode on the opposite faces thereof;
- a cylindrical brass cup having a closed bottom and a wall;
- a threaded opening in the base of the liquid chamber larger than the diameter of the brass cup and of the polarized ceramic disc;
- a lip in the base of the liquid chamber overlying the threaded opening;
- an insulating ring surrounding the brass cup and having external threads engaging the threaded opening to electrically insulate the brass cup from the liquid chamber;
- the polarized ceramic disc being mounted above the brass cup so that its lower electrode makes contact with the brass cup and its upper electrode makes contact with the lip in the base of the liquid chamber;
- an insulated O-ring surrounding the polarized ceramic disc to inhibit the flow of liquid out of the liquid chamber; and
- means for making electrical connection to the brass cup and to the liquid chamber.

9. The invention of claim 1 wherein the truncated conical cup is formed of a material such as a polycarbonate resin which is stable at sterilization temperatures.

10. The invention of claim 9 wherein the base of the truncated conical cup is thinner than the walls thereof so that maximum ultrasonic energy is transmitted from the transducer through the liquid to the medicated solution.

11. The invention of claim 1 wherein:

- the gas flow regulating means is a valve; and
- the means and introducing gas into the inner, vertically disposed, column comprises:
- a blower;
- a pipe connecting the blower to the top of the inner, vertically disposed, column such that the valve is open when the pipe is connected thereto and is closed when the

pipe is disconnected therefrom.

12. The invention of claim 11 wherein the opening in the valve may be varied to thereby control the flow rate of the gas entering the inner, vertically disposed, column.

13. The invention of claim 1 wherein the means for exciting the transducer at an ultrasonic rate comprises:

- an electronic signal generator having a transformer with a primary and a secondary;

- the primary being connected to a source of three wire, AC voltage and the secondary being connected to a rectifier power supply;

- a switch connected in series with the primary; and

- a pilot light connected from one side of the primary to ground such that if the connection to the source of AC voltage is improper, the pilot light is lit with the switch open and is extinguished with the switch closed.

14. The invention of claim 1 wherein the outer surfaces of the walls of the receptacle are finned to facilitate the transfer of heat therefrom.

15. In an ultrasonic drug nebulizer having a liquid chamber in which a driving transducer is mounted adjacent an opening in the base of the liquid chamber, the improvement comprising:

- a polarized ceramic disc having an upper electrode and a lower electrode on the opposite faces thereof;

- a cylindrical brass cup having a closed bottom and a wall;

- a threaded opening in the base of the liquid chamber larger in size than the diameter of the brass cup and of the polarized ceramic disc;

- a lip in the base of the liquid chamber overlying the threaded opening;

- an insulating ring surrounding the brass cup and having external threads engaging the threaded opening to electrically insulate the brass cup from the liquid chamber;

- the polarized ceramic disc being mounted above the brass cup, the upper electrode making contact with the lip in the base of the liquid chamber;

- an insulated O-ring surrounding the polarized ceramic disc to inhibit the flow of liquid out of the liquid chamber; and
- means for making electrical connection to the brass cup and to the liquid chamber.

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