U.S. Patents 3,697,222 3,912,450 3,968,248

WAVICIDE®-01

SPORICIDAL, VIRUCIDAL
BACTERICIDAL, FUNGICIDAL
TUBERCULOCIDAL
PSEUDOMONACIDAL

A STABLE, RAPID ACTING, STERILIZING AND DISINFECTING SOLUTION FOR HOSPITALS, DENTAL AND MEDICAL OFFICES AND VETERINARY HOSPITALS

CAN BE USED IN ULTRASONIC CLEANERS

RECOMMENDED FOR:
Rubber and plastic objects.
Lenses and
Stainless steel instruments

ACTIVE INGREDIENTS.
Glutaraldehyde (1.5 Pentanedial) 2%
INERT INGREDIENTS 98%
Inert ingredients contain. non-ionic ethoxylates of isomeric linear alcohols
$[CH_3-(CH_2)_n-CH-(CH_2)_{n'}-CH_3]$
$O-(CH_2CH_2O)_x-H$ with $n + n' = 8$-12 as synergistic agent.
Contains Sodium Nitrite.

KEEP OUT OF REACH OF CHILDREN

WARNING: HARMFUL IF SWALLOWED

E.P.A. Registration No. 15136-1
This product must be kept in locked storage.
See other precautions on back label

Distributed by Lot No

Manufactured by
Wave Energy Systems, Inc., Newtown, PA 18940 USA

Net contents 1 U.S. gallon (128 fl. ozs.)—3.785 liters

E.P.A. Establishment No. 15136-Pa01

ACCEPTED
with COMMENTS
In EPA Letter Dated:

NOV 24 1982

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 15136-1

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WAVICIDE®-01 DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

PREPARATION

Instruments should be thoroughly cleansed rinsed and drained before immersing in WAVICIDE-01 Hollow objects and needles should be flushed and filled

STERILIZATION

Immerse objects to be sterilized in WAVICIDE-01 (2% Active Ingredients) solution maintained at **60°C** for **60 minutes** Remove and rinse with sterile water This is a complete sterilization procedure including the destruction of viruses and tubercle bacilli

DISINFECTION

MIX ONE PART BY WEIGHT OR VOLUME OF THIS SOLUTION TO THREE PARTS OF POTABLE WATER FOR 1:4 DILUTION (0.5% Active Ingredients)

Thoroughly wet or immerse equipment wares or instruments in the 1:4 diluted solution (0.5% Active Ingredients) for 10 minutes at room temperature to destroy *Staphylococcus aureus Salmonella choleraesuis Escherichia coli Pseudomonas species Klebsiella pneumoniae* and *pathogenic fungi (Tricophyton mentagrophytes* and *Candida albicans)*

OR

When treating objects such as respiratory therapy equipment in the model 512 WES Decontaminating machine use the 1:4 dilution (0.5% Active Ingredients) for **single cycle** use

For **multiple cycles** (120 cycles) continuous use over a 28 day period use the non-diluted (2% Active Ingredients) solution

For use in the 512 WES Decontaminating machine follow instructions as directed in the brochures "Model 512 Ultrasonic Cleaner Decontaminator" and "Maintenance Manual"

VIRUCIDAL ACTION

When used as directed at room temperature the non-diluted 2% solution will destroy Influenza A (Hong Kong) virus Herpes Simplex virus Newcastle Disease virus and ECHO virus type 25 on inanimate surfaces

TUBERCULOCIDAL DISINFECTION

When used as directed at room temperature, the non-diluted 2% solution will destroy *Mycobacterium tuberculosis* in 10 minutes on inanimate surfaces Instruments should be removed and rinsed with water that fulfills federal drinking water standards

STORAGE AND DISPOSAL

Triple rinse with water and dispose in an incinerator or landfill approved for pesticide containers or bury in a safe place Do not reuse empty containers This product should be stored at room temperature preferably in a cool place

PRECAUTIONS

For Professional Use Only

WARNING

Causes eye irritation In case of contact with the eye flush well with water and seek medical aid Avoid prolonged and repeated contact with skin as possibility of sensitization exists Avoid contamination of food

Use in covered containers to avoid evaporation and to minimize odor

DISINFECTION EFFICACY DEMONSTRATED WITH THE MODEL 512 WES DECONTAMINATOR MACHINE

After 120 cycles simulated hospital use during a 28-day period WAVICIDE-01 (2% active ingredients) in combination with high intensity ultrasonic field generated in the Wave Energy Systems Inc Model 512 Hospital Decontaminator machine was found to be an effective surface disinfectant

BACTERICIDAL – When tested for 20 minutes at 40 C against *Salmonella choleraesuis Staphylococcus aureus, Klebsiella pneumoniae* and *Escherichia coli*

PSEUDOMONACIDAL – When tested 20 minutes at 40 C against *Pseudomonas aeruginosa*

FUNGICIDAL – When tested for 20 minutes at 40 C against *Trychophyton mentagrophytes, Aspergillus fumigatus* and *Candida albicans.*

VIRUCIDAL – When tested for 20 minutes at 40 C against Poliovirus type I (vaccine strain) Herpes simplex type I and Rotavirus (SA-11)

MYCOBACTERICIDAL – When tested for 20 minutes at 40 C against *Mycobacterium smegmatis*

Continuous 28 days use tests were conducted with the following load in the rotating basket six 36" corrugated breathing tubes three 5 liters breathing bags and three adult face masks (size 5)

Tob # 204-448

DESCRIPTION

OF THE

HOSPITAL ULTRASONIC CLEANER/DECONTAMINATOR

MODEL 512 WES

REVISED: SEPTEMBER 1982

Model 512 Ultrasonic Cleaner/Decontaminator Function and Operation

1. Function

- The Model 512 Ultrasonic Cleaner/Decontaminator has been developed to take advantage of the increase in biocidal efficacy* observed when combining ultrasonic irradiation (also called insonation) with certain types of chemical sterilants and disinfectants.

  The principle and mechanisms on which this machine is based have been described at length in the following paper:

  > *R.M.G. Boucher, Ultrasonics - A tool to improve biocidal efficacy of sterilants or disinfectants in hospital and dental practice. Can. Journ. Pharm. Scien. Vol. 14, No. 1, 1 - 12, January 1979.*

- The Model 512 was also designed to provide a solution to the difficult problem of cleaning respiratory therapy equipment such as masks and inside portions of long corrugated breathing tubes.

- Last but not least, the Model 512 was designed to deliver, at the end of its processing cycle, clean and decontaminated equipment with the lowest level of chemical residuals (thanks to multiple ultrasonic rinses).

2. Why was the Model 512 developed?

It is well known that the problem of thorough cleaning of long plastic or rubber corrugated tubing has never been satisfactorily solved in hospital practice. This is especially true for tubing greater than four feet long. In 1978, WES conducted a research study to assess the efficacy of high intensity ultrasonics to remove tough artificial stains.

*Process and products covered by US Patent No's: 3,697,222; 3,968,248 and others.

The Corrugated tubes were stained* inside and outside with organic contaminants (10% serum, 5% mucin, and 1% TiO_2), and they were dried overnight at room temperature before testing. The corrugated tubing (rubber and PVC) was placed in high-intensity ultrasonic cleaners (frequency 27kHz) with a density of acoustic energy as high as 30 watts/liter. To accelerate the removal of the artificial stains both a surface agent (Alkyl Aryl Sodium) and proteolytic enzymes** were added to the aqueous solution of 2% potentiated acid glutaraldehyde. The final temperature of the bath after 30 minutes of high power insonation averaged 45°C. Most of the organic stains or rubber corrugated tubing could not be removed, regardless of the ultrasonic intensity, the temperature or the contact time (up to several hours). This was especially true for the stains inside the corrugated tubing.

It is common knowledge that mechanical cleaning systems which are based upon the kinetic energy of jets, sprays, and agitation, are in general not as efficient as heavy-duty ultrasonics in removing organic stains on materials with convoluted surfaces or small orifices. To double check this statement, in the case of corrugated breathing tubes, we submitted the same contaminated tubing to the standard cleaning cycle of an RCA automatic clothes washer (contact time: 40 minutes at 30°C). Here again most stains could not be removed.

One of the reasons why the inside stains could not be removed by ultrasonics was the fact that cavitating bubbles could implode inside the tubing but the partially lifted stain matter could not be carried away and was often redeposited at short distance due to the lack of macroturbulence (fluid flow) inside the tubing. In a mechanical washer, (RCA, CIDEMATIC, etc..), the liquid circulated inside the tubing but there was not enough localized impact energy to blast away stains in dead zones.

Only a combination of localized cavitational energy with a dynamic fluid flow (to lift and carry away broken particles or matter) could provide the satisfactory cleaning of external and internal surfaces in corrugated tubing.

*About 1cc of stain mixture per piece.

**Those enzymes were chosen for their activity at temperature as high as 60°C.

The Wave Energy Systems Model 512 was designed to provide such a solution to this cleaning problem.

As we shall later explain, the 512 system enables a perfect pre-cleaning which is a "must" before any disinfecting or sterilizing operation, and it also insures the virtual elimination of all disinfectant residuals during final ultrasonic rinses. Since the equipment to be decontaminated is submitted to a specific disinfectant (WAVICIDE-01®- EPA Reg. No. 15136-1) between pre-cleaning and final ultrasonic rinses, the system provides optimal conditions for both cidal action and removal of residuals.

Another important advantage of the 512 system lies in the fact that its strong ultrasonic scrubbing action allows one to clean and decontaminate equipment whithout disassembling it. This is indeed an enormous "time-saving" feature when handling complex industrial or medical equipment such as breathing masks, medical nebulizers, etc.

Moreover, it was discovered by Sierra and Boucher in the early seventies that (*see G. Sierra and R.M.G. Boucher, Applied Microb., Vol. 22, No. 2, 160-164, August 1971*), under certain conditions, the combined action of ultrasonics with aldehyde radicals improves the cidal mechanisms during exposure phase to the glutaraldehyde disinfectant.

3. How does the Model 512 work?

The main idea behind the design of the Model 512 was the use of a slowly rotating drum which provides constant liquid flow inside convoluted tubing, or restricted zones. It was, for instance, discovered that a drum rotating at a speed of between one and thirty revolutions per minute will allow enough turbulent flow inside long corrugated tubing* to avoid redeposition of sticky matter or microparticles removed by localized ultrasonic cavitation blasts. The most desirable speed seems to be around three revolutions per minute. Such a speed still allows a fair penetration of the ultrasonic energy inside recessed areas. When the rotational speed increases, the ultrasonic level must also increase to allow a satisfactory cavitation level. Above thirty revolutions per minute, one would have to use unreasonable amounts of acoustic energy to create cavitation inside the recessed areas of hollow tubing. This is of course due to the high absorption and screening effects observed in turbulent liquids.

*The corrugated tubings are coiled around the periphery of the drum.

The enclosed schematic shows the main components and explains the principle behind the Model 512.

On the right side of the diagram one can see the stainless steel processing chamber, which has a nominal capacity of approximately 15 gallons. At the bottom (slanted side plates) of the chamber are fastened twenty-two ULTRABLAZE® transducers, which transform high frequency electrical currents into ultrasonic vibrations (27 kHz). These piezo-electric transducers, of proprietary design, are of the Langevin sandwich type. They do not use epoxy bonding, but are 100% metallurgically bonded to the processing chamber walls. The transducers are activated by a solid-state generator, which transforms standard alternating current (AC 60 hertz, 115 volts) into high frequency (HF) electrical current. The energy output from the HF generator into the loaded transducers is approximately 1000 watts. The transducers, in turn, release around 800 watts of acoustic energy into the liquid of the processing chamber.

Inside the processing chamber a cylindrical stainless steel drum (16" diameter with lateral apertures) rotates at the speed of three revolutions per minute. The material to be processed (masks, tubing, etc.,) is loaded and fastened inside the rotating drum.

On the left side of the diagram one can see the stainless steel reservoir (24"L x 16"W x 24"D), which contains the disinfectant. A combined system of two pumps with four solenoid valves is used to inject liquids (water and disinfectant) or remove them from the processing chamber. The opening and closing of the fast response valves is controlled by signals sent from an electro-mechanical timer.

The following defined conditions are those which correspond to what can be called a "full operational cycle." This standardized cycle was repeated one hundred twenty (120) times over a 28 day period when testing the biocidal efficacy of the 512 machine with the same disinfectant, according to an EPA protocol:

(a) 10 minutes ultrasonic pre-rinse with a detergent (through valve 4).

(b) 3 minutes ultrasonic rinse (with automatic drainage of dirty liquid through pump 2 and valve 3).

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*ULTRABLAZE® is a registered trademark of WAVE ENERGY SYSTEMS INC.

(c) 20 minutes exposure to ultrasonics with a full load of WAVICIDE-01 (injected through pump 1 and valve 1). At the end of 20 minutes the disinfectant is pumped back (through pump 2 and valve 2), and filtered before it is returned to the reservoir.

(d) 10 minutes ultrasonic rinse with water through valve 4.

(e) 3 minutes of final ultrasonic rinse with water that fulfills federal drinking water standards. The rinsed water is then drained through pump 2 and valve 3.

4. Loading Respiratory Therapy Equipment into Model 512

Operating the machine is extremely simple. First, lift the lid of the left side of the Model 512 to introduce 15 gallons* of WAVICIDE-01 into the reservoir.

- If using the machine for a single cycle disinfection (i.e., with the disinfecting solution drained at the end of the cycle), the WAVICIDE-01 (2% glutaraldehyde) diluted four times (0.5% glutaraldehyde) should be used.

- If using the machine for multiple series' of one hundred twenty (120) cycles over a 28-day period, the non-diluted WAVICIDE-01 (2% glutaraldehyde) solution should be used.

After filling the reservoir, the lid on the right side of the machine is lifted and the perforated metal drum into which the equipment is loaded is taken out. Cylindrical perforated metal rods of pegs are fastened to the bottom of the drum; their relative positions can be adjusted according to the type of equipment to be placed in the drum. Breathing tubes can be placed on top of each other. They are laid between the metal pegs and the outer perimeter of the drum in a circular manner.

For example, during a 28-day, 120 cycle simulated use test, the rotating drum of the Model 512 contained three respiratory therapy sets positioned as follows (see photo):

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*To avoid losses by spillage or evaporation, we recommend adding one gallon to the nominal 15 gallon load of WAVICIDE-01 when using the machine for an extended period of time (120 cycles). For single cycle use, the extra gallon of disinfectant is not needed.

- Six breathing tubes (each 36" long) were laid on top of one another and placed between metal pegs and the outer perimeter of the drum in a circular manner. The metal pegs were sufficient to keep the hoses in position.
- Three face masks (size 5) were placed on the inner metal pegs (peg through the mask opening).
- Three breathing bags were also placed on the metal pegs. (The two rubber "eyelets" near the opening of each bag were placed onto a peg. The elasticity of the rubber kept the bags firmly in place while the balloon end of the bag was free to move within the drum.) The bags also served to keep the masks on their respective pegs.

After loading the equipment into the drum, its lid is closed and the drum is slided into position in the right-end processing tank. The gear on the drum lid should face the WAVICIDE reservoir. After checking to be sure that the AC electrical power line is connected to a wall outlet, the MAIN POWER button in depressed, released, and depressed again until the button engages. The "cycle start" button is then pressed.

Two ounces of detergents are then poured into the right-side processing tank and its hinged lid is closed. Cationic or anionic surfactants are the preferred type of detergent to be used, but there is no objection to the use of non-ionic types, since the high intensity ultrasonic rinse removes all traces of surface-active agents that could have remained at the end of the pre-cleaning cycle.

After choosing a particular sequence of events for cleaning, disinfecting, or both, the system runs automatically at the push of a button on the control panel. At the end of a full operational cycle, the lid of the processing chamber is lifted and the equipment-loaded drum, which slides upward, is easily removed. The lid on the left-side reservoir chamber can be lifted at any time to check the quality and volume of the recycled WAVICIDE-01 disinfectant solution.

Listed below are the main specifications of the Model 512 (for more details see Instruction Manual):

Overall Dimensions:	48"L x 24"W x 35"H
Rear Panel Height:	10"

Chamber Sizes:	Reservoir - 24"L x 16"W x 24"D Ultrasonic - 12½"L x 17"W x 19"D
Rotating Drum:	16" Diameter, 12" Width
Ultrasonic Generator:	1000 watts output
AC Power Requirements:	120/240V, 30 Amps

For some applications which involve only cleaning, or do not involve the decontamination of complicated structures (such as corrugated tubing, large masks, breathing bags, etc...) the drum can be eliminated and replaced by a non-rotating perforated basket of appropriate shape. Special baskets are availavle for the cleaning and decontamination of laboratory glassware.

The length of a full decontaminating cycle varies, of course, according to the type of process chosen, i.e., disinfection, pasteurization,* or simple cleaning. It should be noted that the disinfectant reservoir can be independently heated by external electrical resistances if it is to be used for ultrasonic pasteurizing** applications. Specific instructions for this type of use may be obtained by contacting Wave Energy Systems.

The filtered water used in pre-cleaning and rinsing can be either room temperature drinking water or standard warm water available in most hospitals (average temperature 38°C). For heavy loads of large-size, full-face respirators, systems can be custom designed whose cidal efficacy will be assessed each time they are used according to design characteristics.

All details regarding proper maintenance of the Model 512 machine are provided in the Instruction Manual, which is available upon written request.

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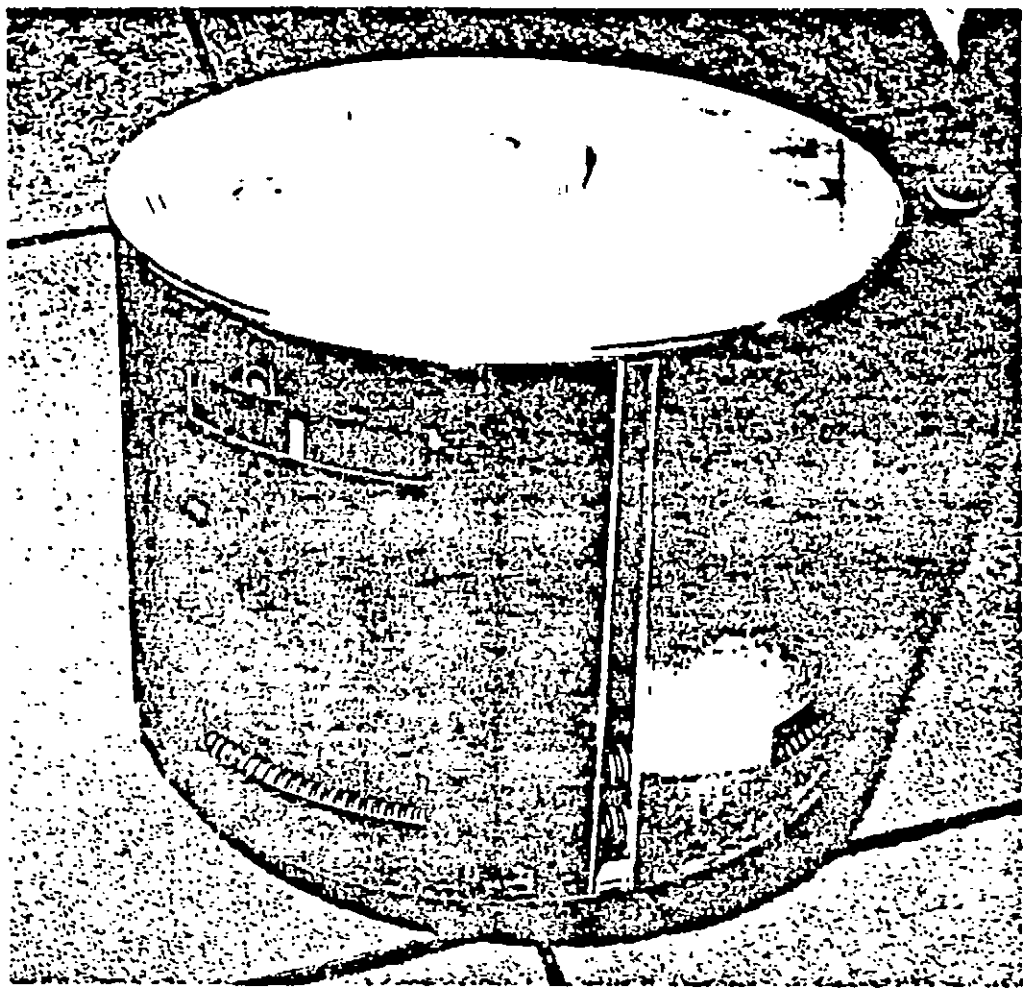
*Pasteurizing effectiveness has been demonstrated satisfactorily to the CDC at a temperature of 70°C for 30 minutes.

**See U.S. Patent no. 4,211,744 - Process for Ultrasonic Pasteurization, (July 8, 1980).



View of the loaded rotary drum in a vertical position after closure of the top with the lid. Latch to close lid can be seen on the left side. In operation the plastic gear seen on the center of the lid is facing the WAVICIDE-01 reservoir side when the drum slides into position in chamber. The vertical and lateral openings seen on the stainless drum walls improve ultrasonic energy penetration into the loaded drum.

Top view (lid removed) of the rotary drum loaded with three respiratory sets.

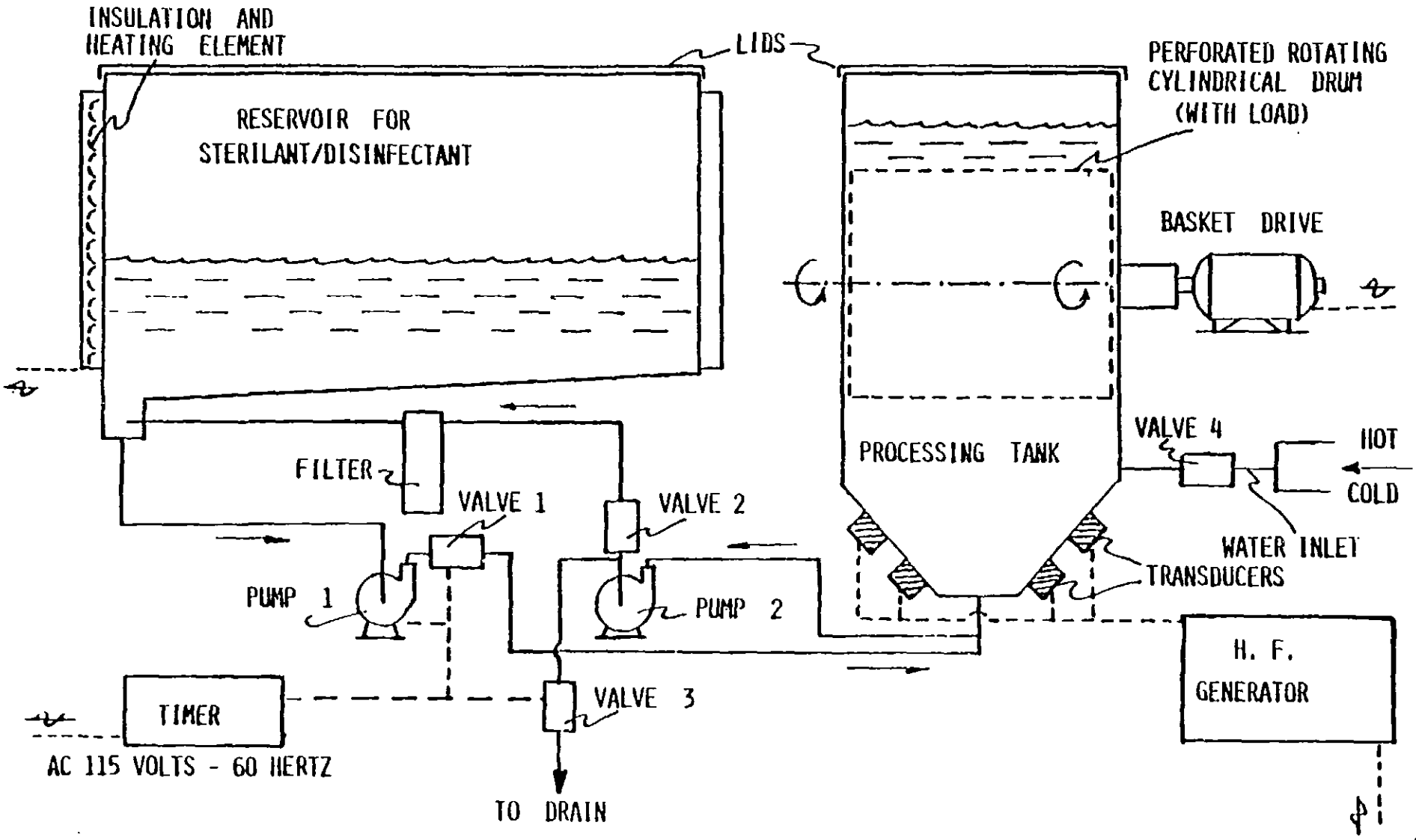
Six 36" breathing tubes coiled and stacked on the periphery of the drum between pegs and cylinder wall.

Three 5 liters breathing bags

Three adult face masks fasten through metal pegs.

Lateral and vertical openings for the penetration of the ultrasonicated liquid can easily be seen on the photo

Model 512 Ultrasonic Cleaner/Decontaminator



Wave Energy Systems Inc.

PROCEDURE FOR
LOADING AND UNLOADING
RESPIRATORY THERAPY EQUIPMENT
IN HOSPITALS

1. First, lift the two-handled cover on the upper left side of the machine to check that the disinfectant reservoir has been filled with the proper WAVICIDE-01 solution.

   The 512 machine can be used either for a single cycle of disinfection or for a series of consecutive disinfection cycles (up to 120).

   - For a single disinfection cycle, the WAVICIDE-01 (2% glutaraldehyde) solution diluted four times - down to a glutaraldehyde level of 0.5% - should be used. Fifteen gallons of this diluted solution should be poured into the left-side reservoir of the 512 machine.
   - For continuous use during a 28-day period (i.e., up to 120 cycles), the WAVICIDE-01 solution containing 2% glutaraldehyde should be used. In this case, sixteen gallons of the solution should be used to fill the left-side reservoir.

   After pouring the proper amount of the correct solution into the reservoir, replace the cover on top of the reservoir.

2. Next, lift the counter-balanced, hinged cover on the right side of the Model 512 Automatic Ultrasonic Cleaner/Decontaminator. Once the hinged cover is open, you will notice a rotating drum inside. This drum is removed by grasping it with both hands and raising it vertically until it has cleared the wash tank. Once the drum is removed, it should be placed on top of the Model 512 or on a nearby workbench, as illustrated on page 7 of this manual. It should be placed in such a position that the gear on the rotating drum is facing up and the cover is easily removed by inserting a finger into the finger latch and pulling straight up. The cover will come off very easily by unlatching the unit and disengaging the guide pin. In the rotating drum there is a series of pegs for placement of respiratory equipment. The drum is now ready for placement of the contaminated respiratory equipment with its respective hoses, breathing bags, and masks, for ultrasonic cleaning.

3. The placement of the contaminated respiratory equipment is begun by positioning the breathing hoses between the pegs and the inside wall of the respirator drum. The breathing tubes are placed around the periphery because while the Model 512 is operating, the drum rotates 360°, so that liquids flow through the breathing hoses. The drum rotates at 3 r.p.m. in the respirator cleaner, producing a continuous flow that washes away ultrasonically loosened contamination and also removes it from the inside diameter of the tube. The inside of the tube is thereby cleaned equally as well as the outside.

With the hoses placed in the drum, the half face-piece respirators should be placed with the nose area between the pegs for secure cleaning.

The breathing bags whould be placed within the inside diameter of the pegs within the rotating drum, as illustrated on page 8 of this manual.

If full face-piece respirators are to be decontaminated, they should be placed at a 90° angle from their normal operating position, and placed between the pegs and the outer periphery of the drum - one on top of another - in the four quadrants of the rotating drum. Two additional full face-piece respirators can be placed between the pegs and the inside diameter of the drum, along with the respective breathing bags. You now have completed the loading procedure.

4. The lid is then placed back on the rotating drum by inserting the pin into the drum through the hole in the edge of the finger latch cover. Next, raise the finger latch and press down on the cover until secure, then release the finger latch to lock the cover onto the rotating drum.

   To return the drum to the wash tank, grasp the unit with both hands through one of the slots on the periphery, and ease it down by matching its sides with the plastic slides in the wash tank, located on the right-hand side of the Model 512. Lower the rotating drum straight down between these slides until it rests on the motor drive gear. This procedure should be done with the rotating drum cover's gear placed on the left-hand side.

5. After checking to be sure that the AC electrical power line is connected to a wall outlet, depress the MAIN POWER button, release it, then depress it again, until the button engages. The CYCLE START button can then be pushed.

   Two ounces of detergents are then poured into the right-side processing tank and the hinged lid is closed. Cationic or anionic surfactants are the preferred type of detergent to be used, but there is no objection to the used of non-ionic types, since the high-intensity ultrasonic rinse removes all traces of surface-active agents that may have remained at the end of the pre-cleaning cycle.

   Respirator equipment is then automatically cleaned and disinfected, without the constant presence of an operator. The whole cleaning/decontaminating cycle lasts around 45 minutes. The sequence of operations can be followed at any time by glancing at the panel lights, which indicate at what processing stage the machine is operating. At the end of the processing cycle the machine will stop automatically.

<u>For Single Cycle Use Only</u>

6. After completion of a single complete cycle of the Model 512 respirator/decontaminator using WAVICIDE-01 0.50% solution, the WAVICIDE must be purged. This is begun by placing the purge/auto button on the back panel of the Model 512 in the "purge" position.

   Next, place the main power button in the "on" position. Insert the key provided into the system purge lock. Turn the key to the right for approximately five seconds, then release. This will activate the drain-opening valve in the pump motor unit, and automatically purge the WAVICIDE-01 0.50% solution into the sewer system.

When the WAVICIDE reservoir is completely empty, the pump motor unit will automatically shut off. After this has happened, rinse the reservoir thoroughly with clean tap water and squeegee all remaining liquid into the sump.

To remove this liquid from the sump, turn the key in the system purge lock to the right and hold it until the sump is completely empty.

24 NOV 1982

Wave Energy Systems, Inc.
655 Madison Avenue, 16th Floor
New York, NY 10021

Attention: Raymond M. G. Boucher

Gentlemen:

Subject: Wavicide - 01
EPA Registration No. 15136-1
Your Submission Dated October 8, 1982

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable, provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

a. Product Label

(1) The use directions must indicate that the used 1:4 diluted solution is to discarded after a single use or cycle.

(2) The label must indicate that the 1:4 diluted solution is not to be used for disinfecting when tuberculocidal and/or virucidal activity is required or desired for the items to be treated.

(3) The label must include directions for disinfecting with the undiluted solution in 10 minutes at room temperature by manual operational procedures. The proposed virucidal and tuberculocidal claims are not considered to be acceptable substitutes for these use directions.

(4) For clarity, the directions for use should also be separated from the efficacy claims indicated for manual use operations.

(5) The ultrasonic machine should be identified by the same name throughout the label text.

(6) Since only one active ingredient is declared, delete the letter "s" from the statement: Active Ingredients.

(7) Revise the statement (back panel) Precautions to read, "PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals."

(8) Revise the referral statement (front panel) - See other precautions on back label to read, See back panel for additional precautionary statements."

b. Collateral Labeling (Description of the Hospital Ultrasonic Cleaner/ Decontaminator Model 512 WES Revised September 1982)

(1) On page 5 of the brochure, the instructions should read: "When using the machine for multiple cycles up to one hundred twenty (120) over a 28-day period of disinfection, the non-diluted Wavicide-01 (2% glutaraldehyde) solution must be used."

c. Collateral Labeling (Section 7, Appendix A & B, revised September 1982)

(1) Instructions to purge the used non-diluted Wavicide-01 (2% glutaraldehyde) solution after the 120-cycle/28-day period of use should also be specified.

3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely yours,

John H. Lee
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)