

WAVICIDE-01

Concentrate

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

42 and 21 Day repeated re-use in manual (bucket and tray) systems for disinfection.

RECOMMENDED FOR: Rubber, aluminum, plastic objects, lenses, stainless steel instruments, burs, mirrors, dental tools and fiberscopes.

SPORICIDAL

VIRUCIDAL*

TUBERCULOCIDAL**

PSEUDOMONACIDAL

BACTERICIDAL

FUNGICIDAL

1:80
DILUTION
INACTIVATES
HIV-1 (AIDS VIRUS)
IN ONE MINUTE ON
ENVIRONMENTAL
SURFACES!

ACTIVE INGREDIENT: Glutaraldehyde (1,5 Pentanedial) 20.5%
INERT INGREDIENTS: 79.5%

NET CONTENTS: 13.53 oz (400cc)

E.P.A. Registration No. 15136-2

Manufactured by:
WAVE ENERGY SYSTEMS, INC.
E.P.A. Establishment No. 15136-NJ1
218 Little Falls Road
Cedar Grove, NJ 07009
(800) 252-1125

**DILUTE FOR STERILIZATION AND DISINFECTION
CAN BE USED IN ULTRASONIC TANKS**

! See box side panel
for HIV related
use information

**KEEP OUT OF REACH OF CHILDREN
DANGER: MAY BE FATAL
OR HARMFUL IF SWALLOWED**

See Precautionary Statements on side panel.



ACCEPTED

OCT 2 1991

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under
EPA Reg. No. 15136-2

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 cleaned, rinsed and rough dried before immersing in WAVICIDE-01. Hollow objects and needles should be flushed and filled.

STERILIZATION

To prepare a 2% sterilizing solution pour contents of both concentrate and corrosion inhibitor into a 128 fl. oz. (one gallon) container and fill with distilled water.

Immerse objects to be sterilized in 2% active ingredient solution observing one of the following sets of conditions: 5 hours contact time at 40°C (104°F) for single use or 10 hours contact time at 21°C (70°F) for re-use. Remove instruments from the solution using a sterile technique and rinse thoroughly with sterile water. This procedure will also destroy the Hepatitis B virus (HBV). When sterilizing at temperatures above 21°C (70°F), keep solution in covered containers or machine. Do not open lid until solution has cooled to room temperature. At 21°C (70°F) the 2% Wavicide-01 can be used and re-used as a sterilant for up to 30 days in manual systems (bucket and tray).

DISINFECTION

To prepare a 0.5% disinfecting solution use 1 gallon of 2% sterilizing solution pour into tray and add 3 gallons of potable water.

To prepare a 1% solution for disinfecting pour 1 gallon of 2% sterilizing solution into tray and add 1 gallon of potable water. . . or pour half the content of a one gallon 2% sterilizing solution into another gallon bottle and fill with potable or distilled water.

Contact equipment, wares or objects by mop, spray or immersion with 0.5% active ingredient solution for 30 minutes at room temperature. After processing, instruments should be rinsed with water that fulfills federal drinking water standards.

The 2% active ingredient solution will destroy vegetative organisms and pathogenic fungi (Trichophyton mentagrophytes and Candida albicans).

* For virucidal action at room temperature use the 0.5% active ingredient solution to destroy Herpes simplex types I and II, Rotavirus types SA 11 and WA and Poliovirus types I and II, Influenza virus type A/PR8, Rhinovirus type 1A, Respiratory Syncytial virus ATCC VR-26, and Cytomegalovirus/Davis on inanimate surfaces.

** To destroy Mycobacterium tuberculosis at 20°C on inanimate surfaces use either the 2% active ingredient solution for 42 days or the 0.5% active ingredient solution for 21 days by immersing completely for 30 minutes. For single use of fresh 2% active ingredient solution at 20°C immerse for 10 minutes. Remove equipment from the solution and rinse thoroughly.

FOR CLEANING IN ULTRASONIC TANKS

The sterilizing (2%) or disinfecting (0.5%) solutions can also be used for pre-cleaning of instruments in ultrasonic tanks. A 10 minute exposure in a high intensity cavitation field should be satisfactory for pre-cleaning of most instruments. Solutions used for ultrasonic cleaning should be discarded after each use.

STORAGE AND DISPOSAL

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions or instructions on this product's material safety data sheet, contact your state pesticide or environmental control agency, or the nearest EPA regional office for guidance.

Container Disposal: Do not re-use empty container. Rinse thoroughly with water and dispose in trash. The product should be stored at room temperature, preferably in a cool place. Do not contaminate water, food or feed by storage or disposal.

PRECAUTIONARY STATEMENTS: Hazardous to Humans and Domestic Animals

Keep out of reach of children. Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed or absorbed through skin. Avoid contamination of food. Use in a covered container to avoid evaporation and to minimize odor.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water. For eyes, call physician. If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

FOR PROFESSIONAL USE ONLY

See bottom for Expiration Date and Lot Number

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WAVICIDE-01

CORROSION INHIBITOR

Sodium Nitrite Solution

This solution will help protect metal instruments against corrosion when used as directed.

NET CONTENTS: 2 oz (60 cc)

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218 Little Falls Road
Cedar Grove, NJ 07009
(800) 252-1125

DIRECTIONS FOR USE

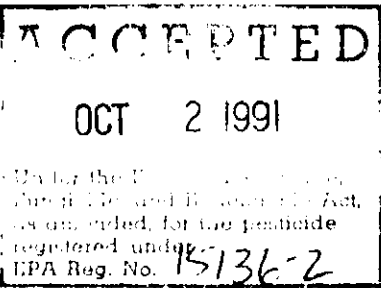
See Mixing Directions

STORAGE AND DISPOSAL

Do not re-use empty container. Rinse thoroughly with water and dispose in trash. This product should be stored at room temperature, preferably in a cool place. Do not contaminate water, food, or feed by storage or disposal.

WARNING: HARMFUL IF SWALLOWED

KEEP OUT OF REACH OF CHILDREN



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:90
h b e

WAVICIDE-01 Concentrate

WAVICIDE-01

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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 cleaned, rinsed and rough dried before immersing in WAVICIDE-01. Hollow objects and needles should be flushed and filled.

STERILIZATION

Immerse objects to be sterilized in 2% active ingredient solution observing one of the following sets of conditions: 5 hours contact time at 40°C (104°F) for single use or 10 hours contact time at 21°C (70°F) for re-use. Remove instruments from the solution using a sterile technique and rinse thoroughly with sterile water. This procedure will also destroy the Hepatitis B virus (HBV). When sterilizing at temperatures above 21°C (70°F), keep solution in covered containers or machine. Do not open lid until solution has cooled to room temperature. At 21°C (70°F) the 2% Wavicide-01 can be used and re-used as a sterilant for up to 30 days in manual systems (bucket and tray).

DISINFECTION

Contact equipment, wares or objects by mop, spray or immersion with 0.5% active ingredient solution for 30 minutes at room temperature. After processing, instruments should be rinsed with water that fulfills federal drinking water standards.

This procedure will destroy vegetative organisms including *Staphylococcus aureus*, *Salmonella choleraesuis*, *Escherichia coli*, *Pseudomonas* species, *Klebsiella pneumoniae*, *Streptococcus mutans*, *Serratia marcescens*, *Mycoplasma pulmonis*, and pathogenic fungi (*Trichophyton mentagrophytes* and *Candida albicans*).

* For virucidal action at room temperature use the 0.5% active ingredient solution to destroy Herpes simplex types I and II, Rotavirus types SA 11 and WA, Poliovirus types 1 and 1', Influenza virus type A/PR8, Rhinovirus type 1A, Respiratory syncytial virus ATCC VR-26, and Cytomegalovirus/Davis on inanimate surfaces.

** To destroy *Mycobacterium tuberculosis* at 20°C on inanimate surfaces use either the 2% active ingredient solution for 42 days or the 0.5% active ingredient solution for 21 days by immersing completely for 30 minutes. For single use of fresh 2% active ingredient solution at 20°C immerse for 10 minutes. Remove equipment from the solution and rinse thoroughly.

STORAGE AND DISPOSAL

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions or instructions on this product's material safety data sheet, contact your state pesticide or environmental control agency or the nearest EPA regional office for guidance.

Container Disposal: Do not re-use empty container. Rinse thoroughly with water and dispose in trash. The product should be stored at room temperature, preferably in a cool place. Do not contaminate water, food or feed by storage or disposal.

PRECAUTIONARY STATEMENTS: Hazardous to Humans and Domestic Animals

Keep out of reach of children. Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Hazardous if fatal if swallowed or absorbed through skin. Avoid contamination of food. The most serious consequences to avoid are ingestion and to minimize risk.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water. For eyes call physician. If swallowed: Call physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by sticking your finger back of throat with finger. Do not induce vomiting if you are vomiting by mouth to an unconscious person. **Note to Physician:** For better results, drainage may contribute to the use of gastric lavage.

WAVICIDE-01 Concentrate

POTENTIATED GLUTARALDEHYDE FOR STERILIZATION/DISINFECTION FEATURES:

- 2-year shelf life.
- Can be used and re-used as a sterilant for up to 30 days.
- 42 days re-use for disinfection with 2% bovine serum and 2% active ingredient.
- 21 day re-use for disinfection with 2% bovine serum and 0.5% active ingredient.
- 0.25% active ingredient (1:80 dilution) in presence of 5% blood serum inactivates HIV-1 (AIDS virus) in one minute on environmental surfaces. See below.
- Single use fresh 2% active ingredient solution tuberculocidal in 10 minutes at 20°C.

(WAVICIDE 01 is an effective virucidal agent against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) when used at 1:80 dilution (0.25% glutaraldehyde) for a contact time of at least 1 minute at room temperature (20°-25°C) as a previously unused (no re-use) solution.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surface/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS

PERSONAL PROTECTION: Disposable latex gloves should be worn by all personnel engaged in activities that may involve skin contact with potentially infectious fluids, tissues, or cultures. Gowns, masks and eye covering devices will be needed if there is a risk of generating aerosols, splashes, or spills of potentially infectious materials.

CLEANING PROCEDURE: Blood and other body fluid contaminants must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluid contaminants should be collected and disposed of according to federal, state and local regulations.

CONTACT TIME: Although effective against HIV, contact time has been shown to be adequate against HIV-1. This time would not be sufficient for other organisms. Therefore, for other microorganisms, longer contact time indicated on the label.

WAVICIDE-01

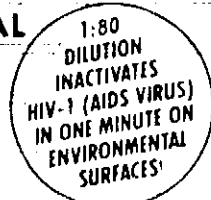
WAVICIDE-01 Concentrate

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

RECOMMENDED FOR: Rubber, aluminum, and plastic objects, lenses, stainless steel instruments, burs, mirrors, dental tools, and fiberoptic.

CAN BE USED FOR CLEANING IN ULTRASONIC TANKS

- SPORICIDAL
- VIRUCIDAL*
- TUBERCULOCIDAL**
- PSEUDOMONACIDAL
- BACTERICIDAL
- FUNGICIDAL



* See label side panel for HIV related use information.

ACTIVE INGREDIENT: Glutaraldehyde (0.5 Pentamethyl) 20.5%
 INERT INGREDIENTS 79.5%

EPA REGISTRATION NO. 15136-2

NET CONTENTS: Concentrate - 13.5 l or 300 cc
 Corrosion Inhibitor - 2 oz (60 cc)

DILUTE FOR STERILIZATION AND DISINFECTION INCLUDES CORROSION INHIBITOR

KEEP OUT OF REACH OF CHILDREN
DANGER: MAY BE FATAL OR HARMFUL IF SWALLOWED

WAVE ENERGY SYSTEMS, INC.
 P.O. Box 111111
 200 Little Falls Road
 Little Falls, NJ 07424
 (201) 272-1525



FOR PROFESSIONAL USE ONLY

WAVICIDE-01 Concentrate

MIXING DIRECTIONS:

FOR STERILIZATION OF HOSPITAL AND DENTAL INSTRUMENTS

To prepare a 2% sterilizing solution, pour contents of both Wavicide-01 Concentrate and Corrosion Inhibitor into a 128 fl. oz. (1 U.S. gallon) container and fill with distilled water.

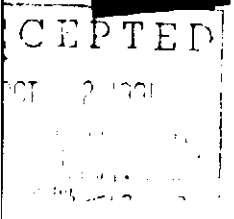
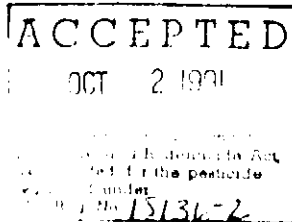
FOR DISINFECTION OF HOSPITAL AND DENTAL INSTRUMENTS

To prepare a 0.5% disinfecting solution, pour 1 gallon of Wavicide-01 2% sterilizing solution into a tray and add 3 gallons of potable water.

To prepare a 1% solution for disinfecting scopes, pour 1 gallon of 2% Wavicide-01 sterilizing solution into a tray and add 1 gallon of potable water or pour half the contents of 1 gallon 2% Wavicide-01 sterilizing solution into another gallon bottle and fill with potable or distilled water.

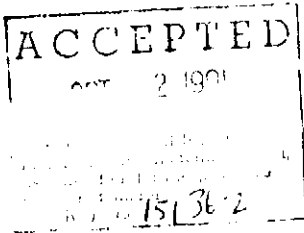
FOR CLEANING IN ULTRASONIC TANKS

The sterilizing (2%) or disinfecting (0.5%) solutions can also be used for pre-cleaning of instruments in ultrasonic tanks. A 10 minute exposure in a high intensity cavitation field should be satisfactory for pre-cleaning of most instruments. Solutions used for ultrasonic cleaning should be discarded after each use.



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

WAVICIDE-01 Concentrate



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DIRECTIONS FOR USE

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PREPARATION

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STERILIZATION

Immerse objects to be sterilized in 2% active ingredient solution observing one of the following sets of conditions: 5 hours contact time at 40°C (104°F) for single use or 10 hours contact time at 21°C (70°F) for re-use. Remove instruments from the solution using a sterile technique and rinse thoroughly with sterile water. This procedure will also destroy the Hepatitis B virus (HBV). When sterilizing at temperatures above 21°C (70°F), keep solution in covered containers or max line. Do not open lid until solution has cooled to room temperature. At 21°C (70°F) the 2% Wavicide-01 can be used and re-used as a sterilant for up to 30 days in manual systems (bucket and tray).

DISINFECTION

Contact equipment, wares or objects by mop, spray or immersion with 0.5% active ingredient solution for 30 minutes at room temperature. After processing, instruments should be rinsed with water that fulfills federal drinking water standards.

This procedure will destroy vegetative organisms including *Staphylococcus aureus*, *Salmonella*, *histeria*, *Escherichia coli*, *Pseudomonas* species, *Klebsiella pneumoniae*, *Streptococcus mutans*, *Serratia marcescens*, *Mycoplasma pulmonis*, and pathogenic fungi (*Trichophyton mentagrophytes* and *Candida albicans*).

For virucidal action of room temperature use the 0.5% active ingredient solution to destroy Herpes simplex types I and II, Rotavirus types SA 11 and WA, Poliovirus types I and II, Influenza virus type A/PR8, Rhinovirus type 1A, Respiratory syncytial virus A/C C VR 26, and Cytomegalovirus/Davis on inanimate surfaces.

** To destroy *Mycobacterium tuberculosis* at 20°C on inanimate surfaces use either the 2% active ingredient solution for 42 days or the 0.5% active ingredient solution for 21 days by immersing completely for 30 minutes. For single use of fresh 2% active ingredient solution at 20°C immerse for 10 minutes. Remove equipment from the solution and rinse thoroughly.

STORAGE AND DISPOSAL

Pesticide Disposal: Pesticide wastes are acutely toxic. If an improper disposal of these wastes, spray mixture or residue in violation of Federal Law, if these wastes cannot be disposed of by use according to label instructions or instructions on this product, a material safety data sheet, contact your state pesticide or environmental control agency, or the nearest EPA regional office for guidance.

Container Disposal: Do not re-use empty container. Rinse thoroughly with water and dispose in trash. The product should be stored at room temperature, preferably in a cool place. Do not contaminate water, food or feed by storage or disposal.

PRECAUTIONARY STATEMENTS: Hazardous to Humans and Domestic Animals

Keep out of reach of children. Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed or absorbed through skin. Avoid contamination of food. Use in covered container to avoid evaporation and to minimize odor.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water. For eyes, call physician. **Swallowed:** Call physician or Poison Control Center. Drink 7-8 glasses of water and induce vomiting by sticking back of throat with finger. Do not induce vomiting if person is unconscious. **Note to Physician:** Pesticide material may contain toxicants; the use of gastric lavage is not recommended.

WAVICIDE-01 Concentrate

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- Single use fresh 2% active ingredient solution tuberculocidal in 10 minutes at 20°C.

WAVICIDE-01 is an effective virucidal agent against HIV-1 (AIDS virus) on hard, non porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) when used at 1:80 dilution (0.25% glutaraldehyde) for a contact time of at least 1 minute at room temperature (20°-25°C) in a previously unused (no re-use) solution.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface objects with blood or body fluids, and in which the surface objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACE OBJECTS SOILED WITH BLOOD/BODY FLUIDS

PERSONAL PROTECTION: Disposable latex gloves should be worn by all personnel engaged in activities that may involve skin contact with potentially infectious fluids, tissues, or cultures. Goggles and eye covering devices will be needed if there is a risk of generating aerosols, splashes, or other potentially infectious materials.

CLEANING PROCEDURE: Blood and other body fluids can penetrate most materials, soiled surfaces and objects before application of the disinfectant.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids contaminated glass and plastic surfaces and objects should be decontaminated and disposed of according to federal, state and local regulations.

CONTACT TIME: Although the label states that the 1:80 dilution has been shown to be effective against HIV-1, this time would be the minimum contact time required to inactivate the virus. For other microorganisms, the contact time would be longer.

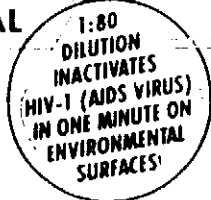
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WAVICIDE-01 Concentrate

A STABLE, RAPID-ACTING, STERILIZING AND DISINFECTING SOLUTION FOR HOSPITALS AND DENTAL OFFICES. RECOMMENDED FOR: Rubber, aluminum, and plastic objects, lenses, stainless steel instruments, burs, mirrors, dental tools, and fiberscopes.

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- SPORICIDAL
- VIRUCIDAL*
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 INERT INGREDIENTS: 79.5%
 E.P.A. REGISTRATION NO. 15136-2
 NET CONTENTS: Concentrate 13.53 oz (400 cc)
 Corrosion Inhibitor - 2 oz (60 cc)

DILUTE FOR STERILIZATION AND DISINFECTION INCLUDES CORROSION INHIBITOR

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DANGER: MAY BE FATAL OR HARMFUL IF SWALLOWED

WAVE ENERGY SYSTEMS, INC.
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 Cedar Grove, NJ 07009
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WAVICIDE-01 Concentrate

MIXING DIRECTIONS:

FOR STERILIZATION OF HOSPITAL AND DENTAL INSTRUMENTS

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FOR DISINFECTION OF HOSPITAL AND DENTAL INSTRUMENTS

To prepare a 0.5% disinfecting solution, pour 1 gallon of Wavicide-01 2% sterilizing solution into a tray and add 3 gallons of potable water.

To prepare a 1% solution for disinfecting scopes, pour 1 gallon of 2% Wavicide-01 sterilizing solution into a tray and add 1 gallon of potable water or pour half the contents of 1 gallon 2% Wavicide-01 sterilizing solution into another gallon bottle and fill with potable or distilled water.

FOR CLEANING IN ULTRASONIC TANKS

The sterilizing (2%) or disinfecting (0.5%) solutions can also be used for pre-cleaning of instruments in ultrasonic tanks. A 10 minute exposure in a high intensity cavitation field should be satisfactory for pre-cleaning of most instruments. Solutions used for ultrasonic cleaning should be discarded after each use.