



Cristófoli, Brazilian company importer and manufacturer of health products certified by ISO 9001 - Quality Management System, ISO 13485 - Medical Devices - Quality Management System - Requirements for Regulatory Purposes, ISO 14001 - Environmental Management and *BPF - Boas Práticas de Fabricação - ANVISA.



Cristófoli Ultrasonic Cleaner

CRISTÓFOLI'S MISSION

Develop innovative solutions to protect life and promote health.

CRISTÓFOLI QUALITY AND ENVIRONMENTAL POLICY

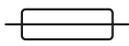
Cristófoli Equipamentos de Biossegurança Ltda., established at Rodovia BR-158, nº 127, Jardim Curitiba in Campo Mourão, Paraná, Brasil, manufactures biosafety equipment to assist the health field having as policy: "Develop innovative solutions for the health field by using agile, robust and objective processes to better serve its clients. Fulfill the requirements for regulatory purposes of the applicable standards, promote the continuous improvement of its quality and environmental systems, prevent pollution, reduce its environmental impacts and continuous training of its employees, achieving this way, a sustainable profitability and the maximization of the company's value". Rev. 2.

*BPF - Boas Práticas de Fabricação: Brazilian standard similar to the GMP - Good Manufacturing Practices (FDA / US).

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LEGEND OF SYMBOLS

	Caution! Consult accompanying documents		Good Manufacturing Practices		Keep away from sunlight
	Alternate Current		ISO 9001		Keep dry
	Dangerous Electrical Tension		ISO 13485		Recyclable
	Date of manufacture		ISO 14001		Fragile - Handle with care
	Manufacturer		Protection Grounding Terminal		This side up
	Maximum pile		Batch code		Fuse
	Serial Number		Class II Equipment		

INTENDED USE

This equipment was developed to clean dentistry, veterinary and laboratory instruments/articles as well as any other material which is suitable for ultrasonic cleaning (cavitation).

OPERATION PRINCIPLE

What is cavitation?

Cavitation is the formation and collapse of millions of tiny little bubbles or cavities inside a liquid produced by the alternation of high and low pressure waves that are generated by the ultrasonic cleaner. The bubbles appear in the water/solution and the effect of millions of implosions per second help the enzymatic detergent to break the molecules of dirt and contaminants, resulting in an efficient cleaning.

CONTENTS OF THE BOX

Items included in the product box:

- | | |
|------------------------------------|-------------------------|
| - 1 Cristófoli Ultrasonic Cleaner; | - 1 basket; |
| - 1 power cable; | - 1 instruction manual. |

RECOMMENDATIONS AND WARNINGS

- ▶ Read all the instructions in this manual before using your ultrasonic cleaner. Incorrect use may result in deficient cleaning, damage to the equipment and/or accidents.
- ▶ The equipment must be handled by qualified and well-informed personnel, regarding its features and functioning.
- ▶ For your safety, when performing any kind of maintenance, remember to unplug the equipment and use PPE (Personal Protective Equipment).
- ▶ Never turn the equipment on without water in the vat, that will cause immediate burn out of the equipment and loss of warranty.
- ▶ Never put the instruments/articles or beaker directly into the stainless steel vat for cleaning without the plastic basket.
- ▶ Never put paper, plastics, towels or any other kind of fabric under the cleaner, this may obstruct the side vents located on the lower part of the equipment causing overheating and damage to the equipment.
- ▶ Do not allow patients or especially children to get close to the equipment.

IMPORTER

Cristófoli Equipamentos de Biossegurança Ltda.

Rod. BR 158, nº127 - Campo Mourão - PR - Brasil.

CEP 87309-650

CNPJ 01.177.248/0001 - 95 - Inscr. Est. 90104860-65

Website: www.cristofoli.com - e-mail: cristofoli@cristofoli.com

MANUFACTURER

Shenzhen Codyson Electrical Co. Ltd.

2/F,B & 3/F, East A, Minlida Industrial Building, The 4th Block,
Honghualing Industrial Zone, Xili, Nanshan District,
Shenzhen - China

Responsible Technician

Eder William Costa Camacho

CREA/PR – 87826/D

- ▶ Before initiating the cleaning process, make sure the material to be cleaned may be submitted to ultrasonic cleaning (cavitation).
- ▶ Never put your hand or any other part of your body inside the cleaner when it is in use, this procedure may be harmful to your health.

INSTALLATION INSTRUCTIONS

The storage must be done in a place protected from the weather action (indoors) in normal temperature conditions.

Install the ultrasonic cleaner in an exclusive sterilization room, ventilated and clean, on a flat, leveled and firm surface, at a proper height for the operator to handle it. Leave enough room next to the equipment for handling the instruments/articles.

Electrical

See “*Authorized Technical Assistance*” (Page 13). In case the user chooses an unauthorized electrician or technician to install the equipment, Cristófoli Biossegurança will not be responsible for any services performed in disagreement with the instructions described in the product manual.

- 1▶ The voltage of the ultrasonic cleaner is 127V **or** 220V, as informed on the identification label located on the bottom of the equipment. (Fig. 1, pág. 6). Make sure the wiring **voltage** where the equipment will be installed is in accordance with these values.
- 2▶ For the installation, use a three pin outlet with grounding pin (2P + T, 10A).
- 3▶ **Never** use extensions, adapters or voltage transformers.

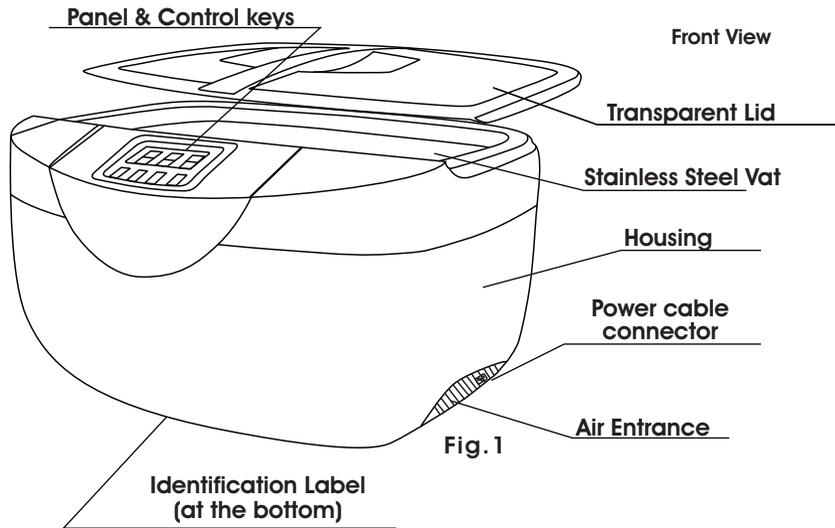
ATTENTION! Grounding is very important for the safety of the operator and the warranty of your equipment. Install the ultrasonic cleaner where it can be easily unplugged.

The electrical installation must follow the data from the table below.

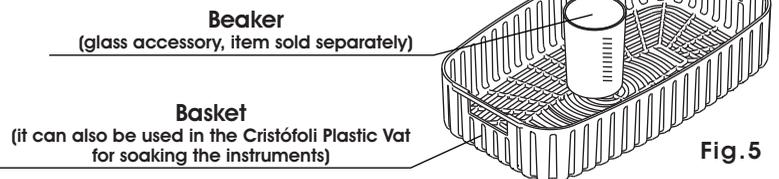
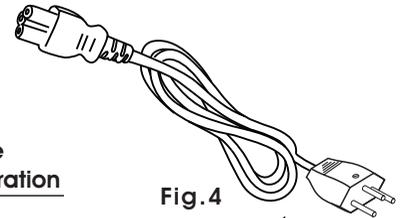
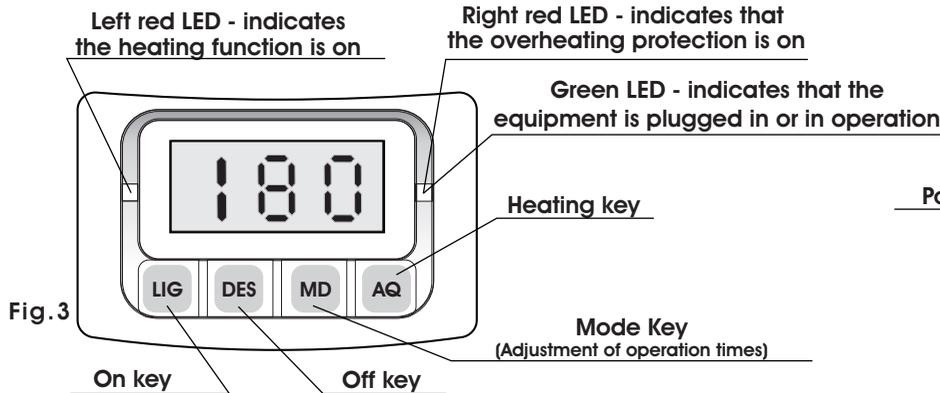
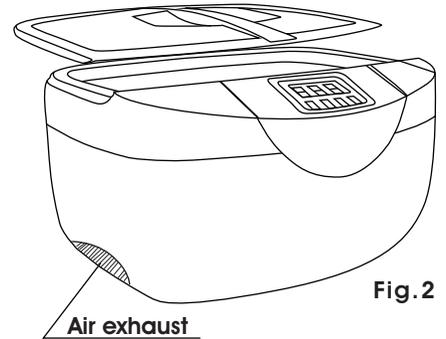
MODEL	AMPERAGE	WIRING GAUGE (DIAMETER)
Cristófoli Ultrasonic Cleaner (127 V)	1,5 A	The wiring from the breaker to the electrical outlet used to connect the equipment must have a diameter of at least 2.5 mm.
Cristófoli Ultrasonic Cleaner (220 V)	0,8 A	

Table 1

COMPONENTS IDENTIFICATION



Front View



SAFETY DEVICES

- 1► **FUSE** - Internal safety device built into the electronic board which cuts the power from the equipment. See "Troubleshooting" (Page 12).
- 2► **OVERHEATING PROTECTION SENSOR** - It protects the cleaner against overheating. If the **LiG** (On) key is pressed, the display shows the remaining time and there's no cavitation (production of ultrasonic waves), that means that the equipment needs to cool down for about 15 minutes. After that, press **LiG** again and the equipment will resume operation.

DEGASSING / USING THE BEAKER

The water degassing has the purpose of removing the gases dissolved in the water that impair the cavitation process and must be repeated every time the water/solution is changed. The procedure consists in leaving the equipment on for 8 minutes (480s cycle) without any instruments/articles in the vat.

When using the beaker (accessory that must be purchased separately used to clean very small items (burs, files, etc.) that would certainly go through the basket orifices falling on the bottom of the vat, remember that the water inside the beaker must also be degassed. Use always a heat resistant glass beaker specific for this purpose. Put the water in the stainless steel vat, the basket, the beaker on top of the basket and water inside the beaker, seal it with some PVC film (the same used for food wrapping) and proceed the degassing.

Always use the lid when the equipment is operating with the basket, when using the beaker, remove it, unless the beaker being used has a compatible size for the basket depth and allow the use of the lid.

The Cristófoli Ultrasonic Cleaner may also be used to clean dental prosthesis like dentures, bridges or orthodontic devices like braces, etc., as shown by the drawing (Fig. 6).

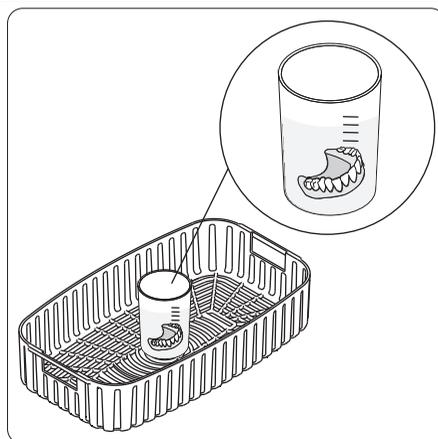


Fig.6

HEATING

For a deeper cleaning, with the presence of fat, optionally, the water heating function can be used. Just press the **RC** key to start the water heating (Fig. 7) that will take approximately 40 minutes to achieve the ideal temperature for cleaning, which is 65°C.

Once the right temperature is reached, heating will turn off automatically. The red LED on the left side of the display will be on when the heating is in use. If it's needed to reduce the heating time, water already warm may be used by the operator. Do not use water too hot (above 65°C), this will hinder the cleaning of the instruments/articles.

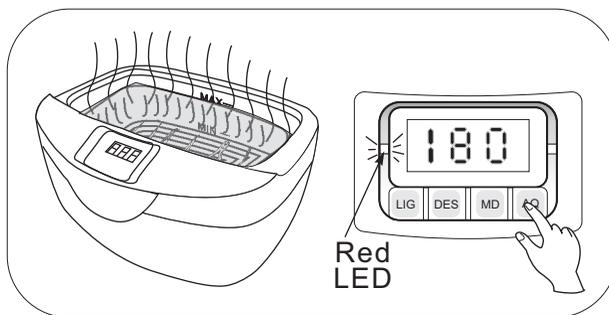


Fig.7

HOW TO USE THE CRISTÓFOLI ULTRASONIC CLEANER

For a better visualization, the drawings below do not show the lid. Remember to always use the lid when the equipment is in operation.

- 1▶ Pour preferably **filtered water** up to the maximum level of 2,1 liters indicated on the vat **MAX** (Fig. 8).
- 2▶ Insert the power cable in the cleaner connector and the other end to the wall outlet (Fig. 9). The green LED indicates that the equipment is plugged in. The display will show the standard cycle of 180s (3 minutes).
- 3▶ Proceed the water degassing according to the instructions on the topic "Degassing / Using the Beaker" (Page 7).

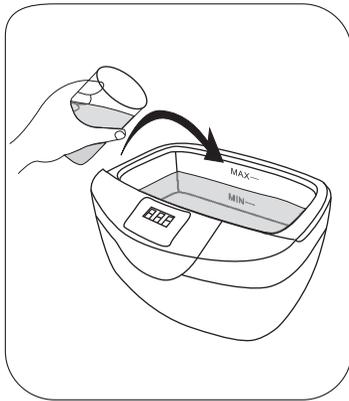


Fig. 8



Fig. 9

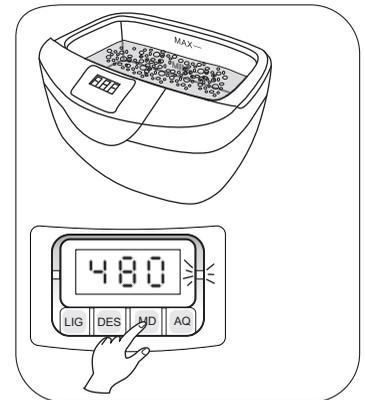


Fig. 10

- 4▶ Add the right amount of enzymatic detergent in the vat or beaker, diluting it according to the recommendations specified by its manufacturer. We suggest, for your convenience that you use a small medicine measuring cup or syringe without the needle to measure the volume of detergent, make sure to reserve this syringe for this purpose only in case the detergent doesn't have its own measurer (Fig. 11). Do not use anti-crust solutions/products, they have a highly acid concentration, that may damage the vat, its sealing and the instruments.
- 5▶ Put the instruments/articles in the basket or beaker, see the topic "Degassing / Using the Beaker" (Page 7). Do not put instruments/articles in the basket at the same time you are using the beaker. The instruments must be totally immersed but not overlapped (Fig. 12).

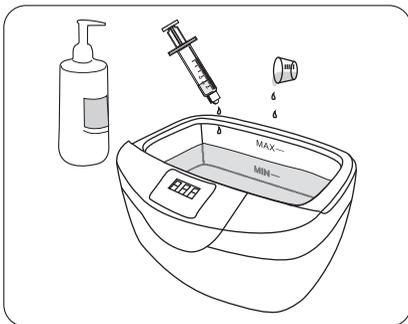


Fig. 11

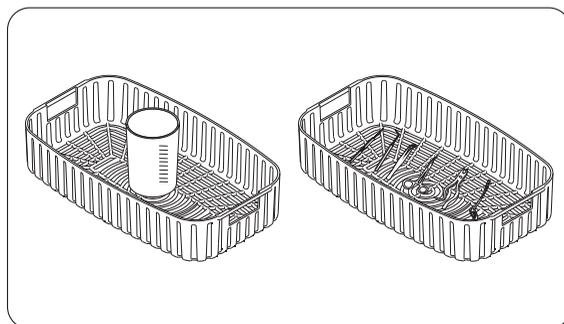


Fig. 12

- 6► Select the time desired on the panel using the **MD** key. The time selection begins with the standard cycle of 180s (3 min.). Each touch on the **MD** key, the display will show one of the 5 preset cleaning times (Fig. 13).

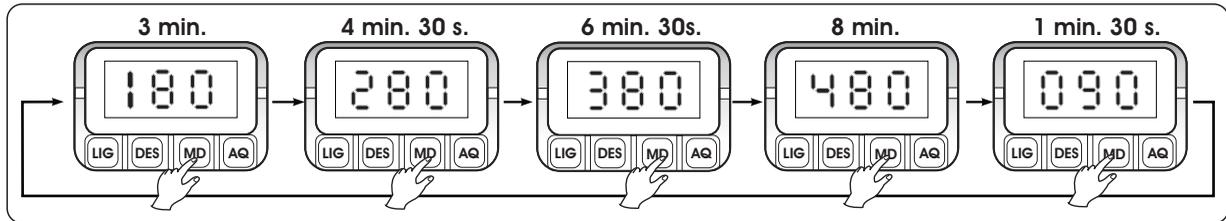


Fig.13

- 7► Press the **LIG** key to start cleaning (Fig. 14), at this moment the operator will hear the typical sound of the cavitation process. To pause the cycle press the **DES** key (Fig. 15) to resume cleaning, press **LIG** again.

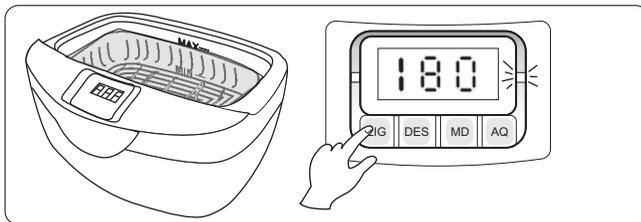


Fig. 14

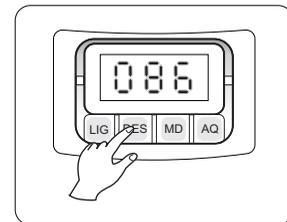


Fig. 15

- 8► At the end of the cycle the display will show 000 and the cavitation process will stop automatically. Unplug the equipment and open the lid. (Fig. 16).
- 9► Remove the beaker or the basket with the instruments/articles from the vat as soon as the cleaning finishes and perform a visual inspection, if there's still any residue left, remove it with a proper brush.

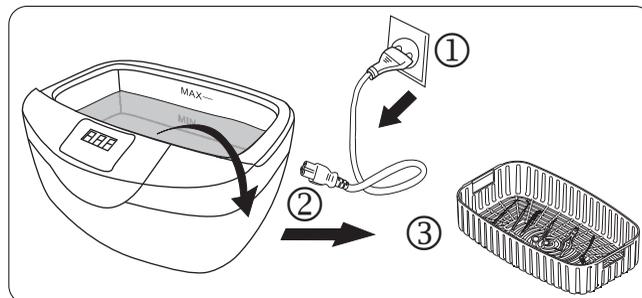


Fig. 16

10►Finally, pour the contaminated solution into an appropriate sink, used exclusively for this purpose proceeding like this: carefully tip the equipment over one of its back corners to avoid getting the control panel wet (Fig. 17) and dispose the solution into the sink. For a new cycle, wait 15 minutes and then follow the use instructions again.

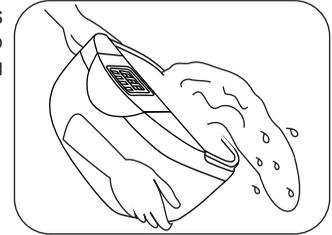


Fig. 17

TECHNICAL DATA

TECHNICAL DATA	CRISTÓFOLI ULTRASONIC CLEANER
Total Capacity	2,5 liters
Useful Capacity	2,1 liters
Net weight	2,5 kg. (with components)
Gross weight	3 kg. (in the box)
External dimensions (W x H x D)	28,5x 18,5 x 22,5 cm
Internal dimensions (W x L x D)	28,8x 14,8x 8 cm
Voltage	127 or 220 V
Frequency	50/60 Hz
Power	160 Watts (127 V model)
.....	170 Watts (220 V model)
Ultrasonic frequency	42 kHz
Timer	Digital: 5 preset time cycles (180s - 280s - 380s - 480s - 90s)
Power consumption	16 Watts/hour (127 V model)
.....	17 Watts/hour (220 V model)
Proper working ambient temperature	15 to 40 °C
Certifications	This equipment is imported by Cristófoli Biossegurança, company which Quality Management System is certified and in accordance with the ISO 9001:2008, ISO 13485:2003, BPF- Boas Práticas de Fabricação - ANVISA, (Brazilian standard similar to GMP-FDA/US) and ISO 14001:2004 - Environmental Management standards.

Table 2

HOW TO IDENTIFY YOUR ULTRASONIC CLEANER

The identification label is affixed on the bottom of the equipment (Fig. 1, page 6).

ATTENTION - Removing the identification label and/or any other stickers from the product will cause automatic loss of warranty.

PREVENTIVE MAINTENANCE

Some procedures are necessary for the best functioning and durability of your equipment. The preventive maintenance corresponds to the fulfilment of all procedures listed below.

Make sure the equipment is unplugged before performing any kind of maintenance.

PERIODICITY	MAINTENANCE
DAILY	<p>External cleaning: Unplug the equipment. Clean it with a soft cloth moistened in water and neutral biodegradable detergent, next, use another soft cloth moistened with alcohol 70% or peracetic acid at 1%. Clean the lid the same way. Wipe it with smooth movements in only one way.</p> <p>Vat cleaning: Clean the stainless steel vat and change the cleaning solution after each cycle to maintain the cleaning efficiency. The contaminated solution must be disposed according to the instructions of the topic "How to Use the Cristófoli Ultrasonic Cleaner", instruction 10 (Page 10).</p> <p>After disposing the water/solution, remove the excess of residues that may have accumulated at the bottom of the vat with a soft sponge, cloth or even paper towels, then clean it with a soft sponge with water and neutral detergent, rinse it with running water (be careful not to get the control panel wet, avoiding this way that some water get into the equipment through any of its many orifices), dry the vat with a soft cloth or paper towel and finish by disinfecting it with alcohol 70% three times according to the technique recommended for its use (BRASIL 1994).</p>
ANNUAL	<p>We recommend performing a general preventive maintenance of the equipment with a Cristófoli authorized technician. See "Authorized Technical Assistance" (Page 13).</p>

Table 3

TROUBLESHOOTING

For any replacement of parts, contact your local retailer or an authorized Cristófoli representative. It's strongly not recommended the replacement of any parts by non-qualified people.

We have listed below the most frequent problems and possible solutions the operator can try in his/her own office.

THE ULTRASONIC CLEANER DOES NOT TURN ON

POSSIBLE CAUSES	SOLUTIONS
• The equipment is not plugged in -----	• Plug the power cable on both ends, the power connector of the cleaner and the wall outlet (Fig. 9, page 8).
• No power -----	• Check if there's a power outage in your building.
• Burned out fuse -----	• See "Authorized Technical Assistance" (Page 13).

LOW CAVITATION OR NO CAVITATION AT ALL

POSSIBLE CAUSES	SOLUTIONS
• The equipment may be 220V and be connected to a 127V power outlet -----	• See that the necessary arrangements for the electrical wiring are made as shown on item "Installation Instructions" (Page 5).
• Damaged circuit board -----	• See "Authorized Technical Assistance" (Page 13).
• The transducer burned out because of the lack of water in the vat or incorrect voltage installation -----	• See "Authorized Technical Assistance" (Page 13).

THE ULTRASONIC CLEANER TURNS ON BUT THE HEATING DOES NOT WORK

POSSIBLE CAUSES	SOLUTIONS
• The heating element has burned out -----	• See "Authorized Technical Assistance" (Page 13).

If the problem persists after the verification of all the items listed, contact your local retailer or an authorized Cristófoli representative.

QUALITY CONTROL

The Cristófoli Ultrasonic Cleaners are tested on a batch basis according to the internal parameters of tests and manufacturing approved by the Cristófoli Quality Control Department.

AUTHORIZED TECHNICAL ASSISTANCE

If there's any problem with your equipment, first, take a look at the topic "Troubleshooting" (Page 12), in case the problem persists, get in touch with your local retailer or an authorized Cristófoli representative to schedule an evaluation or repair of your equipment.

Before making contact, please have in hands the model of your equipment, voltage, serial number and the date of manufacture found on the identification label located on the bottom of the equipment (Fig. 1, page 6) and a description of the problem.

CUSTOMER SERVICE DEPARTMENT - CSD

In case you have doubts, complaints or suggestions, contact Cristófoli through the *Customer Service Department - CSD* by the e-mail: cac@crisstofoli.com.

GUIDANCE FOR FINAL DISPOSAL OF THE EQUIPMENT

The environment is something that belongs to everyone, therefore, it is up to each one of us to make the decisions that will help in its preservation and reduction of the damages resulting from human activities.

All products have a useful life span, but it is not possible to determine how long, as it varies according to the intensity and how the equipment is used or handled.

Cristófoli Equipamentos de Biossegurança Ltda., makes clear its concern, already demonstrated by the implementation of the Environmental Management System, according to standard NBR ISO 14001:2004, strongly recommends users of their products to seek the best destination when disposing your equipment or its components, taking into account the materials recycling legislation effective in your country.

We advise you to take your equipment to specialized recycling companies that, due to the continuous and fast paced development of new recycling technologies and materials reuse, provide the best way of disposing the equipment. Cristófoli contributes this way to reduce the consumption of non-renewable raw materials.

On behalf of all users, we thank you for your comprehension and cooperation.

WARRANTY TERMS

CRISTÓFOLI EQUIPAMENTOS DE BIOSSEGURANÇA LTDA., warrants the Cristófoli Ultrasonic Cleaners for 01 (one) year against any manufacturing defect from the date of the purchase receipt (provided it contains the serial and lot numbers of the equipment), of which 03 (three) months refer to the legal warranty (established by section II, art. 26, CDC, Brasil) and nine (09) months to the contractual warranty (arranged in art. 50, CDC, Brasil). Visit our website www.cristofoli.com and register your product online.

Traveling costs (based on the distance traveled in km) and the stay of the authorized technician for installation, repair or maintenance **before or after the warranty period** will be responsibility of the buyer/owner as well as the freight charges for shipping the equipment to the authorized technical assistance office for repairs or if necessary, to the factory itself.

The warranty will be voided in cases of:

- Problems arising from natural causes (such as floods, landslide, building collapse, lightning, etc.);
- Damage caused by accidents, such as: dents, drops, short circuits, fire, etc.;
- Sinister (theft or robbery);
- Improper use / installation of the equipment and/or plugging it into an incorrect voltage outlet;
- Problems due to failure of the power supply and/or building wiring;
- Removal and/or tempering of the serial number shown in the identification label of the product;
- Signs of tampering and/or blotted out data on the purchase or service receipt of the equipment;
- Signs of external violation of the product or broken factory seal;
- Lack of preventive maintenance of the equipment or neglect regarding any item presented on the topic "*Preventive Maintenance*" of this instruction manual;
- Use of non-original parts or parts not acquired at the Cristófoli Authorized Service Network;
- Repairs performed by technicians who are not part of the Cristófoli Authorized Service Network;
- Noncompliance with any measure or caution recommended in the instruction manual of the product.

The internal fuse, the basket and the power cable are not covered by the warranty. The warranty will also not cover damages caused to instruments / articles with low resistance to ultrasound cleaning or their natural wearing.

ATTENTION! In order to validate the contractual warranty of the product it is necessary to send a copy of the purchase receipt to the following e-mail address: garantia@cristofoli.com.

