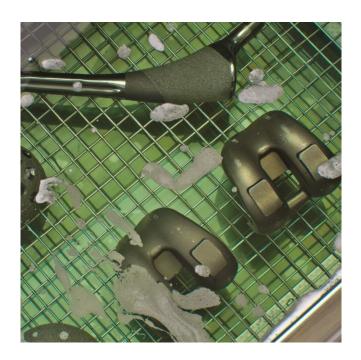


Ultrasonic Cleaning Equipment



Pharmaceutical & Medical Device Buyers' Guide

MADE IN BRITAIN

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W Ultrawave

Precision ultrasonic cleaning equipment



Ultrasonic Cleaning in the Pharmaceutical and Medical Device Industry

Accredited to ISO13485 and ISO9001, Ultrawave's ultrasonic cleaning systems ensure the highest quality performance and results for cleaning a wide range of precision components used by many pharmaceutical, medical device manufacturers in the UK and Ireland.

Pharmaceutical and Medical Device Cleaning

- Stents
- Orthopaedic implants
- Tablet presses
- Guide wires
- Surgical instruments

Benefits

- Cost saving
- Reduced process time
- Ability to clean inaccessible areas
- Improved cleaning quality
- Environmentally friendly
- Non-destructive
- Non labour intensive











What is Ultrasonic Cleaning?

Ultrasonic cleaning is the rapid and complete removal of contaminants from objects, achieved by immersion in a tank of liquid which is then flooded with high frequency sound waves.

These non-audible sound waves create a scrubbing action within the fluid, brought about by high frequency electrical energy that is converted by a transducer into high frequency sound waves – ultrasonic energy.

How does it work?

Ultrasonic energy enters the liquid within the tank and causes the rapid formation and collapse of minute bubbles; a phenomenon known as cavitation. The bubbles travel at high speed within the tank, causing them to implode against the surface of the immersed item with an enormous release of energy. This gently lifts contaminants from both the surface and innermost recesses of intricately shaped parts.

As the bubbles implode and cavitation occurs, the cleaning solution rushes into the gap left behind by the bubbles. When the cleaning solution makes contact with the item in question, any contaminants, dirt and tarnishing which are present simply falls away.



The ultrasonic cleaning action occurs on any part of the component that is in contact with the water. As water is able to penetrate the smallest holes, tubes and threads, even the hardest to reach areas of intricate components are cleaned in the ultrasonic tank.

Choosing the right ultrasonic cleaning system

Size

Ultrasonic cleaners come in a wide range of dimensions and capacities. You need to consider how large the items are that will be cleaned and how many items on average will be cleaned during one cycle. Ultrawave manufacture ultrasonic cleaners ranging from small baths of less than one litre to larger multistage systems.

Tank Specification

The specification and thickness of the tanks in ultrasonic cleaners can vary. For light and infrequent use, Benchtop ultrasonic baths have a pressed tank of 0.6-0.8mm thick stainless steel.

For applications where the machine is to be used more regularly, an Industrial grade tank of 2mm thick stainless steel is always recommended.

In many cases, 316 stainless steel tank is specified for cleaning medical device components with radius corners. This prevents trapped dirt and facilitates easy cleaning.

Control

Entry level ultrasonic baths have an analogue dial for simple time and/or temperature control. For more advanced applications, ultrasonic systems incorporate a menu-driven digital control allowing more accurate and precise programming of the system functions.

Validation and Cycle Traceability

Cleaning processes in the medical device and pharmaceutical industries often require a validated process. Ultrasonic cleaning systems with sophisticated controls allow data from each cycle to be recorded and logged.

Ultrasonic cleaners can incorporate programmes which allow both hard copy and electronic cycle traceability to be stored. This process validation gives assurances that each batch of components is cleaned to the same high standards.











Transducer Efficiency

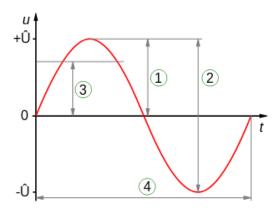
The efficiency of the transducer used in your ultrasonic cleaning tank will affect both the cleaning time and efficiency achieved during the cycle. A poor quality transducer will use more power and take longer to clean items than an advanced transducer. Ultrawave have invested a significant amount of time and money into the design and development of our transducers, providing you with superior cavitation performance.

Ultrasonic Power

The level of ultrasonic power is commonly referred to in ultrasonic Watts per litre capacity. For example a 25 litre tank with 250W of ultrasonics will give 10W/litre.

In general, the level of ultrasonic power should not be less than 8W/litre although this can sometimes be reduced for very large tanks.

Ultrawave measure the power of our ultrasonic systems in RMS. This gives the total power of the transducers. Some manufacturers measure the ultrasonic power in "peak to peak" which doubles this value so it is important to compare the same measurements when purchasing an ultrasonic system.



- A <u>sinusoidal</u> curve
- 1 = Peak amplitude (\hat{U}) ,
- 2 = <u>Peak-to-peak</u> amplitude $(2\hat{U})$,

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Precision ultrasonic cleaning equipment

- $3 = \underline{\mathsf{RMS}}$ amplitude $(\hat{U}/\sqrt{2})$,
- 4 = <u>Wave period</u> (not an amplitude)

Contributing Factors

Timer

Different applications will require different cycle times, depending on type and level of contamination.

Ultrawave's ultrasonic systems incorporate a timer which allows the cycle time to be programmed to within one minute.

Temperature

Ultrasonic cleaning is commonly most effective at temperatures between 50 and 65°C. Heat acts as a catalyst for all cleaning applications but the level of ultrasonic activity will actually begin to decrease above 80°C.

For validated processes where accurate and precise temperature requirements exist, ultrasonic cleaning systems can incorporate multi temperature programme to ensure that components are not processed outside these parameters.

Detergents

The detergent is an essential component in the overall cleaning process. Different detergents will provide different results depending on the item to be cleaned and the contamination to be removed.

In addition to their cleaning properties, ultrasonic detergents optimise ultrasonic activity by reducing the surface tension of the fluid.









What should I look for in my ultrasonic cleaning system?

Drain valve

The fluid in ultrasonic cleaners needs to be changed on a periodic basis. A drain valve will allow easy emptying of the tank.

Level Protection

Operating an ultrasonic cleaner without liquid in the tank will cause damage to the heaters, transducers and tank. A level sensor or float switch ensures that the system cannot be operated without enough liquid in the tank.

Basket

It is essential that items being processed in the ultrasonic cleaner do not rest on the base of the tank. Components should be placed in the supplied basket or if necessary, suspended within the cleaning fluid.

When an item is in contact with the base of the tank, damage will be caused and the efficiency of the ultrasonics will be significantly reduced.

Lid

The lid will help to minimise evaporation, aid in the heating of the cleaning fluid and reduce the noise levels of the ultrasonic cleaner.







Specialised Features

Overflow-weir and jetting systems

Incorporating a weir and jetting system into the ultrasonic tank will help reduce surface grease and contamination.

By improving water turbulence and skimming the fluid, surface drag through factors that can be associated with ultrasonic cleaning are reduced.

Pump and Filtration Systems

A pump and filter system can be installed to maintain the cleanliness level of the cleaning fluid, thus saving costs in water usage, detergent dosing and heating.

Irrigation Systems

An irrigation system allows hollow instruments and tubes to be connected to a manifold, thus ensuring both the internal and external surfaces are cleaned thoroughly.

Agitation Systems

Basket agitation moves the basket and component vertically within the tank, thus ensuring that there is no trapped air in difficult to reach areas and that any removed contaminants do not sit on the surface of the components.

Automatic Handling Systems

Automatic handling systems are included on multi-stage systems as a means to reduce the labour involved in the process. A robotic handling system will transfer the basket load from stage to stage providing a complete and consistent process with minimal operator intervention.

Multi-Stage Systems

A multi-stage ultrasonic cleaning system ensures the most thorough cleaning results are achieved. Combining ultrasonic wash, rinse and dry stages, these systems are ideal where the highest cleaning standards are required.













Testing

Ultrasonic cleaning systems used in the medical device and pharmaceutical industries need to be subject to regular and periodic testing.

Installation Qualification (IQ)

The IQ is conducted to check that all equipment has been correctly assembled and installed and all documentation is in place.

Operation Qualification (OQ)

The OQ is conducted to ensure the system performs according to the functional specification and requirement.

Performance Qualification (PQ)

After IQ and OQ, the performance of the system is periodically qualified.



Maintenance

It is essential to regularly clean your ultrasonic system to ensure longevity of the tank. It is also recommended that the cleaning fluid is changed on a regular basis, depending on your application.

About Ultrawave

Ultrawave have over 25 years of experience in the design and manufacture of precision ultrasonic cleaning equipment, our in-house design team work constantly to push the boundaries of ultrasonic technology in order to provide all of our clients large and small with the very best ultrasonic cleaning equipment available today.

Ultrawave

Precision ultrasonic cleaning equipment

We have manufactured and sold over 50,000 ultrasonic cleaning systems to customers throughout the world. The Ultrawave team of engineers, designers and production technicians are able to interpret your demands and deliver top quality products to meet any cleaning and processing requirements.

By maintaining complete control over all of our design and production processes, we can offer the flexibility to meet each individual customer's requirements and provide the appropriate cleaning solution for many different markets and applications.

We are accredited to ISO13485 (Medical Device Manufacturing) and ISO9001 standards, and are committed to ensuring that our products and technological developments continue to meet the rigorous demands laid out by these regulations.

On-going investment in research and design ensure that Ultrawave remains at the head of the pack when it comes to designing and producing the most effective ultrasonic cleaning equipment available. Our in-house demonstration suite is at your service to carry out sample testing ensure that the products which we supply to you are tailored to meet your own individual requirements.

For more information or a free no obligation initial consultation:

Tel: +44 (0) 845 330 4236

Email: <u>admin@ultrawave.co.uk</u>

Web: <u>www.ultrawave.co.uk</u>

Twitter: twitter.com/ultrawave_uk



Ultrawave Ltd Eastgate Business Park Wentloog Avenue Cardiff CF3 2EY United Kingdom

Tel: +44 (0) 845 330 4236 Email: <u>admin@ultrawave.co.uk</u> Web: <u>www.ultrawave.co.uk</u>







