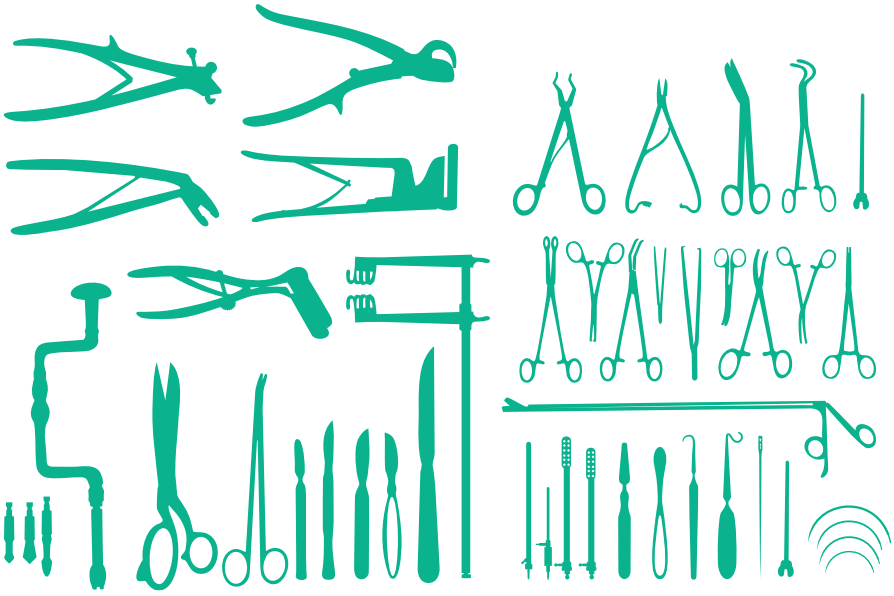


ALPHASONICS

ADVANCED ULTRASONIC CLEANING SYSTEMS

SURGICAL SITE INFECTION PREVENTION

HOW WE STRIVE FOR ZERO

MADE IN BRITAIN

ALPHASOUND a world of difference

BetaSound Ultrasonics. Advanced.

active CAVITATION

CERTIFIED ISO 13485 UKAS MANAGEMENT SYSTEMS 001

How We Strive **For Zero**

The application of sound into fluid to deliver an efficient cleaning process has been around for many years and has been utilised to great effect. However, there's clean and then there's clean. What do we actually mean when we use this word? The requirements for general commercial and industrial cleaning are far removed from what is required in the decontamination sector and as such, special technology is needed.

Historically, ultrasonics have been used in an attempt to remove proteins from surgical equipment prior to processing in a thermal device. The results however were erratic, leading the sector in many cases to discard the process altogether through uncertainty of the results achievable with the equipment provided.

The fact remains however, that if set up correctly in a controlled manner with complete focus on the application of sound, nothing even remotely compares to what ultrasonic technology can achieve to provide precision cleaning in the healthcare and medical sectors.

How does fluid based ultrasonic cleaning technology work?

Transducers bonded to the base or side of a tank are excited by high frequency electricity, causing them to expand and contract at very high rate. This mechanical action causes high speed flexure of the radiating tank face(s). The speed of this movement is too fast for the fluid in the tank to follow, resulting in the production of vacuum chambers.

On the upward flexure, the vacuum is released in the form of a vacuum bubble that rises up through the fluid until it hits an object (or the surface of the fluid), upon which the bubble implodes under high pressure, creating a micro-jet that draws away any contamination that may be on the surface of the object. This in a nutshell is how the technology works. However, there are limitations as to how effective and efficient the cleaning action will be in isolation.

Attaining and Maintaining Zero

Alphasonics blindly took up this challenge in 2013 when nothing was known by the company about the problems surrounding consistent infection control, or how to achieve it. The one thing that was known, was that the company had a very special technology under its belt; having operated predominantly in a sector that required regular, precision cleaning of very delicate components without causing damage. It was pondered if the same technology could provide the elusive 'Zero' that the decontamination sector was striving for.

The fundamental question is what are we actually trying to achieve - zero what? Zero bacteria or zero protein? From the research and development carried out since 2013, it has become clear that one cannot be achieved without the other. Zero bacteria will never be consistently reached if there is protein remaining on the instrument as bacteria can exist on, in or under an area of protein, so to get at the bacteria, the protein has to be completely and consistently removed.

But here lies the problem. As others have found out, protein is extremely difficult to remove and becomes more tenacious when heat is applied. This fact alone makes it incredibly difficult to consistently remove the protein fully in any thermal device. I'm not saying that it can't be done, as others have shown (unpublished), but the inclusion of heat simply makes the task much more difficult. Ever put an 'eggy' plate in your dishwasher? Science in everyday action.

protein is **extremely difficult** to remove and becomes more tenacious when heat is applied

Obtaining ‘Zero’ has always been the goal, ever since the baton was picked up. It took some time to understand the issue fully and of course the potentially devastating consequences of failure. The real breakthrough came in 2014 when a ProReveal device was purchased. This investment enabled a ‘test and measure’ regime to be quickly established that yielded great progress.

Our research found that the removal of protein is easier in cold water with the optimum temperature being between 17° to 20°C. By 2016 before the launch of the revised HTM01-01, the point had reached whereby complete and consistent removal of protein had been achieved well into the ng range (as measured with a validated ProReveal device).

Then came the Health Technical Memorandum (HTM), that alongside other things stipulated that the ultrasonic activity should be validated on a very regular basis. This threw a spanner into the works as how on earth could this be achieved? With a foil test? Surely not. As no technology existed at that time to measure ultrasonic cavitation, a sub-project was embarked on to develop a device that would accurately and consistently validate the ultrasonic activity in a tank of fluid.

Two years later and in collaboration with a University, the world’s first device to measure electrical activity caused by cavitation and by proxy provide a measure of the cavitation itself was developed. This unique piece of equipment opened several doors and in addition enabled full compliance with the HTM.

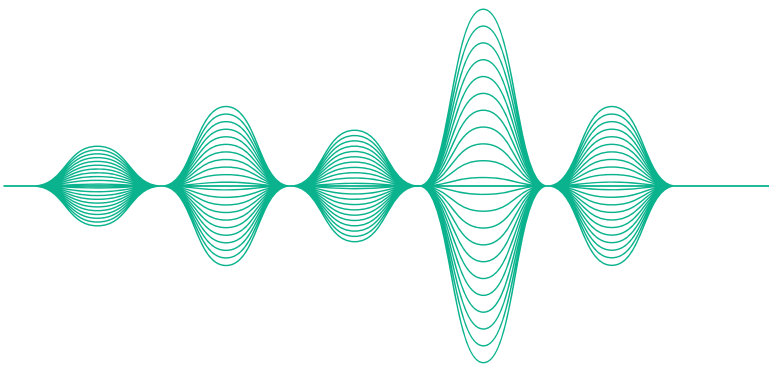
The development of the Cavitation Validation Device (CVD), coupled with a unique methodology of applying sound into fluid, delivered startling results and provided a major breakthrough in striving for ‘zero’ as not only were the levels of cleanliness achievable, but more importantly consistently delivered.

The real **breakthrough** came in 2014 when a ProReveal device was purchased.

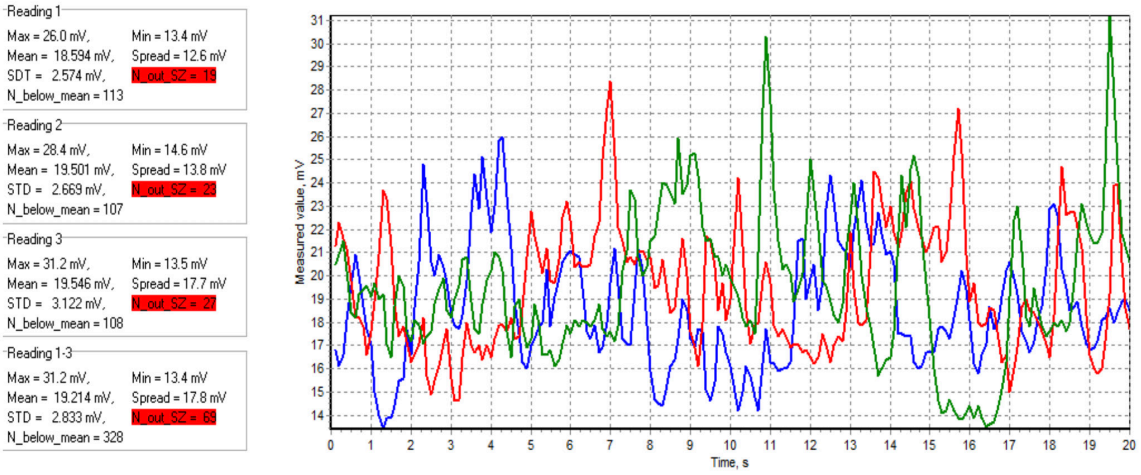
Natural dispersion

The natural dispersion of high frequency sound when applied into fluid is of a somewhat erratic nature. Fine for cleaning jewellery or spectacles, but not for achieving consistent precision cleaning that is required for healthcare. It is this natural dispersion of sound that is at the heart of the failure of successive manufacturers of surgical equipment cleaning systems to produce devices that consistently deliver what the sector needs.

The graphs on the next page give some indication of what is meant by ‘erratic dispersion’.



Graph 1

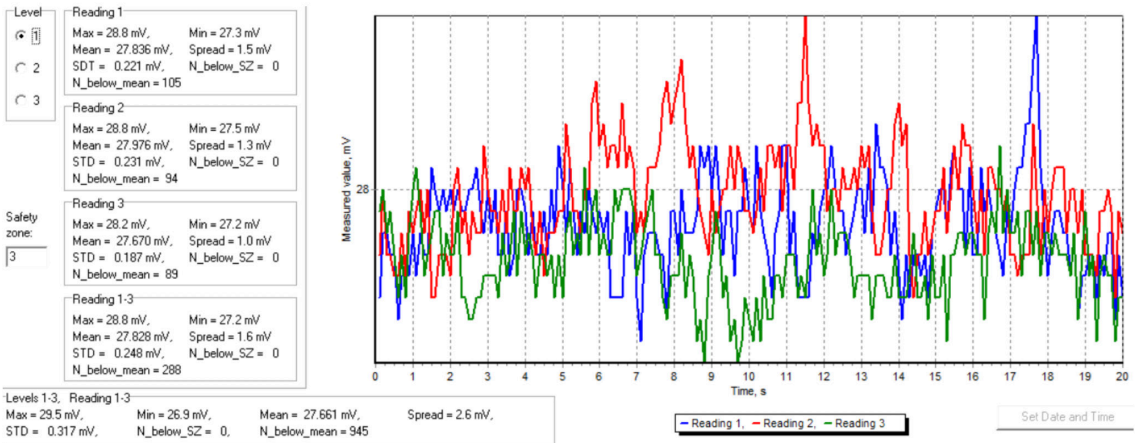


The above graph shows the cavitation activity in a system that historically has been used to clean surgical equipment. It can be noted that there are both 'spikes' and troughs' of sound about a mean. In surgical instrument cleaning settings, the spikes of sound are of little consequence, but the size and duration of the troughs of sound are of great concern and where we need to focus our attention.

The CVD device that produced these graphs achieves its results via 9 sets of readings, each of 20 seconds duration, with 10 individual readings per second, meaning 1800 individual readings overall. The section 'readings 1-3' gives us the average size of the spikes and troughs across the whole 1800 individual readings and it is noted that in this set the mean voltage was 19.254mV and the min reading was 13.4mV.

A 5.85mV variance does not sound like a lot, but when cleaning at this level on a contaminant that is extremely difficult to remove, it is too much and trials carried out between 2014 and 2016 proved this conclusively. What is also of concern is the length of time that a trough can last. In graph 1, we can clearly see a trough of sound (in green) that is 2 seconds in duration, plus a further 2 seconds while the power fell before recovering again. This highlights a period of 4 seconds where cleaning can be impaired.

Graph 2



Graph 2 shows the activity in a system, where the incoming sound has been manipulated to greatly reduce the size of the spikes and troughs, while still creating the chaos required to deliver an effective clean. Again, looking at 'readings 1-3', we can see that the mean in this set of readings was 27.828mV and the min voltage was 27.2mV, showing a variance of only 0.628mV across 1800 individual readings.

The readings taken with this device are done across 3 levels within the fluid depth and from side to side. In essence, these results are unique, extremely accurate and deliver a never-seen-before insight into the activity of high frequency sound when applied into fluid. Readings such as this have been taken in tanks 5m in length that delivered very similar results.

It is a simple fact that if something can be measured, it can be improved. This has been the case with the CVD, as apart from being able to look at competitor equipment and having a product to sell, we have also been able to insert this probe into our own equipment, enabling several unique modifications to be made to further enhance the performance, efficiency and capability of the cleaning system.

Foil test

This erratic dispersion of sound is clearly highlighted when conducting a foil test. It is a misconception that when holes are created in the tin foil, it is an indication of good ultrasonic activity - quite the opposite! The holes created in the tin foil are as a result of the spikes of sound as shown in graph 1 and as such, clearly demonstrate erratic dispersion. As sure as night follows day, if spikes are present there will inevitably be troughs, leading to potentially poor cleaning. Where ultrasonic activity is homogenous, there should be pummeling in the tin foil, but no holes. If holes are present the system should be considered as not fit for purpose at this level.

Through intense experimentation and great assistance from several eminent colleagues, we now sit on a technology that delivers what we originally set out to accomplish: Complete Protein Removal.

Bacteria

But what about bacteria? It was decided in 2018 to engage an outside laboratory to look for and measure any residual bacteria that may still linger on the instrument after processing. The results obtained came as bit of a shock and a further leap in understanding of the relationship between bacteria and protein.

The results matrix below highlights what is achieved in terms of bacteria removal following processing in an advanced ultrasonic cleaning system. The laboratory used their own heavily soiled instruments and removed them for measuring immediately after a 20-minute cleaning cycle at 20°C.

Instrument	Weight of Instrument before soiling (g)	Weight of Instrument after soiling (g)	Weight of soil (g)	Proportion of positive soiling	*S.aureus* on Instrument	Log of *S.aureus* on Instrument	*E.faecium* on Instrument	Log of *E.faecium* on Instrument	*S.aureus* survivors	Log of S.aureus survivors	*E.faecium* survivors	Log of *E.faecium* survivors	*S.aureus* reduction	S.aureus Log reduction	*E.faecium* reduction	*E.faecium* Log reduction	Rank (1 = Lowest reduction, 15 = highest reduction)
1	158.455	159.146	0.691	1.567	-	-	8.9313E+08	8.95	-	-	34036	4.531938515	-	-	4.4190E+00	4.42	2
2	18.802	19.091	0.289	0.655	-	-	3.7354E+08	8.57	-	-	3360	3.526339277	-	-	5.0460E+00	5.05	8
3	34.471	34.758	0.287	0.651	-	-	3.7095E+08	8.57	-	-	35864	4.554658726	-	-	4.0147E+00	4.01	1
4	33.352	33.686	0.334	0.757	8.9067E+08	8.95	-	-	3143	3.50	-	-	5.4524E+00	5.45	-	-	11
5	26.056	26.383	0.327	0.741	8.7200E+08	8.94	-	-	8092	3.91	-	-	5.0325E+00	5.03	-	-	6
6	37.903	38.407	0.504	0.944	-	-	5.3798E+08	8.73	-	-	6295	3.798995734	-	-	4.9318E+00	4.93	3
7	15.814	16.194	0.38	0.712	-	-	4.0562E+08	8.61	-	-	2135	3.329397879	-	-	5.2787E+00	5.28	10
8	44.106	44.766	0.66	1.236	-	-	7.0449E+08	8.85	-	-	1755	3.244277121	-	-	5.6036E+00	5.60	12
9	34.601	35.028	0.427	0.968	1.1387E+09	9.06	-	-	13134	4.12			4.9380E+00	4.94	-	-	4
10	46.092	46.433	0.341	0.773	9.0933E+08	8.96	-	-	17	1.23			7.7283E+00	7.73	-	-	15
11	44.828	45.444	0.616	1.154	-	-	6.5753E+08	8.82	-	-	6625	3.821185883	-	-	4.9967E+00	5.00	5
12	21.643	21.864	0.221	0.414	-	-	2.3590E+08	8.37	-	-	6	0.77815125	-	-	7.5948E+00	7.59	14
13	50.134	50.789	0.655	1.227	-	-	6.9916E+08	8.84	-	-	6052	3.781898919	-	-	5.0627E+00	5.06	9
14	32.904	33.39	0.486	1.102	1.2960E+09	9.11	-	-	11523	4.06	-	-	5.0510E+00	5.05	-	-	7
15	21.353	21.541	0.188	0.426	5.0133E+08	8.70	-	-	32	1.51	-	-	7.1950E+00	7.19	-	-	13
positive control 1 E.faecium	64.444	64.978	0.534														
positive control 2 S.aureus	64.836	65.277	0.441														

Total	82.34
Average	5.49

Total CFU recovered from positive 1	570000000
Total CFU recovered from positive 2	1176000000

What this table of results clearly indicates is that once the protein is completely removed, it is a relatively easy job to remove bacteria with the right chemistry in an advanced ultrasonic tank with homogenous activity.

While disinfection cannot be claimed as the device doesn't have a thermal disinfection cycle, the results clearly speak for themselves. A log reduction of 5.5 in cold water. 'Side effect disinfection' is disinfection that is achieved, not as the primary aim of the equipment but as a 'side effect' of the protein removal process.

Further trials were carried out on 'lightly soiled' instruments that returned an average log reduction figure of 6.65, giving further proof of the efficiency of this technology. Several articles have been written about cold sterilization. The below shows that it is indeed possible.

			Light Soiling											
Ultrasonication exposure period	Instrument	Recovery volume	100ml	10ml	1ml	0.1ml	0.01ml	Survivors (CFU/ml)	Survivors per instrument	Starting titre	log of starting titre	log of end titre	Log reduction R	Mean log reduction
>5 <10	**16**	**117**	**>**	**>**	**>**	**366**	**-**	**3660**	**428220**	**59075000**	**7.77**	**5.63**	2.14	3.024428
	17	**149**	**>**	**>**	**41**	**ND**	**-**	**41**	**6109**	**59075000**	**7.77**	**3.79**	3.99	
	18	**187**	**>**	**>**	**356**	**-**	**-**	**356**	**66572**	**59075000**	**7.77**	**4.82**	2.95	
10	19	155	3	ND	ND	ND	-	0.03	4.65	59075000	7.77	0.67	7.10	6.653651
	20	111	46	ND	ND	ND	-	0.46	51.06	59075000	7.77	1.71	6.06	
	21	95	10	ND	ND	ND	-	0.1	9.5	59075000	7.77	0.98	6.79	
7.5	22	234	>	180	11	ND	-	18	4212	59075000	7.77	3.62	4.15	4.367777
	23	112	>	>	17	2	-	17	1904	59075000	7.77	3.28	4.49	
	24	298	>	68	4	ND	-	6.8	2026.4	59075000	7.77	3.31	4.46	
6	25	130	>	>	114	12	-	114	14820	59075000	7.77	4.17	3.60	3.481474
	26	112	>	>	>	>	60	600	67200	59075000	7.77	4.83	2.94	
	27	124	>	>	60	4	-	60	7440	59075000	7.77	3.87	3.90	
3.45	28	159	>	>	>	300	-	3000	477000	59075000	7.77	5.68	2.09	1.780484
	29	138	>	>	>	410	-	4100	565800	59075000	7.77	5.75	2.02	
	30	116	>	>	>	>	300	30000	3480000	59075000	7.77	6.54	1.23	
	positive control	139	count per 0.1ml at 10^{-3} dilution				42.5	425000	59075000					

once the protein is completely removed, it is a relatively easy job to remove bacteria with the **right chemistry**

HTM 01-01 compliance and how advanced ultrasonics helps to achieve this

It's one thing being able to remove protein and bacteria from surgical equipment, but something entirely different if this task is to be undertaken within the auspices of the HTM. Maintaining the processed instruments at under 5µ of residual protein is not difficult or particularly expensive to attain, but delivering the level and sophistication of control and validation doesn't come cheap.

The more that the requirements are looked at, the more aspects of control and validation are uncovered. From a personal point of view, I feel that the HTM threw down a gauntlet to companies such as Alphasonics to find a solution to a problem that was stumping the sector. Without doubt, what was revealed, apart from being challenging was in many ways enlightening and highly satisfying.

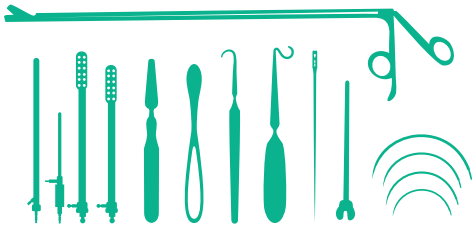
What do we mean by advanced ultrasonics?

No matter how good, even or aggressive the distribution of sound is, this in itself will not deliver the consistency required for this application. More is needed.

The core technology used in the contamination removal process must be supplemented by a suite of additional technologies to ensure that the consistency and performance of the device is maintained. Furthermore, every aspect of the system has to be monitored as much as possible from start to finish not only to ensure compliance, but to reduce theatre-bourne infections and reduce the risk to life.

With this in mind, every aspect of the device should be monitored to ensure that the system is functioning as it should, with appropriate alarms in place to warn and also cut the electrical supply to the machine if required.

One such aspect, although not stipulated within the HTM is the control of bio-film and the negative impact this can have on cleaning performance. During the many trials carried out between 2013 and 2016, it was noted that the first trial carried out after a weekend always rendered poor results. It was concluded that this was in fact caused by bio-film settling on the walls and base of the tank over the weekend (even with the lid closed). We found it astounding that such a small element could affect cleaning in such a way, even after such a short



length of time. What this highlighted was that every aspect of the device needed to be exactly right before the cycle start if system and consequently output control were to be achieved. Recognition of and cognisance to bio-film is a critical requirement in any cleaning device that hopes to deliver the desired results.

To avoid the use of foil tests as a means of gauging the ultrasonic output, it is important that in some way the core cleaning technology itself should be self-monitoring, with suitable safeguards in place to take corrective action should the generator tuning drift, or a transducer fail for example. This feature comes into play where lumens and rigid endoscopes are to be cleaned, alongside standard surgical instruments.

When validating the ultrasonics, where should the parameters and limits be set? Outside or inside the lumen? Measuring the ultrasonic activity down the inside of the lumen is an impossibility with a foil test, however with a CVD, experiments have been undertaken to determine the losses through the wall of a lumen/rigid endoscope that enable the generator output control system to be set to accommodate this.

There are several other inherent features that need to be included within a successful device which although not directly linked to HTM compliance itself, enable the conditions for compliance. For example, we have known for a long time that ultrasound when applied into a fluid, actually works at its best during something called the 'de-gassing phase'. De-gassing of the tank fluid can take a few seconds or several minutes, depending on the watts per litre of sound applied. Active Cavitation is a technology that greatly assists with cleaning performance and consistency. So too is Betasound, another technology that delivers the ultimate in even distribution of sound into a tank of fluid.

Medstar 3 protein removal system

The ultimate robot ready fully compliant cleaning device for surgical instruments, lumins and rigid endoscopes.
The unique design and functionality of Medstar 3 has taken 8 years to perfect. The equipment renders instruments and lumens completely protein free to both inside and outside surfaces and has several patented features that enhance the performance and enable compliance with the HTM. Every aspect of control has been considered. The system is also built to last with an exceptionally high build quality.

This device is an ideal addition to any sterile services unit and has been designed to accept robotic instruments.

Dedicated protein removal system for surgical instruments, lumens and rigid endoscopes
This comprehensive system will remove blood-based proteins from either rigid endoscopes/ lumens and/ or surgical instruments and its size is more suited to Sterile Service Unit environments. Instruments and endoscopes are cleaned on 3 levels in full din baskets in a structured and managed cycle.

Features
- Automatic cycle.
- Easy to use.
- LCD display.
- Automatic chemical dosing.
- Free-standing model.
- Fully Compliant with HTM 01-01 2016.
- Full and comprehensive validation system.
- Can clean both instruments and rigid endoscopes
- Protein removal to under 1µg
- >Log5 bacterial removal in cold water
- Integrated operator security protocol
- Robot ready

Medstar Compact systems

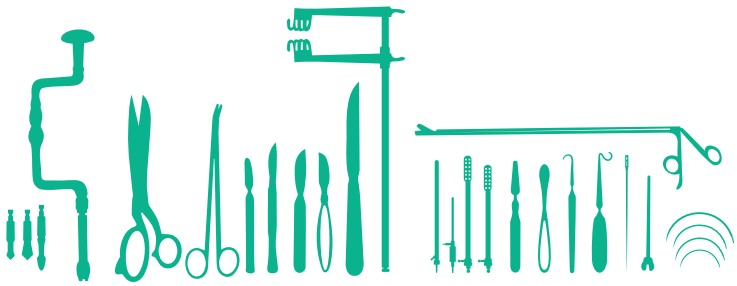
It is appreciated that not all sterile services departments have the requirement for HTM compliant equipment. Hospitals and clinics outside the UK for example may not need such a sophisticated device.

Features

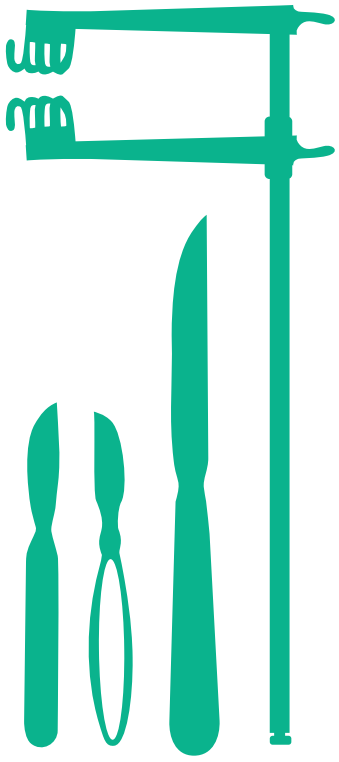
- Automatic cycle.
- Easy to use.
- LCD display.
- Automatic chemical dosing.
- Free-standing model.
- Can accept half DIN and full DIN trays
- Compliant in part with HTM 01-01 2016.
- Validation optional.

Benefits

- Lower cost device.
- Can clean both instruments and rigid endoscopes.
- Protein removal to under 1µg.
- >log5 bacteria removal.



Many discoveries were made on this journey. Things that ordinarily would never have been considered but which have ultimately led to the development of equipment and technologies that truly do deliver ‘Zero’.



Author:
David Jones, Managing Director

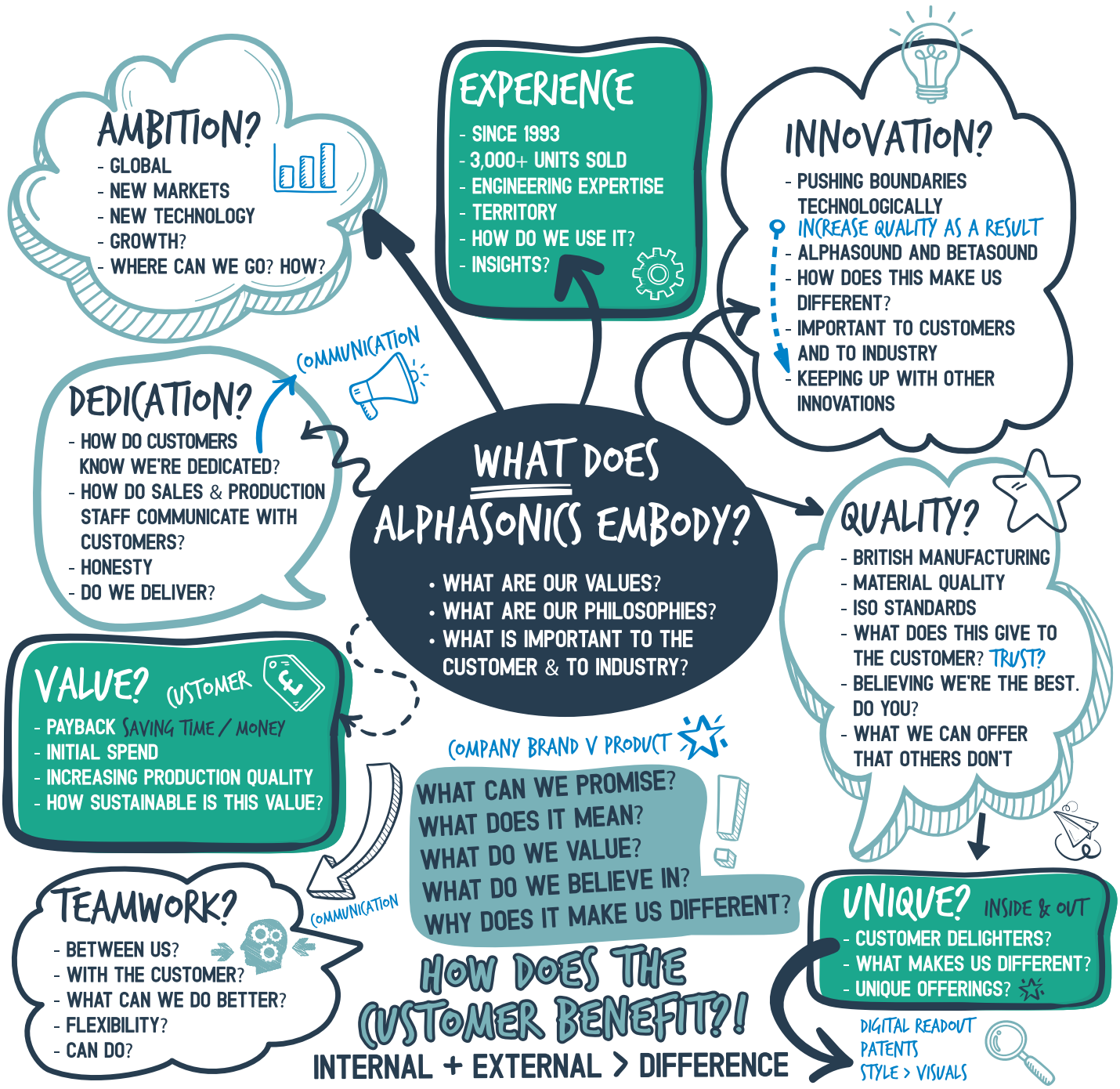
David Jones, a design engineer, founded Alphasonics in 1993 and since that time has steered the company in the development of precision ultrasonic cleaning technology and equipment. Continuous R&D, coupled with sound engineering principles are at the heart of what Alphasonics stands for.

About Us:
Alphasonics is the world’s leading designer and manufacturer of advanced ultrasonic cleaning systems, specifically for precision cleaning applications.

ALPHASONICS
ADVANCED ULTRASONIC CLEANING SYSTEMS

Founded in 1993, Alphasonics has developed a worldwide reputation for innovation and technical excellence within the field of precision cleaning. Our globally supplied advanced ultrasonic cleaning systems are unique in both their design and construction, delivering incredibly consistent results. All devices include several patented features that offer enhanced performance and a short ROI.

www.alphasonics.co.uk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- GLOBAL
- NEW MARKETS
- NEW TECHNOLOGY
- GROWTH?
- WHERE CAN WE GO? HOW?
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- 3,000+ UNITS SOLD
- ENGINEERING EXPERTISE
- TERRITORY
- HOW DO WE USE IT?
- INSIGHTS?
INNOVATION?
- PUSHING BOUNDARIES TECHNOLOGICALLY
INCREASE QUALITY AS A RESULT
- ALPHASOUND AND BETASOUND
- HOW DOES THIS MAKE US DIFFERENT?
- IMPORTANT TO CUSTOMERS AND TO INDUSTRY
- KEEPING UP WITH OTHER INNOVATIONS
COMMUNICATION
DEDICATION?
- HOW DO CUSTOMERS KNOW WE'RE DEDICATED?
- HOW DO SALES & PRODUCTION STAFF COMMUNICATE WITH CUSTOMERS?
- HONESTY
- DO WE DELIVER?
WHAT DOES ALPHASONICS EMBODY?
• WHAT ARE OUR VALUES?
• WHAT ARE OUR PHILOSOPHIES?
• WHAT IS IMPORTANT TO THE CUSTOMER & TO INDUSTRY?
QUALITY?
- BRITISH MANUFACTURING
- MATERIAL QUALITY
- ISO STANDARDS
- WHAT DOES THIS GIVE TO THE CUSTOMER? TRUST?
- BELIEVING WE'RE THE BEST. DO YOU?
- WHAT WE CAN OFFER THAT OTHERS DON'T
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- PAYBACK SAVING TIME / MONEY
- INITIAL SPEND
- INCREASING PRODUCTION QUALITY
- HOW SUSTAINABLE IS THIS VALUE?
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WHAT DOES IT MEAN?
WHAT DO WE VALUE?
WHAT DO WE BELIEVE IN?
WHY DOES IT MAKE US DIFFERENT?
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TEAMWORK?
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