

The History of Alkaline Hydrolysis

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Alkaline hydrolysis was originally patented in the United States Patent Office by Amos Herbert Hobson of Middlesex, England. His patent No. 394,982 was issued on December 25, 1888.

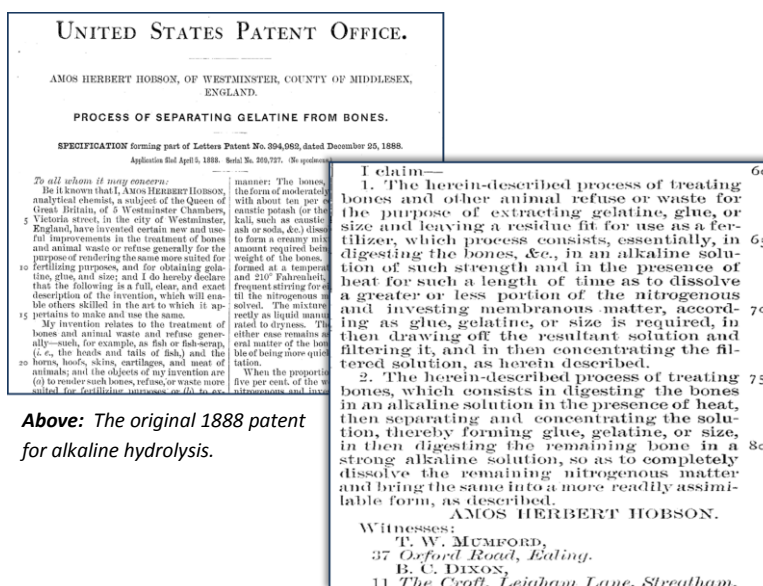
While Amos was concentrating on the removal of nitrogenous materials from the bones to make a suitable fertilizer and byproducts, he saw the benefits of alkaline hydrolysis as a process to treat animal carcass materials. More importantly, he literally defined the process of low temperature alkaline hydrolysis in great detail.

The Fathers of the Modern Tissue Digester

In the early 1990s, Dr. Gordon I. Kaye was Alden March Professor of Pathology and Laboratory Medicine at Albany Medical College when he became involved in the New York low level radioactive waste consortium. The group was trying to gain reasonable disposal options for animals researched with low level radioisotopes; at the time it could cost over \$150 just to dispose of a single rabbit. Dr. Kaye was talking about this problem to his colleague, Dr. Peter B. Weber, Professor of Biochemistry and Molecular Biology, and he made the statement that if the animals were in liquid form they could go directly down the drain citing NRC Standard 10CFR20.

Since they knew that animals were 65% water already, they contemplated the idea of using alkali to dissolve the animals into liquid. Dr. Weber showed up the next morning with a small pile of rat bone powder and said, "Is this what you were looking for?" With that the two scientists experimented and confirmed that indeed they could separate the radioisotopes into the liquid fraction completely removed from the bone remnants, and the Modern Tissue Digester was born.

Kaye and Weber along with David Lovenheim (their business partner) formed the company WR² and proceeded to file a patent for the process. U.S. Patent No. 5,332,532 was granted in July 1994 and their fledgling virtual company was now a reality. During the first few years of operation they successfully built and installed five



Above: The original 1888 patent for alkaline hydrolysis.



Above (Left to Right): Dr. Gordon I. Kaye; Dr. Peter B. Weber; The original digestion performed by Dr. Weber showing the alkaline hydrolysis reduction of a rat to bone powder.

tissue digesters. The first unit was placed in Albany Medical College. Shands Hospital at the University of Florida (Florida State Anatomical Board) purchased the first commercial system for the disposition of human remains donated for medical research. Units were sold to SmithKline Beecham in Rennes, France and



Collegeville, Pennsylvania as well as a large unit (3,000 pound capacity) sold to University of Florida Vet Diagnostic Lab. All of the original units are still in use today.

Prior to this work, scientist Dr. F. Taguchi was researching how to destroy the infectivity of the elusive and yet to be understood causative agent of Creutzfeldt-Jacob Disease (CJD). He published in May 1990 in the “Archives of Virology” that the agent causing CJD could be inactivated by soaking in alkali followed by autoclaving. In 1993 Dr. David Taylor, from the Institute of Neuropathogenesis in Edinburgh, Scotland had been studying inactivation of the infectivity of TSE agents (prions) and was experimenting with all known disinfectants and sterilants. His work continued into the 2000s, and is still today considered one of the most thorough works ever performed in this field. His conclusions led to the use of hot alkali as one of the few ways, and by far the most effective way, to reliably destroy the infectivity of these agents. In 1995 a Mad Cow Disease (BSE) outbreak caused CJD-v in over 50 people in the UK. As a result, Taylor’s work was accelerated. While his early work was at higher temperatures, he repeatedly demonstrated that in a 1 molar solution of sodium hydroxide he could eliminate all infectivity of a very virulent strain (301-V mouse passaged BSE) at boiling temperature for 1 minute contact time. This information was presented at numerous scientific symposia without ever a single challenge.



Top: The 1995 Florida Anatomical Board AH system used for the disposition of human remains donated for medical research. **Bottom:** University of Florida Vet Diagnostic Lab 3000-pound capacity AH system, pictured in front of the incinerator it replaced.

In late 1997, I was serving as vice president of Solid Waste Management Systems for STERIS Corp., Mentor, Ohio. While attending a medical waste conference, I met Dr. Kaye while he was presenting on the topic of alkaline hydrolysis. While I had been involved in biohazardous waste processing system design and development for 20 years, I had always believed that the only way to handle pathologic waste (human tissues, animal carcasses, etc.) was by incineration. I was amazed that in addition to handling pathologic materials, the process also destroys fixing agents, cytotoxic drugs, and all biological toxins and pathogens. After the presentation, I approached Dr. Kaye to see if he would be interested in selling his company and technology to STERIS. Dr. Kaye was amenable to the idea, and we presented the case to STERIS’s top management. It was ultimately rejected as not being in line with their business objectives.

After resigning from STERIS, I accepted the position of President and CEO of WR², which I held from early 1998 through 2001. From 2002 to 2006 I served as President and led design and manufacturing for the company. The first system sold under my leadership was to Health Canada in Winnipeg. This system was used to dispose of mice used in prion research. From 1998 to 2006, more than 75 tissue digesters were sold and installed. Among some of the first systems we made was a horizontal single body vessel with a coffin-shaped basket. At that time, the market did not seem ready to discuss this type of application.

WR2's board of advisors included a funeral director in early 2000. Kevin McCabe (of McCabe Funeral Home, Bloomfield Hills, Michigan) was excited about the prospect of bringing alkaline hydrolysis to the death-care industry, and he helped WR2 perform market research. At the time, Kevin suggested the process be called "Water Reduction" for this application (the laboratory term "tissue digester" did not bear any sensitivity to the funeral industry). In 2005, I led the design, development, and manufacture of a single body system for Mayo Clinic in Rochester, Minnesota, to replace their incinerator. The Mayo unit was the first single body human alkaline hydrolysis system put into commercial operation. A market for this product emerged in Europe in 2006, particularly rooted in the U.K. WR2's European subsidiary, WRE Ltd., was led by Sandy Sullivan. Sandy researched the European market and recognized the funeral industry to be one of the greatest E.U. opportunities. In the U.K., mercury scrubbers were being mandated for crematories at an additional cost of nearly \$500,000!

WR2 was impeded by significant financial difficulties in early 2006. Regulatory approvals in the E.U. consumed a great deal of the company's resources to an extent that the company closed WRE. Concurrently, a diminishing demand for large veterinary digesters in a saturated market and other market pressures ultimately led to the closure of WR2 later that year. After the fall of WR2, Sandy Sullivan formed Resomation Ltd. in 2007, developing a high temperature system specifically for human disposition.

In late November 2006, I formed Bio-Response Solutions. The company was set up as a horizontally integrated company with our longtime partner Feldmeier Equipment, the largest U.S. manufacturer of stainless steel tanks and pressure vessels. We also worked with several other companies I had cultivated relationships with over my 29 years in the business of designing and manufacturing biohazardous materials processing systems. My son, Luke Wilson, directed engineering and manufacturing. While at WR2, Luke had moved from the manufacturing floor to a technical writer, and for several years had written the operation manuals for the alkaline hydrolysis and effluent decontamination systems.

Low temperature technology had been a passion of mine since the 2002 installation of a low-temperature digester at Texas A&M University. I hired my daughter, Sam Sieber, as a biologist to further develop low-temperature alkaline hydrolysis. Our goal was to develop a mobile low-temperature tissue digester for emergency response and disease control



Top: Joe Wilson tests the first single-body human vessel for fit in 1998. **Middle:** Wilson inside the first single-body human vessel he put into commercial operation, which was manufactured for Mayo Clinic in 2005. **Bottom:** Wilson with the system he manufactured for Edwards Funeral Service in Columbus, Ohio.

operations. The systems (called BioLiquidator) were demonstrated at multiple venues. During a USDA demonstration, samples were collected and analyzed to establish that the end product from low-temperature hydrolysis was the same as the end product from high-temperature hydrolysis. The peptide sizing (MALDI) and amino acid profile data confirmed that this was the case. In 2008 we found ourselves back in the death-care industry when we placed a BioLiquidator system at a pet crematory in Ohio.

The technical success of the mobile low-temperature system led us to apply the technology in research laboratory settings. Soon after, inquiries from the U.S. and Australia led Bio-Response Solutions to consider the merits of a design for a lower cost, low-temperature human disposition system. We had previously developed a design that would allow us to achieve the same agitation results we had in our other low-temperature units, and we filed a priority with the U.S. Patent office to protect the design. We were granted “patent pending” status and received an order shortly thereafter for the first prototype system. The first system was purchased by John Humphries of Aquamation Industries, a private label customer in Australia. Before shipment, this prototype system

was shown to several funeral industry professionals brought to see the system by Ed Gazvoda of CycledLife, who was at the time trying to develop a U.S. market for the system under his private label. The system was demonstrated by running two cycles, each with large pigs (280 and 250 pounds respectively).

In 2010 through Ed Gazvoda of CycledLife, an order for the first production system was placed by Jeff Edwards of Edwards Funeral Service in Columbus, Ohio. The system was delivered in late January 2011 and immediately put into service. In March of 2011, Ohio Department of Health stopped issuing permits for alkaline hydrolysis pending regulatory review. Jeff Edwards was able to offer the disposition option to 19 families, and is now awaiting the conclusion of the regulatory review.



Above: The demonstration of a 2500-pound capacity mobile low-temp AH system (BioLiquidator) to University of Maryland, MD Department of Transportation, MD Department of Agriculture, MD EPA, USDA-APHIS, USDA-FAS, and USDA-ARS.

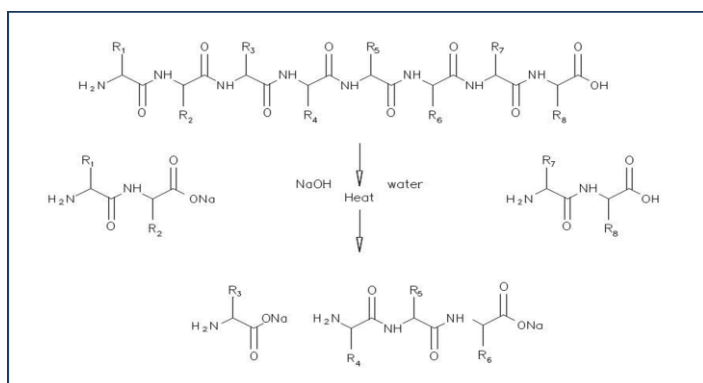


Above: Demonstration of the Bio-Response prototype AH system (low-temperature, single-body) with patent-pending tip technology. **Top Row** (Left to Right): 280 pound pig loaded with dry KOH alkali; an attendee tipping the vessel into the angled operating position (“tip technology”); starting the AH cycle. **Middle Row** (Left to Right): Process after 2 hours at 199°F; bone remains after the completed cycle (rinsed and concentrated at the end of the basket for simplified removal); the basket being pulled out. **Bottom:** Our visitors viewing the results and talking about the demonstration they had just participated in.

Overview of Alkaline Hydrolysis

Alkaline hydrolysis is a natural process. Here is some information:

- Bodies buried in the earth are degraded by alkaline hydrolysis, expedited by the soil bacteria – a slow process.
- Food in the small intestine is digested to usable nutrients by alkaline hydrolysis, expedited by enzymes that operate at pH 7-8 at body temperature – a moderately fast process for relatively small amounts of tissue.
- The use of strong alkali (pH 14) solubilizes and hydrolyzes tissue, expedited by heat in stainless steel vessel – a very fast process for large amounts of tissue.



Above: This chain of eight amino acids (called an octopeptide) is broken down into smaller random fragments in the alkaline hydrolysis process.

•Alkaline hydrolysis (AH) generates a sterile, EPA neutral solution of amino acids, peptides, sugars, and soap that is suitable for release to a sanitary sewer, dehydration for landfill, or for use as fertilizer or for composting.

•Proteins are hydrolyzed to amino acids and small peptides by breaking of amide (peptide) bonds.

•Carbohydrates are clipped from glycoproteins.

- Fats: Ester bonds between fatty acids and glycerol are hydrolyzed, yielding completely biodegradable soaps; Glycolipids and polyunsaturated fats are also destroyed.
- Nucleic acids: Phosphodiester bonds of nucleotide chains are hydrolyzed, RNA rapidly, DNA more slowly.
- AH destroys all pathogens, including prions.
- AH converts fixatives (such as embalming agents including glutaraldehyde, formaldehyde, phenol, etc.), cytotoxic agents (such as chemotherapy drugs), and other toxins to harmless, biodegradable derivatives.
- AH converts biological and chemical warfare agents, to harmless, biodegradable derivatives.

So What Does All of This Mean?

Alkaline hydrolysis is in a sense the opposite of burning by fire. Burning is an oxidative process, whereas alkaline hydrolysis is a reductive process. Muscles, collagen, and hair are made of protein. In the AH process, proteins are reduced to their basic building blocks, called amino acids. Small groups of amino acids remain and are called peptides. Fats are reduced to biodegradable soap. Sugars are formed and nutrients are released (minerals). Chemicals such as embalming agents, cytotoxic drugs, etc. are broken down into basic nutrient elements. Water is liberated as the fats and proteins are reduced, and the bones and teeth, which are made of mineral ash called calcium phosphate, are not dissolved. Bones and teeth are like a sponge interlaced with collagen. As the collagen is broken down the bones become more and more fragile. The ends of the bones, the skull, the pelvis and other bones become very fragile while the denser shafts of the long bones and the teeth retain

some strength due to the density of the calcium phosphate. All materials become sterile due to the temperature of the process and the breakdown of the proteins. All microorganisms consist of protein, and they are broken down into amino acids and small peptides as well. DNA and RNA are proteins, and as stated above those are also broken down into the basic elements.

Why Alkaline Hydrolysis is Green

Two alkalis are effectively used in alkaline hydrolysis. As an analogy, just as you can use sodium chloride (salt) in a water softener, you can also use potassium chloride (potassium salt) in a water softener.

- The alkali known as NaOH (sodium hydroxide, or caustic soda) is derived by electrolysis of salt water into sodium hydroxide. The planet has abundant quantities of sodium chloride (salt) to produce this alkali. NaOH is commonly used in making hard soap and other products, many of which are used for personal hygiene. After the process of hydrolysis, sodium chloride reforms as one of the end products.
- The alkali known as KOH (potassium hydroxide, caustic potash, or potash lye) is derived by electrolysis of potassium salt water into potassium hydroxide. The planet has abundant quantities of potassium chloride to produce this alkali. KOH is commonly used in the making of soft soap among other products, many of which are used for personal hygiene. Potassium (K) is an essential nutrient for plant growth; you see it on every bag of fertilizer. After the process of hydrolysis, potassium remains as one of the end products.

Alkaline hydrolysis of a body can be carried out with either of the two alkalis, but the best combination of effectiveness is realized with a mix of the two hydroxides. This has been learned over many years of working with these alkalis individually and in combination. Most of the alkaline hydrolysis systems in use today for animal disposition are using a mix of the two alkalis.

The effluent from the process is called hydrolysate. This material is a beneficial, highly nutritious, true solution that is an excellent form of fertilizer for crops or trees. It is also an excellent nutrient source for anaerobic or aerobic sewage treatment plants, often providing micronutrients that improve the function of the wastewater treatment.

Any phosphorous (P) that comes from the process of alkaline hydrolysis is in the form of bone remnants or bone particulates. Phosphorous is also an essential nutrient for plants, and the form of phosphorus resulting from this process is not in the form that causes the issues of run-off for lakes, streams, and rivers. Phosphorous in the form of calcium phosphate requires soil microbes to slowly release this bound form of the nutrient for use by plants.

After passing through the sewage treatment process, or through the biological process of fertilization, the end products of alkaline hydrolysis are not harmful to the environment in any way.

Unlike cremation, alkaline hydrolysis does not produce, liberate, or form harmful end products from metals found in the body such as implants, pacemakers, bone screws, dentures, jewelry, and particularly the silver/mercury amalgam so often used as fillings in teeth.

As numerous studies show, there is no air pollution or other harmful emission from alkaline hydrolysis.

Low Temperature vs. High Temperature Systems

Alkaline hydrolysis can occur at any temperature and the end product is exactly the same. However, at room temperature the process could take up to 6 weeks or so to complete, which is impractical. The process approximately follows the rule established by Arrhenius that for every 10 degrees Celsius increase in temperature the process time is cut approximately in half.

There are two basic types of alkaline hydrolysis systems; those that operate at no pressure and up to 210 degrees Fahrenheit, and those that operate at pressure and over 212 degrees Fahrenheit. All systems must be loaded, brought to temperature, cycled at temperature, cooled down, discharged and rinsed, then be unloaded, and the next body loaded. The time for all of this is called turnaround time.

- Low-temperature systems do not require a pressure vessel.

Alkaline hydrolysis can be effective at 200 degrees Fahrenheit within a 16 hour cycle time in a conventional hydrolysis system. By optimizing agitation during the process, it can be accelerated to approximately a 10 hour cycle time or a 12 hour turnaround time. This allows the possibility in a low temperature system to remain a non-pressurized process and still yield up to 2 dispositions per day.

- High-temperature pressurized systems require an ASME (or EU) certified pressure vessel.

If the process is heated up to 250 degrees Fahrenheit, then it can be reduced to approximately an 8 hour turnaround and 3 dispositions per day, at approximately 25 pounds per square inch vessel pressure.

At 300 degrees Fahrenheit, the pressure is approximately 65 pounds per square inch, and the process can be reduced to approximately a 6 hour turnaround and 4 dispositions per day.

At 350 degrees Fahrenheit or greater, the pressure is over 100 psi and the process can conceivably be reduced to 4 hours turnaround time, or up to 6 dispositions per day.

There are other issues that come into play in an alkaline hydrolysis system such as geometry, water to body ratio, agitation, etc. Higher temperature systems use more energy to heat, and more water or energy to cool than do low temperature systems. For example, if water is used to cool a 200 degree Fahrenheit system, it will be approximately the same amount of water as hydrolysate. To cool a 300 degree Fahrenheit system would take almost 3 times the amount of cooling water (or cooling energy). There are methods to cool that use less resources such as a dry cooler or cooling tower, but this requires additional apparatus and complexity.



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To learn more about Bio-Response Solutions, Inc., please visit the company's websites:

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