Ultra Sonigraphic Probe
A Corporate Overview

Visual Programs, Inc.
Jack Singer, President
11357 Nuckols Road
Suite 105
Glen Allen Virginia, 23059
804-399-2552 804-756-6595 fax
www.usprobe.com

Executive Summary

Visual Programs, Inc is applying advanced technologies to address unresolved medical needs in the dental industry. Building on over 30 man-years of experience in the dental industry and partnering with premier technology institutions, the company is prepared to provide a novel and unique capability to dental professionals around the world. Visual Programs, Inc. has developed the **US Probe** as the next generation, state-of-the art diagnostic tool for detecting and characterizing periodontal disease. The US Probe is an ultrasonographic instrument that integrates diagnostic medical ultrasound techniques with advanced artificial intelligence to automatically detect, map, and diagnose periodontal disease. Visual Programs, Inc. expects that the US Probe will quickly become the industry standard technique for diagnosing periodontal disease.

The Opportunity

The pervasiveness and potential cost of periodontal disease necessitate a better diagnostic tool and provides a genuine need for the US Probe. According to the American Academy of Periodontology, approximately 35.7 million Americans have some type of periodontal disease. ***Eighty percent*** of the world's population will have some form of periodontal disease in their lifetime. Besides causing bad breath and eventually leading to tooth loss, research has shown that chronic oral infections are related to ***life threatening*** health problems like heart disease, strokes, diabetes and spontaneous pre-term births. Furthermore, misdiagnosis of periodontal disease has become the leading source for malpractice litigation in the dental industry.

The seriousness of the problem and the enormous consumer base provides a vast market for the US Probe. There are over 150,000 dentists in the United States and an equal number of registered dental hygienists. Worldwide, there are ***over half a million*** dental professionals that could utilize the US Probe. The domestic market for dental services is projected to reach $79 billion in 2005, up from $42.9 billion in 1995.

In response to this need, Visual Programs, Inc. has developed the US Probe, a ***painless*** and portable ultrasonographic instrument that provides much more accurate and detailed information than the standard methods for periodontal examination. The US Probe integrates diagnostic medical ultrasound with advanced artificial intelligence software to automatically detect, map, and diagnose periodontal disease. This is the first use of diagnostic medical ultrasound in the dental industry. The US Probe will be at least ten times more accurate than current techniques. Furthermore, the US Probe will provide significantly more information in a shorter period of time without pain or any sensation for the patient. The ultimate result is a superior characterization of the periodontal condition and more effective disease treatment and management.

The Company

Visual Programs, Inc. is composed of approximately 20 full time personnel and consultants. Jack Singer serves as president and CEO. In 1989 he founded and was President of Chart-It, Inc., which is the leading supplier of dental operatory software products including, Chart-It, Capture-It, Image-It, and Xamine-It. John Senn is Director of New Product Development and worked for American Dental Technologies where he was involved with the development of the best selling computerized periodontal probe system, the Probe One. James Aldrich is Director of Marketing. He has an extensive dental background as well as being experienced in taking a startup to a full fledged company. Mr. J Meeks is the resident software engineer. He has 13 years of experience developing software for the dental industry and was a principal programmer on the development team that created the Chart-It and Capture-It software. He was a lead programmer on the Probe One, Periotemp, Florida Probe and Practice Mangement interface software.

Consultants on the research and development team include scientists from the Department of Applied Science at the College of William & Mary in Williamsburg and the NASA Langley Research Center in Hampton, VA. The research team also includes dentists, periodontists, oral pathologist, and dental hygienists from the Naval Dental Research Institute, Bethesda Detachment, the School of Dental Hygiene at Old Dominion University (ODU) in Norfolk, VA, and the Medical College of Virginia in Richmond, VA.

Visual Programs, Inc. has been awarded a National Institutes of Health Small Business Innovative Research (SBIR) grant from the National Institute of Dental and Craniofacial Research (NIDCR), and a grant from the Center of Innovative Technology (CIT) from the state of Virginia. Funding has also been provided for this work at William and Mary by NIDCR, NASA, and the Navy.

Visual Programs, Inc. holds exclusive worldwide rights to the NASA patent that protects the basic technology incorporated in the US Probe. The company is filing for additional patents to protect the enhancements developed after the initial patent. The original inventor remains an active member of the team as William and Mary.

Target Market

Initial sales efforts will focus on the United States Military and the approximate 150,000 privately practicing dentists in the United States. The company expects to enter the Canadian and European market within a year after the initial introduction of the US Probe. It is estimated that over half a million dental professionals worldwide will require the US Probe.

The Product

The US Probe is the first use of diagnostic medical ultrasound in the dental industry. A narrow beam of ultrasound is used to ***painlessly*** interrogate the periodontal anatomy with advanced artificial intelligence that automatically detects, maps, and diagnoses any periodontal disease. The US Probe provides more accurate and detailed information than the standard methods for periodontal examinations, which allows significantly better disease treatment and management.

R & D for the US Probe is on an accelerated schedule, with clinical testing of the second prototype on human patients now completed at ODU. During this testing, input from dental hygienists and from dentists has provided significant improvements for the third prototype, which is in final fabrication at William and Mary. The company is currently negotiating with MCV and others to conduct the next phase of testing of the probe. It is expected that this research will provide all of the necessary data to develop the "expert system" software that will diagnose the periodontal condition.

Sales and Promotion

First sales of the US Probe are expected in the fourth quarter of 2006. Visual Programs, Inc. will introduce the first version of the US probe at professional dental association meetings and though its extensive contacts in the dental industry. The first generation of the "walking" US Probe will replace the current point-measurement manual and computerized periodontal diagnostic tools. The expected retail price for the first generation commercial probe will be between $5 and $10 thousand. An upgrade promotion will be offered to encourage purchase of the later generation "scanning" US Probe that will be ready for the market beginning in the second quarter of 2007. This model will be a more advanced scanning device that will provide full contour maps of the periodontal ligament attachment level. The most advanced "imaging" version of the US Probe will be in production within six months later and will provide a "B-Scan" image similar to prenatal ultrasonographic images. This high-end system is targeted at the smaller specialty periodontal practices and research markets. Visual Programs, Inc. will also market upgrades to the graphical interface and "expert system" diagnostic software, as well as supporting consumables like disposable tips and prophylactic ultrasonic coupling fluid. In addition, Visual Programs, Inc. will continue research affiliations and publish in dental journals to promote the US Probe. As appropriate, Visual Programs, Inc. will establish formal relationships with major dental supply houses to advertise, market, and distribute the US Probe.

The Company

Visual Programs, Inc. was formed to develop high technology tools for the dental industry. The management team of Visual Programs, Inc. has been developing advanced tools for the dental industry for over 30 man-years. The executive officers were responsible for the periodontal charting system "Chart-It" and the dental image capture and manipulation package "Capture-It." Chart-It is currently the industry standard periodontal charting software system and is used by the US, British, and Canadian militaries, and by over 4,500 practicing dentists around the world. The executive officers were also responsible for redesigning the then failing Bausch and Lomb Interprobe® and developing it into the highly successful computerized periodontal probe, the "Probe One." Visual Programs, Inc. is now building on this extensive experience and leveraging the resources of premier research institutions to lead the industry and develop novel methods to detect and treat periodontal disease.

Mission Statement

Visual Programs, Inc. has developed the next generation instrument for detecting and treating periodontal disease. The US Probe is a non-invasive ultrasonographic instrument that detects and images the upper boundary of the periodontal ligament and its variation over time as an indicator of periodontal disease. The US Probe offers fast, consistent, accurate, and ***painless*** evaluation of a patient's periodontal condition. This allows the dental professional to diagnose disease, prescribe preventative treatment, and perform on-going management to prevent the spread of periodontal disease.

The goal of Visual Programs, Inc. is to position the US Probe as the medical standard for diagnosing and treating periodontal disease, replacing the inadequate manual and computerized handheld periodontal probes. In the near term, the company will market the first generation "walking" US Probe that will walk along the gum line (sulcus) and replace the traditional point measurements with a more accurate, comprehensive, and painless alternative. Within six months following the introduction of the walking probe, the company will introduce a more advanced second generation US Probe. This probe will be a continuous scanning version that will provide a full contour map of the gingival condition. Promotional incentives will be offered to upgrade from the first generation of the probe. The most advanced "imaging" version of the US Probe will be in production within six months later and will provide a "B-Scan" image similar to prenatal ultrasonographic images. For each probe, all information will be automatically digitally archived for comprehensive, contiguous patient records. In this manner, subjective operator interpretations of the pocket depth are eliminated and clerical errors are avoided.

Long-term goals include refinement of the US Probe system to provide even more detailed information about the periodontal condition. These refinements will include advances in hardware and software to maximize the diagnostic capabilities of the probe and for optimal robustness and portability. Further long-term goals include extending the

technology for advanced three-dimensional mapping of the complete sulcus and mapping of the tooth bone density. Other future applications include locating cracks in teeth, assessing root health, and checking implant status. Visual Programs, Inc. will provide software support with scheduled upgrades. The company will also market consumables for the US Probe like disposable tips and prophylactic ultrasonic coupling fluid. The eventual goal will be to have the ultrasonic probe fully integrated into a full periodontal practice management software utility.

Business Philosophy and History

The Visual Programs, Inc. paradigm is to identify unresolved or inadequately solved problems and apply advanced technologies to offer a superior solution. From its inception, the company has offered revolutionary products to the dental industry to solve previously unmet needs.

The management at Visual Programs, Inc., created "Chart-It," which is ***the number one*** periodontal software charting system on the market. It is used by the US, British and Canadian Military and by over 4,500 practicing Dentists around the world. The Visual Programs, Inc. team also created "Capture-It," one of the best dental image capture and manipulation package on the market.

In the spring of 1995 Visual Programs, Inc. team purchased the then failing and outdated "InterProbe" periodontal probing system from Bausch & Lomb. The product was redesigned into a new line of probe called the "Probe One." The new probe was integrated with a PC to record the information in a database and produce informative color printouts along with voice feedback. It immediately became the best selling probe in the world, outselling its competition by five to one. Visual Programs, Inc. continued to market the InterProbe and the Probe One until the company became involved with the US Probe. The company has divested the Chart-It software, Capture-It and Probe One to concentrate on the development of the US Probe. American Dental Technologies purchased Chart-It software and the Probe One product line. Jack Singer recently repurchased the Chart-It and Probe One line to get access to the customer base.

Key Accomplishments

Visual Programs, Inc. holds exclusive worldwide rights to the NASA patent that protects the basic technology incorporated in the US Probe. The company is filing for additional patents to protect the enhancements developed after the initial patent.

Visual Programs, Inc. has been awarded a National Institutes of Health (NIH) Small Business Innovative Research (SBIR) grant from the National Institute of Dental and Craniofacial Research (NIDCR), and a grant from the Center of Innovative Technology (CIT) from the state of Virginia.

Clinical testing of the second-generation prototype has been completed at the School of Dental Hygiene at ODU in Norfolk, VA. Preliminary results show good agreement

between the US Probe and the manual probe. Internal Review Board (IRB) and FDA approvals were obtained for these clinical tests so that future approvals will be straightforward because the ultrasonographic probe is classified as a "non-significant risk."

Management

Visual Programs, Inc. has assembled a world-class development and management team to work on the US Probe. The management team has over 30 man-years experience in the dental industry and has already successfully introduced revolutionary products. The research and development team is composed of ultrasonography experts from the College of William & Mary Department of Applied Science and the National Aeronautics and Space Administration/Langley Research Center (NASA/LaRC), dentists and periodontists from The Naval Dental School in Bethesda, and hygienists from the School of Dental Hygiene at Old Dominion University in Norfolk, VA. Visual Programs, Inc. is currently coordinating with periodontists and oral pathologists at the prestigious Goldman School of Dentistry at the Medical College of Virginia to develop experimental assays to further test and refine the US Probe. The company will continue to work closely with each of these organizations to leverage their considerable infrastructure and expertise. Furthermore, Dr. S. Timothy Rose, past president of both the American Academy of Periodontology (AAP) and the American Dental Association (ADA) is a board member and is consulting on the development of the US Probe. The current president of the AAP has also expressed interest in assisting us with the development of the US Probe and the company has retained respected dentists/periodontists to aid in the probe development and refinement. The company anticipates further relationships as the US Probe matures. Finally, from its inception, the development of the US Probe has had critical input from periodontists and hygienists to ensure its functionality and superiority. Visual Programs, Inc. is confident that the meticulous efforts in this endeavor, the close relationships developed with leading research facilities and dental programs, and the advantages offered by this product will guarantee its success.

Mr. Jack Singer is President of Visual Programs, Inc. located in Richmond, VA. In 1989 he founded and was President of Chart-It, Inc., which is the leading supplier of Dental Operatory software products including, Chart-It (periodontal charting), Capture-It (video capture), Image-It (cosmetic imaging), and Xamine-It (digital x-ray capture). From 1988-1989 he was Finance Manager and Director of Budgeting for Blue Cross and Blue Shield. Prior to this, he was Director of International Business for AMF Sporting Goods. He holds a BA degree in Accounting from Pace University, New York. Mr. Singer has also started and sold two successful Internet companies, Internet Connections and CarsTV.com.

Mr. John Senn is Director of New Product Development for Visual Programs. From 1996-2000 he has worked with the development of a computerized periodontal probe system, the Probe One, that works with over 60 Practice Management Software Companies in the US, Canada and UK. He has also worked as Product and Sales

Manager for Chart-It, handling all the technical support and training for both Chart-It and Probe One.

James Aldrich is director of Marketing for TissiUSA, LLC. He is a to producer with 21 years of experience building and directing sales and marketing. His extensive dental experience and contacts will allow us to jump into the market as soon as the product is ready.

Jay Meeks is the resident software engineer. He has 13 years of experience developing software for the dental industry and was a principle programmer on the development team that created the Chart-It and Capture-It software. In addition he was a lead programmer on the Probe One, Periotemp, and Florida Probe interface software.

Professional Consultants

S. Timothy Rose, DDS is a principal investigator for this project. He holds DDS and MS degrees as well as a professional postgraduate certificate in periodontology from The Ohio State University. Since 1972 he has been in private practice limited to periodontology in Appleton, WI. He has a long history of service to the dental profession, serving most recently as the 1997-1998 president of the American Academy of Periodontology and the past 1998-1999 President of the American Dental Association. He has been a clinical instructor and assistant professor in periodontology, and has been a member of the OSSI Dental Research Group since 1989.

Brian Raskin, DDS acts as principal investigator for the NIH SBIR Phase I ultrasonic periodontal probe project. He is a 1982 graduate of the New York University College of Dentistry, and completed his general practice residency at Booth Memorial Medical Center in 1983. He is President of the Rockaway Dental Society, and is a member of the Academy of General Dentistry, the American Dental Society, the American Society of Dentistry of Children, and the Nassau County Dental Society. In his dental practice he employs the most modern clinical imaging tools including digital radiography and computerized intra-oral video imaging systems

Ms. Gayle McCombs, RDH, MS is Clinical Research Director and Assistant Professor at the School of Dental Hygiene and Dental Assisting at Old Dominion University in Norfolk, VA. Ms. McCombs received an MS degree in Dental Auxiliary Teacher Education from the University of North Carolina at Chapel Hill, a BS degree from the University of West Florida and entry-level dental hygiene education from the Florida Community College at Jacksonville. She is a licensed dental hygienist in Virginia, North Carolina and Florida.

Ms. Margaret Lappan Green, **CDA, RDH, MS** is an Adjunct Professor at the School of Dental Hygiene and Dental Assisting at Old Dominion University in Norfolk, VA. In her more than 30 years of experience teaching and researching in the dental hygiene field, she has served as a Governor Appointee to the Virginia Board of Dentistry and has served as a consultant at the National Institute of Dental Research.

College of William & Mary, Department of Applied Science

Professor Mark Hinders, Ph.D. holds B.S. (Aerospace, 1986), M.S. (Mechanical, 1987), and Ph.D. (1990) degrees in Engineering from Boston University. From 1986 to 1991 he was a Research Assistant and Research Associate in Physics and Engineering at Boston University. From 1987 to 1991 he was Electromagnetics Research Engineer (Captain, USAF) at Rome Laboratory, Hanscom AFB. From 1991 to 1993 he was Senior Scientist at Massachusetts Technological Laboratory (Belmont, MA) as well as Research Assistant Professor and Adjunct Assistant Professor of Aerospace and Mechanical Engineering at Boston University. From 1993 to 1999 he was Assistant Professor of Physics and Applied Science at the College of William and Mary in Virginia. Currently a tenured Associate Professor of Applied Science, he is a founding member of that Department and head of the Nondestructive Evaluation group. Prof. Hinders' research group develops analysis techniques and measurement technologies for the quantitative characterization of materials, tissues and structures by noninvasive means. Ultrasonic, radiographic, thermographic, electromagnetic, optical and other methods are employed to probe interior microstructure and characterize hidden subsurface features. Applications are in non-invasive medical diagnostics and on-line manufacturing process control, as well as the traditional NDE areas of flaw detection and materials characterization. Many government agencies, foundations, and industrial partners in the last several years have provided over $5 million in support for this highly collaborative research. Professor Hinders currently has an active NIH grant for ultrasonic periodontal probe research.

Mr. John Companion is a senior Research Associate in the Department of Applied Science at William and Mary and concentrates on medical ultrasound technology development. From 1973 until joining Professor Hinders' research group to he was a Senior Research Technician working in the Nondestructive Evaluation Sciences Branch at NASA's Langley Research Center. Prior to that he was a Field Engineer for Philco-Ford Corp. He holds six U.S. Patents for medical devices, including a U.S. Patent recently awarded for "Ultrasonic Probe for Mapping Periodontal Structures."

Mr. James Hou is a Ph.D. Candidate in Applied Science at William & Mary working under the direction of Professor Hinders. His current doctoral research involves the development of neural-network based artificial intelligence software for automated interpretation of the ultrasonic echoes recorded by the periodontal probe. He holds the B.S. degree in Mechanical Engineering from the Institute of Armored Vehicle Engineering in Beijing and the M.S. degree in Materials Engineering from the National University of Defense Technology in Changsha**.**

NASA Langley Nondestructive Evaluation Sciences Branch

Dr. Eric Madaras is a senior research scientist at NASA's Langley Research Center and an Adjunct Professor of Applied Science at William & Mary. He completed his Ph.D. work twenty years ago in medical ultrasound at an NIH Trainee Fellow in Cardiology, and has been a leading researcher in ultrasonic NDE for advanced aerospace applications at NASA Langley since that time. The periodontal probe work originated at NASA Langley while Mr. Companion was working in Dr. Madaras' group. Dr. Friedman did his doctoral research at NASA Langley under the joint supervision of Prof. Hinders and Dr. Madaras.

Naval Dental School, Detachment Bethesda

Cmdr. Brian Nicoll, DDS is the research coordinator for Endodontics, Periodontics, Oral Medicine, Oral Pathology and Oral Surgery at the Naval Dental School in Bethesda, MD. He holds the DDS degree from University of the Pacific School of Dentistry, with Residencies in General Practice and Periodontics at the Naval Hospital in Oakland and the Naval Dental School in Bethesda, respectively. He has supported this project since its early days with oversight, expert guidance, and by providing cadaver jaw samples for ultrasonic scanning and subsequent histology.

Market and Industry Analysis

The Problem – Why is there a compelling need for the product?

Periodontal Disease

Periodontal diseases are infections caused by bacteria in the biofilm (dental plaque) that forms on oral surfaces. Periodontal disease is classified as gingivitis, which affects the gums, or periodontitis, which may affect all of the soft tissue and bone supporting the teeth.

Gingivitis is an inflammation of the gums characterized by redness, swelling, bleeding, and sensitivity. These changes result from an accumulation of biofilm along the gingival margins and the immune system's inflammatory response to the release of destructive bacterial byproducts. The early stages of gingivitis are reversible with thorough brushing and flossing. Without adequate oral hygiene, however, chronic infections and periodontitis can develop.

The most common form of adult periodontitis is described as general and moderately progressing. A second form is described as severe and rapidly progressing. This second type is often resistant to treatment. The moderately progressive adult form is characterized by a gradual loss of attachment of the periodontal ligament to the gingiva and bone along with loss of the supporting bone. This attachment loss is used to characterize the disease. The destruction of periodontal ligament and bone results in the formation of a pocket between the tooth and adjacent tissues that collects subgingival plaque and food particles. Calculus forms in the pocket from inflammatory fluids and minerals released in adjacent tissues. These conditions exacerbate and accelerate the disease. In advanced cases, surgical treatment may be required to replace lost gingival tissue. Without treatment, severe periodontitis results in the loss of teeth. The effects of peridontitis are illustrated in Figure 1.

Periodontitis is especially difficult to diagnose because it is not a continuous process. Instead, the disease progresses in random bursts in which short periods of breakdown of periodontal ligament and bone alternate with periods of quiescence. Furthermore, these episodes occur randomly over time and at random localized sites in the mouth.

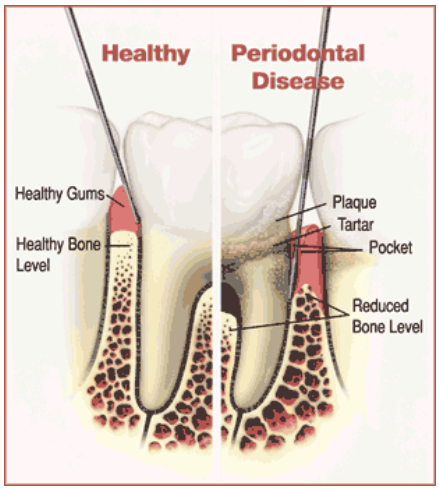

Figure 1. Comparison of healthy and diseased gums.

Besides causing bad breath and potentially leading to tooth loss, bacteria responsible for periodontal disease can spread into the lungs or blood stream and travel throughout the body. *According to the recent Surgeon General's Report on Oral Health, studies have found associations between periodontal disease and heart and lung disease, stroke, diabetes, and*

pregnancy complications. In addition to medical concerns, statistics show that forty-eight percent of all dental malpractice suits can be traced back to misdiagnosis of gum disease.

Who is affected and what is the cost?

Periodontal disease is one of the most pervasive dental diseases in adults. According to the American Academy of Periodontology (AAP), in a recent study of Americans aged 30 years and older, half exhibited gingival bleeding at one or more sites. More than one in three people over age 30 have periodontitis. By a conservative estimate approximately 35.7 million Americans have some type of periodontal disease and 80% of the world's population will have some form of periodontal disease in their lifetime. Furthermore, 80% of adult tooth loss is due to periodontal disease. According to the Surgeon General's Report on Oral Health,

> *Most adult show signs of periodontal or gingival diseases. Severe periodontal disease (measured as 6 millimeters of periodontal attachment loss) affects 14 percent of adults aged 45 to 54.*

From the 1988-94 National Health and Nutrition Examination Survey (NHANES II) moderate attachment loss of 3-4 mm was found in 30% of 25-34 year olds, 63% of 45-54 year-olds, and 80% of people over 65. An attachment loss of 5 mm or more was found in 15% of all people surveyed. According to the Surgeon General's Report on Oral Health,

- *Employed adults lose more than 164 million hours of work each year due to dental disease or dental visits.*
- *Expenditures for dental services alone made up 4.7 percent of the nation's health expenditures in 1998 - $53.8 billion out of $1.1 trillion.*

According to the American Dental Association (ADA) "1990 Survey of Dental Fees," out of $5 billion spent for periodontal treatment, $3.5 billion was spent in general dental practices. An additional $10 billion was spent on the replacement of teeth lost to periodontal diseases. Table 1 shows data gathered for the average cost for periodontal maintenance in all US cities. This data was compiled by the US Bureau of Labor Statistics, the ADA, and by the ACCRA (American Chamber of Commerce Research Association). The table indicates that periodontal maintenance becomes expensive with a full treatment costing between one-half and the full retail price of the US Probe. From the NYSSA 2nd Annual Dental Industry Conference, the domestic market for dental services is projected to reach $79 billion in 2005, up from $42.9 billion in 1995.

Service	Average Fee	Highest Fee (95th percentile)
Periodontic Diagnosis and x-rays	$159.00	$303.00
Periodontal Maintenance	$134.00	$198.00
Full Periodontal Case	$3609.00	$4664.00

Table 1. Average Cost of Dental Care in all US Cities

Current Diagnostic Techniques

Currently, there are no reliable clinical indicators of periodontal disease activity. The best available diagnostic aid, conventional hand probing, is only a retrospective analysis of attachment already lost. The current hand held probes to diagnose periodontal disease are inconsistent, slow, and ***painful***. The probe is typically a metal tool that is inserted between the gum line and the teeth. (See Figure 2.) The depth that the probe can be inserted is subjectively measured by visually reading markings on the probe. Three to six measurements are made at different locations for each tooth. These "pocket depths" are then correlated to the etiology of periodontal disease. The depth that the probe penetrates depends on several factors including the size, shape, and tip diameter of the probe. The insertion depth also depends upon the angle of insertion, applied pressure, presence of obstructions such as subgingival calculus, and the patient's reaction to the discomfort of probing. Consequently, the probing technique is inherently variable and inaccurate. From the Surgeon General's Report on Oral Health,

> *Part of the difficulty in determining the pattern of progression reflects variation in the sensitivity of the instruments used to measure the loss of soft tissue and bone.*

This technique is also time consuming, ***painful*****,** and may allow the disease to spread as the probe is moved between diseased and healthy sites.

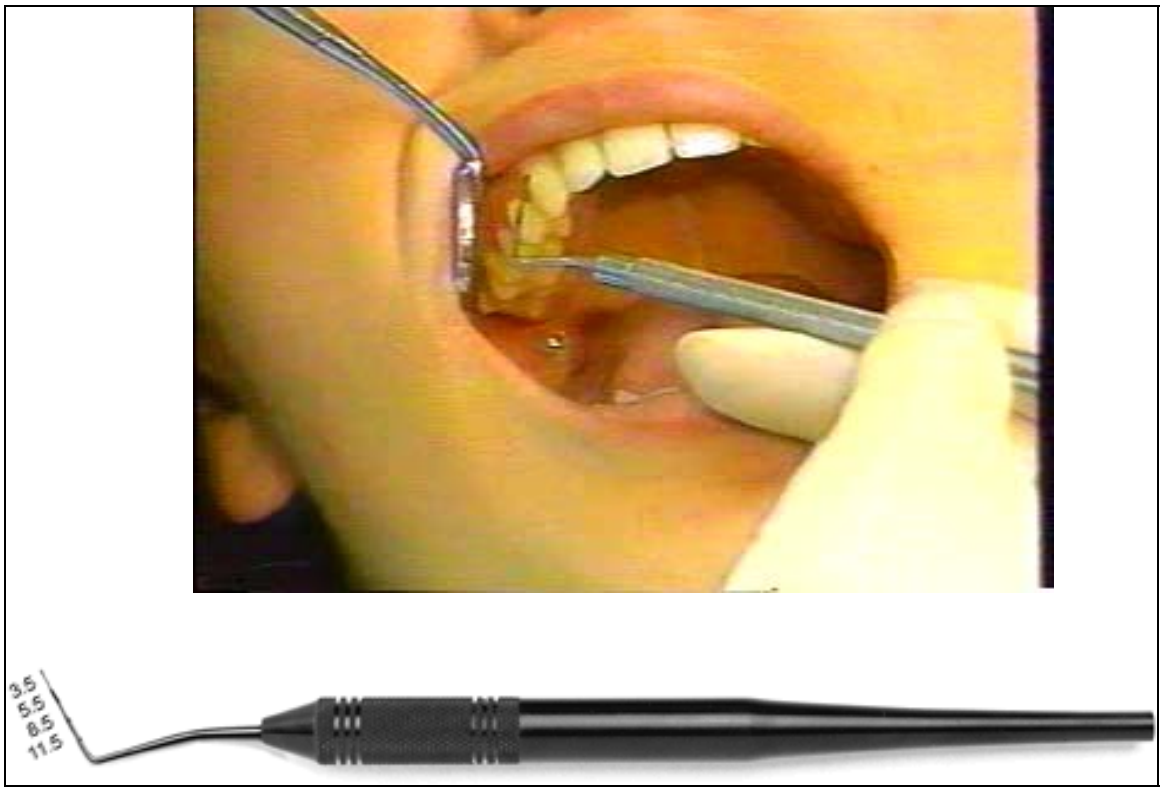

Figure 2. Conventional manual periodontal probe.

Treatment

- Pocket Reduction Procedures: The dentist folds back the gum tissue and removes the disease-causing bacteria before securing the tissue into place. In some cases, irregular surfaces of the damaged bone are smoothed to limit areas that bacteria can accumulate.

- Regeneration: The dentist folds back the gum tissue and removes the disease-causing bacteria. Membranes (filters), bone grafts or tissue-stimulating proteins are used to assist the body's natural ability to regenerate bone and tissue.

- Soft Tissue Grafts: Gum tissue from the palate or another donor source is used to cover exposed roots.

- Periochip®: A biodegradable delivery system for reducing pocket depth. A 4x5 mm chip is inserted directly into infected periodontal pockets that are 5 mm or greater in depth, following scaling and root planning to remove plaque and calculus deposits. The Periochip releases an antimicrobial, Chlorhexidine and is fully absorbed by the body in seven to 10 days.

- Periostat®: A systemic twice-daily oral dosage of 20 mg of the antibiotic doxycycline hyclate administered for 1 to 9 months. Used as an adjunct to scaling and root planing.

- Atridox™: A localized delivery system consisting of a liquid polymer placement vehicle containing a pharmaceutical dosage of the antibiotic doxycycline hyclate 10%. Intended as an alternative to scaling and root planing.

The Solution: The US Probe and Medical Ultrasonography

Medical ultrasonography is a standard and well-established diagnostic technique, perhaps best known for monitoring prenatal development. It is also used in a wide variety of additional applications like monitoring cardiac and intra-vascular functions. In medical ultrasonography, a ***completely benign and painless*** high frequency sound wave is generated in the patient. This wave propagates in the patient's body without any sensation for the patient and interacts with internal structures. Measuring the reflected or transmitted waves and understanding the complex behavior of the sound waves allows a harmless diagnosis of the patient. Although this technique has been used extensively in the medical field, until now, it has not been applied in dentistry.

The US Probe uses this technology to interrogate periodontal structure and detect early signs of periodontal disease. In the US Probe, a narrow beam of ultrasound is projected down into the pockets between the teeth and gums. The ultrasonic wave ***painlessly*** interacts with the periodontal anatomy and the reflected wave is used to image the periodontal ligament attachment and surrounding anatomy. The technique allows much faster, completely painless, accurate and objective measurements of the pocket depth. Consequently, periodontal disease can be diagnosed and treated with greater efficiency.

The Product

History and Recent Developments

Development of the US Probe began when a life-threatening incident motivated the Navy to seek a superior method to diagnose periodontal disease. A Naval serviceman onboard a ballistic missile submarine developed a serious case of gum disease that could not be treated on the vessel. To save the sailor, the submarine had to surface and a helicopter was used to transport him for emergency medical attention. The planned six-month mission had to be scrubbed at a considerable financial cost and at a potential cost to national security. As a result, the Navy solicited the NASA Langley Research Center in Hampton, Virginia to develop a more effective technique to detect the onset of gum disease and avoid similar incidents in the future.

In response, John Companion, then a research scientist at NASA, undertook a research effort to develop an ultrasonic probe to diagnose periodontal disease. Mr. Companion conceptualized a probe that used ultrasound to map the upper boundary of the periodontal ligament to identify periodontal disease. This ultrasonic probe adapted diagnostic medical ultrasonic techniques that have been widely used in fields like cardiology and obstetrics as well as in aerospace structural flaw detection. The basic concept of the probe is illustrated in Figure 3. A small tip is used to direct a stream of water between the gum and the tooth. A transducer generates an ultrasonic wave that propagates down the stream of water until it reaches the ligament attachment to the tooth. The ultrasound then reflects from the ligament attachment point, travels back up the water stream, and is received by the transducer. The periodontal condition is then interrogated by analyzing these received ultrasonic echoes. This technique is superior to existing techniques because it is painless, allows more accurate, thorough and consistent measurements, and because it is more time efficient and provides automated data storage. NASA patented this ultrasonic periodontal probe concept in U.S. Patent No. 5,755,571; issued May 26, 1998; called the "Differential Measurement Periodontal Structures Mapping System." Visual Programs, Inc. currently owns exclusive worldwide licensing rights to this patent.

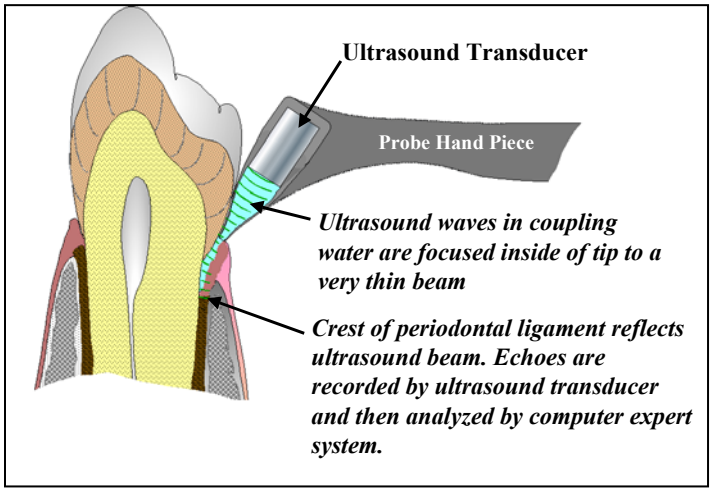

Figure 3. Schematic showing the concept for the US Probe. Ultrasound is projected down between the gum and tooth. The ultrasound reflects from the ligament attachment and returns to the transducer. Analyzing the return signal characterizes the periodontal condition.

Figure 4. First-generation, "proof-of-concept" US Probe.

Subsequently, development of the ultrasonic probe continued in the Department of Applied Science at the College of William and Mary with Mr. Companion working under the direction of Professor Hinders. The initial probe, illustrated in Figure 4 was a simple proof-of-concept device comprised of a plastic tip, a transducer to generate and detect the ultrasound, and a water tube to provide the necessary coupling fluid.

This probe was used to take the data presented in Figure 5. The red arrows along the teeth indicate the location of manual hand probe measurements of the pocket depth. The three numbers immediately below each tooth indicate the corresponding pocket depth recorded in "B-mode" ultrasonic image created with the first generation probe. The lighter areas reveal the pockets and a solid line has been added to map the ligament attachment level along all of the teeth. The depth of the attachment level is measured in millimeters along the right-hand side. The ultrasonic image and the manual probing correlate well.

Following the success of this initial design, a second-generation probe was produced. A new stainless steel hand-piece with removable tips was incorporated so that the instrument could be easily manipulated like existing dental instruments and so that the unit could be sterilized. A preliminary study was carried out to define a better tip design that could couple the ultrasound more efficiently into the gum and teeth. In addition, the probe hand-piece was fully integrated with a portable computer system. The second-generation hand-piece is illustrated in Figure 6. Figure 8 shows a schematic of the hand-piece and supporting computer along with a photograph of the actual computer system.

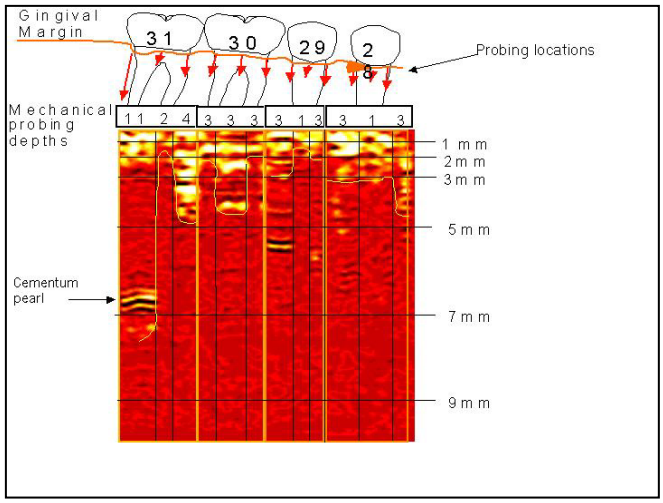

Figure 5. Ultrasonic scan with first generation probe compared to manual hand probing. Yellow contour shows ultrasonic measurement and it agrees well with mechanical probing.

Both FDA and IRB approvals have been obtained to perform tests on human subjects. The second-generation probe has been used in clinical studies to measure the pocket depths of cadaver jaws and of real patients. Figure 7 shows one of the consulting dental hygienists from ODU probing a member of the development team with the current prototype US Probe.

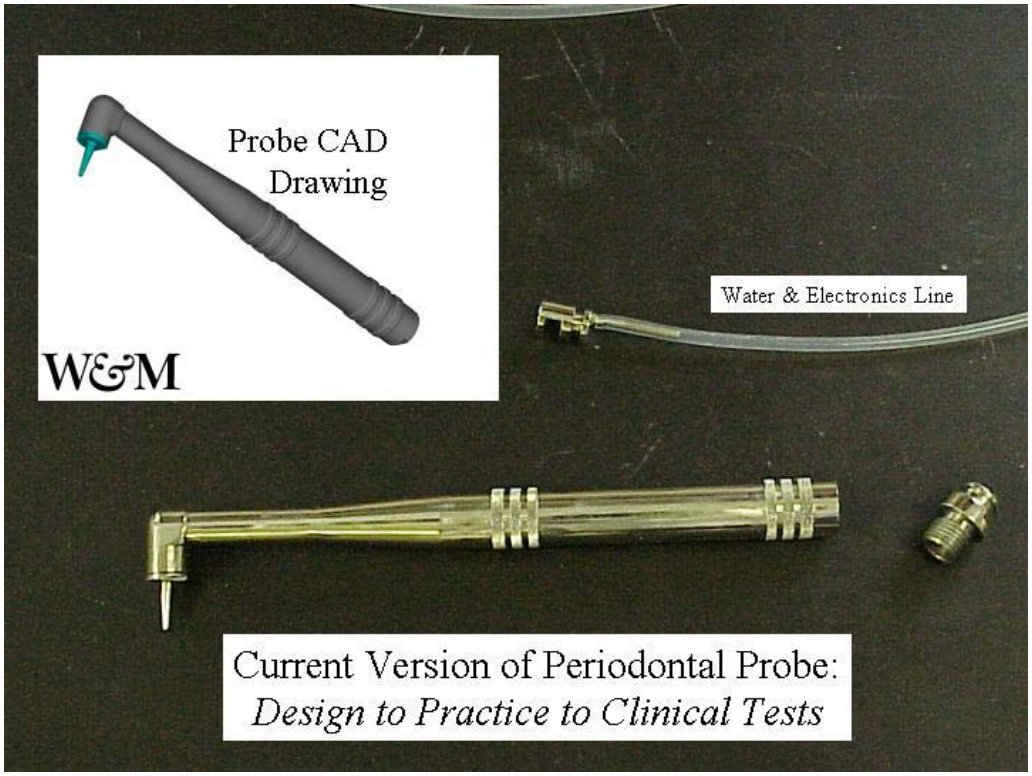

Figure 6. Second-generation hand-piece.

The uncertainty in the manual probe measurement is ± 2mm so that the pocket depths measured by the US Probe are statistically equivalent to the manual hand probing. Currently the development team is performing additional clinical tests to compare the ultrasonic measurements to the manual probe measurements. At the same time, a third-generation hand-piece, illustrated in **Error! Reference source not found.** has been fabricated. This hand-piece offers superior ergonomics and comfort for the dental professional and will accommodate magnetic positioning equipment so that the probe can be scanned across the gum line while its position is automatically recorded. Also, new tips are being tested and more advanced models are being developed to further improve the ultrasonic measurement.

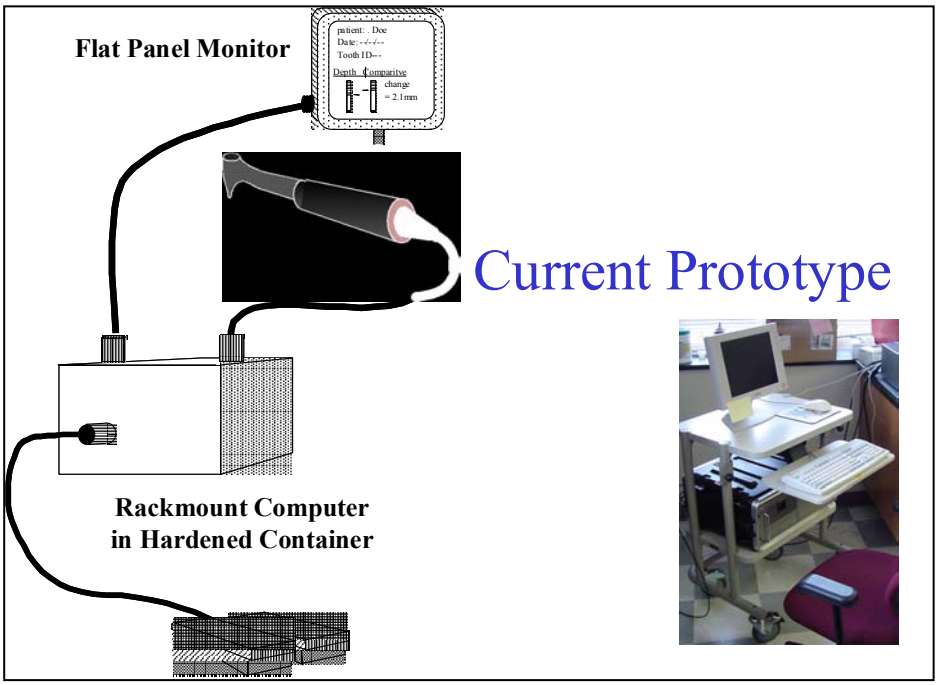

Figure 8. Schematic of current system along with a photograph of the computer system.

Figure 7. Second-generation probe testing a member of the development team.

Research and Development Timeline

The development team has outlined a plan for the development and commercialization of the US Probe. A timeline illustrating the development plan along with commercialization milestones is illustrated in Table 2.

	1st Qtr '06	2nd Qtr '06	3rd Qtr '06	4th Qtr '06	1st Qtr '07	2nd Qtr '07	3rd Qtr '07	4th Qtr '07	1st Qtr '08
Comparison to Manual Probing Study					**Introduction of 1st generation "Walking" US Probe at October ADA** Meeting				
Flap Surgery Study									
En Bloc Study									
Extracted Teeth Study									
Fresh Cadaver Study									
Design of 2nd generation "Scanning" US Probe							**Introduction of 2nd generation "Scanning" US Probe**		
Design of 3rd generation "Imaging" US Probe									**Introduction of 3rd generation "Imaging" US Probe**
Phase II SBIR		Proposal Submittal			Funding				

Table 2 Research and development timeline with commercialization milestones.

Clinical tests comparing the US Probe to manual and computerized probing have been completed at the Dental Hygiene School at ODU in Norfolk, VA. In this study, the gingival pocket depths were measured with a manual probe, a Probe One computerized probe, and the US Probe. The data from this study is currently being analyzed. Preliminary results show good correlation between the US Probe measurements and the

measurements from the other probes. This data is being used to train the expert system to automatically detect and diagnose periodontal disease.

The research team expects that up to one thousand patients could be examined in a two-month period although much less data should be sufficient. This data will be used to further train the expert diagnostic system so that it will be more robust. Visual Programs, Inc. anticipates introducing the walking US Probe to market at the October ADA meeting.

The research team will concurrently begin several more advanced studies to improve the US Probe and develop the next generation probes. The first of these studies will be a "flap surgery" study conducted at MCV in collaboration with Dr. Jeff Rogers of the Periodontology Department. In this study, a human patient volunteer will be ultrasonically scanned with the US Probe immediately prior to gum flap surgery. The gum line will be marked on the tooth and the pocket will be stained. During the gum flap surgery, the gum will be surgically peeled away from the tooth and a digital image of the stained periodontal tissue will be obtained. In this manner, the gingival margin, cemento enamel junction (CEJ), and the bottom of the gingival pocket will be mapped. This mapping will then be used to identify subtle features in the ultrasonic measurements made by the US Probe. From this comparison, the artificial intelligence will be able to make a more detailed diagnosis.

Also at MCV, a second concurrent study will be an "En Bloc" study done in collaboration with Dr. James Burns of the Oral Pathology Department. Here, patients will be ultrasonically examined with the US Probe prior to an *en bloc* procedure where a "block" of teeth, bone, and soft tissue is excised due to cancer or some other condition. This block will then be finely sectioned and histology will be performed. The histological slides will be digitally photographed and the two-dimensional segmented images will be used to construct a three-dimensional image of the periodontal anatomy in a computer. Since the ultrasonic signals recorded by the US Probe are sensitive to the three-dimensional anatomy, this three-dimensional image will be especially valuable in interpreting and refining the US Probe measurements.

Histological studies of condemned and extracted teeth will also be preformed at various sites, including MCV. In these experiments, diseased teeth will be scanned prior to removal. After the teeth have been removed, they will be sliced and examined to locate the ligament attachment. As in the other studies, this assessment will be used to refine the artificial intelligence of the US Probe system.

A final concurrent study will be the fresh cadaver study conducted at MCV. In this test, the jaws of recently deceased bodies will be scanned with the US Probe. As in the En Bloc and extracted teeth studies, histology will subsequently be performed on the jaws to identify critical anatomical features. As before, this information will be used to refine the US Probe diagnosis.

The next generation "Scanning" US Probe is already in development. This generation of the US Probe will incorporate magnetic positioning equipment in the hand piece to track the position and orientation of the probe tip. This probe will be rapidly scanned across the gum line and measurements will be continuously recorded. By using the positioning information, advanced software will reconstruct a full two-dimensional contour image of the pocket depth along the gum line.

This generation of the probe will provide a cross-sectional "B-scan" image of the periodontal anatomy, similar to the images obtained in obstetrics and cardiac medical ultrasound applications. These images can then be compiled into a full three-dimensional picture of the periodontal structure.

Manufacture

The primary components of the US Probe are the hand piece and tip, the piezoelectric transducer, the pulser-receiver board, the data-acquisition board, and a PC computer.

The prototype US Probe hand pieces and tips have been machined out of metal at the William and Mary Machine shop. Once the optimal configuration of the probe has been determined, the company anticipates that the hand piece and tips will be plastic and mass produced by an injection molding process. Visual Programs, Inc., will contract out this work to specialty fabricators.

The prototype electronic components including the transducer, the pulser-receiver board, data-acquisition board, and PC computer have been off-the-shelf components. The transducers and PC computers will remain off-the-shelf components for the commercial versions of the US Probe. The company anticipates that more cost effective, specialty pulser-receiver and data-acquisition boards will be manufactured in house for the commercial versions of the probe. These boards may be combined in a small external box and an interface (USB, port, parallel port, or serial port) to a laptop computer. In the long term, the company expects to offer a PCMCIA card with the pulser-receiver and data-acquisition integrated together so that a more elegant laptop system will be available.

Competition

There are no competing diagnostic tools with comparable technology. "Periodontal disease activity" is defined by measuring the attachment level of the gingiva. Presently there are two computerized probing systems used to measure the gingival attachment level, the Florida Probe and the Probe One (See Figure 8). Although these probes offer computer integration and some added consistency over manual probing, both of these instruments require inserting a probe directly between the tooth and the gum into the pocket to record the pocket depth. The only other method for diagnosing periodontal disease is conventional periodontal probing with a manual probe. All of these techniques are a retrospective analysis of losses in periodontal attachment and are subjective, inconsistent, and ***painful***. Digital subtraction radiography is not sensitive to soft tissue

changes, exposes the patient to potentially harmful ionizing radiation, and is expensive. Currently, the US Probe is ***the only*** non-invasive method available to monitor destructive changes in the gingival attachment level.

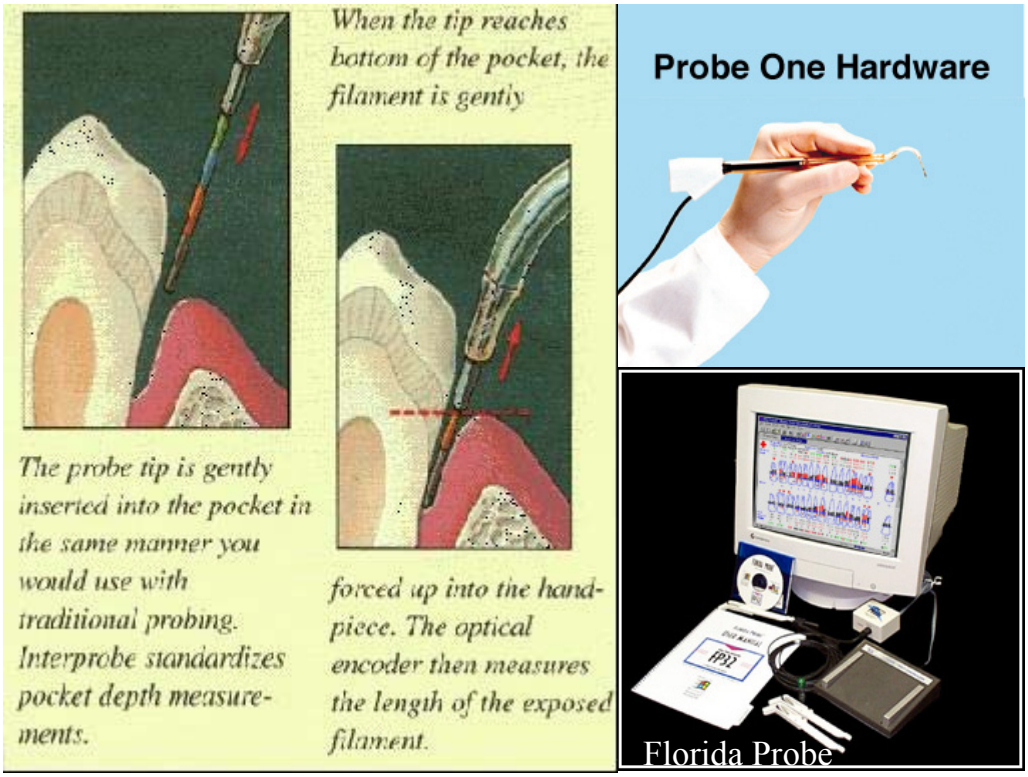

Figure 9. Probe One (top right) and Florida Probe (bottom Right).

Product Regulation

The US Probe is subject to regulation by the U.S. Food and Drug Administration (FDA) and corresponding state and foreign agencies. The FDA requires that all medical devices introduced to the market be preceded either by a premarket notification clearance order under Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended the "FDC Act," or an approved premarket approval (PMA) application. An approved PMA application indicates that the FDA has determined that the device has been proven to be safe and effective for its intended applications. Obtaining a 510(k) clearance take approximately six to nine months, while the PMA application process typically lasts more than a year.

Visual Programs, Inc. will apply for the 510(k) clearance for the commercial US Probe system. Although the US Probe represents a revolutionary innovation for the dental industry, the medical ultrasound technology is substantially equivalent to currently approved devices and presents "non-significant risk" so that this FDA approval will be uncontested.

Patent Protection

Visual Programs, Inc. own ***exclusive*** worldwide licensing rights to the U.S. Patent No. 5,755,571; issued to NASA May 26, 1998; called the "Differential Measurement Periodontal Structures Mapping System." The company is preparing to surround this base patent with additional patents based on subsequent advances discovered during the development of the US Probe.

The company will hold the artificial intelligence software as a trade secret as an additional barrier to competition. The development team has decades of man years invested in understanding complex ultrasonic signals. The company is confident that the difficulty associated with interpreting the ultrasonic information will prevent competitors from offering a similar capability.

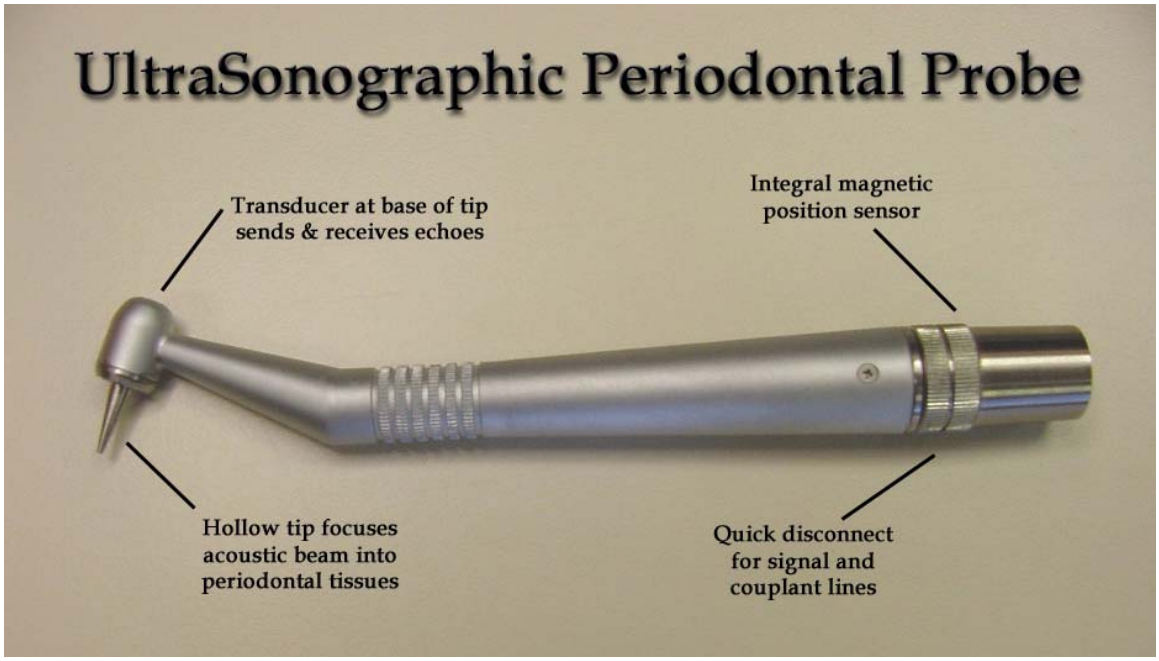

Figure 10 - Latest version of the US Probe.