"Qoustic Wound Therapy System™ was **a life-saver** for me."

I was hospitalized in March for 10 days to reverse a progressive circulation problem in my right hand. The tips of my fingers were not receiving enough blood and started to become necrotic. While the hospital medication was able to reverse the trend, I was released from the hospital with no instruction on how to manage the necrotic wounds on the ends of my fingers.

As the weeks progressed the nerve pain in my right hand and fingers became more and more intense and was unmanageable even using prescribed pain medication. I was referred to your system by Master Chunyi Lin and discovered that while Mayo Clinic has used the system successfully for over two years no other hospital in Minnesota had your system in place. However, Regions Hospital in St. Paul was in the process of purchasing the product and I got on their list before they even were trained.

At that point I had waited three weeks and experienced intense pain on a daily basis. After my first treatment the pain was reduced by 50% and by the second treatment it was reduced by a total of 70%. I had a number of treatments and experienced my pain diminish in additional increments and my wounds heal more quickly after each session. It was a godsend for me and made my life manageable from a pain standpoint as my wounds healed. I looked forward to every session and was so grateful that Regions Hospital added this tool to their wound care. Any medical institution interested in truly helping their patients with wounds needs to have one of these machines.

Thank you. Thank you. Thank you.
And my best to your company for all the help I was given.

Kathryn Loeb

Why Choose Arobella?

Qoustic Wound Treatment System (QWTS)

- Indications for Use
- Core Technology Capabilities
- Case Studies
- Cost-Benefit Analysis
- Coding & Payment
- Appendices

Qoustic
WOUND THERAPY SYSTEM™

Aiding the Healing Process to Improve Patient Outcomes

Innovative Contact and Non-Contact Wound Treatment Using Ultrasound and Irrigation Together with Standard Curettage

Arobella Medical, LLC
(((Sound Touch for Wound Care™)))

Podiatry Today
TOP TEN INNOVATIONS
WINNER
2010

Mayo Clinic

Walter Reed Military Medical Center

John Hopkins Bayview Medical Center

Duke Medicine

Baylor University Medical Center

Welcome to Arobella

Thank you for taking the time to consider using the Qoustic Wound Treatment System (QWTS). Our device has been used to treat chronic wounds, diabetic ulcers, burns, and other highly complex wounds. Our system is being used by The Mayo Clinic, Walter Reed Military Medical Center, John Hopkins Bayview Medical Center, Duke Medicine, and Baylor University Medical Center. We were the first place winner of the Podiatry Today Top Innovations of 2010.

We have received testimonials and consistently seen great results over the years. Several case studies are attached in the appendix displaying results from our physician partners.

We offer a no obligation evaluation of our equipment. If you have questions or need additional information, please contact your sales representative at any time.

Arobella Medical, LLC
Sound Touch for Wound Care™

Best in Ultrasound™
Due to co-founder **Dr. Eliaz Babaev's** lifelong pursuit in understanding ultrasound, Arobella is delivering results where others are failing.

Hand Piece
AR1000D

Appendix B - Bibliography

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CASE STUDY 3

Biofilm Removal

Device can be used for highly complex cases down to bio-film removal providing better outcomes. The photos show the biofilm removal and healing over time. The skin pigmentation did not return, but the wound healed over.

DAY 0: No Treatment

Day 1: Debrided

Day 49

APPENDICES

Appendix A - Case Studies

Amputation Closure
Case study was written up by the East Alabama Medical Center. Subject was diabetic and had his left leg amputated in 2012. Two years later, his right leg needed to be amputated. The patient's doctor had planned the upcoming year as the duration for his leg to heal. Healing from the inside out, while taking longer, would be better for a prosthetic attachment point. The doctor decided to use the Arobella QWTS for wound treatment and therapy to facilitate the healing process. After three months of treatments, the patient was informed that he was ready to be fitted for a prosthetic, a full nine months ahead of schedule.

Increased Blood Flow
The medical team conducted a comparison study to see if there was an increase in blood flow to the wound compared to traditional sharp debridement. Their research concluded there was a statistically significant increase in blood flow compared to the control group.

Chronic Venous Insufficiency
Two patients participated in this study. The first was a 63 year old woman who had two non-healing wounds over 12 months old, one on each leg. The second was a 77 year old man who had seven non-healing wounds, four on the lower left leg, and three on the lower right leg, which had been present for 3 months. Measurements of the wound size were taken every 2-3 weeks with treatments happening more frequently. Both patients experienced improvement of their wounds ranging from full healing to significant healing.

Review the case study: https://goo.gl/653EN1

Human Fibroblast Morphology
A study was conducted in vitro to track the effects of the low frequency ultrasound (Arobella equipment) on the fibroblast growth patterns. Untreated fibroblasts migrated primarily parallel to each other, while the treated migrated in a more perpendicular mode. In turn, the rate of closure for the treated group closed the scratch much more rapidly than the untreated.

Review the case study: https://goo.gl/7vYb64

Reduced Healing Time
An additional study was conducted comparing healing rates because of the increased blood flow. The control group took longer to heal in every case. The control group also took longer than the treated group to heal similar sized ulcers.

Bacteria & Biofilm Activity
The Mayo Clinic College of Medicine conducted research to evaluate the impact of Arobella's QWTS on platonic and biofilm bacteria. The bacteria they evaluated were Pseudomonas aeruginosa, Staphylococcus epidermis, Staphylococcus aureus. Their conclusion was that our device eliminated platonic bacteria and reduced biofilm bacteria.

PPE Use Study
While we advocate wearing appropriate PPE in using our equipment, the doctor conducted a comparison case study by on aerosolization and PPE wear. The comparison was between the Misonix Sonic One device and Arobella's QWTS. The images show the story, showing the PPE differences the medical professional chooses to wear between the equipment.

Aerosolization & Contamination
In working with wound care and fluid washes with our equipment, concerns may arise in the drift of fine liquid particles contaminating a room or potentially spreading bacteria. Two different studies have been conducted on this. The first study concluded that the QWTS has less splatter and aerosolization for any pathogens to circulate in the air.

The second study was conducted to evaluate the bacterial migration due to the QWTS. The study found no contamination from aerosolization in the surrounding area.

Product Description

The Qoustic Wound Treatment System (QWTS) uses ultrasound technology in the sharp debridement process to clean wounds of necrotic tissue. The device is made up of three core parts: the signal generator, the hand piece, and the disposable tubing. The signal generator is the core of the device and generates the ultrasound signal to the hand piece.

AR1000B
Series Generator

The hand piece starts with the curette making its use feel familiar. The curette design is unique because it has a dome shape, from which the ultrasound is emitted and focused. You start the process by hovering over the wound with the Qoustic Qurette. The hand piece has been calibrated to create a stable cavitation field, which helps to separate necrotic tissue from healthy tissue.
After that, it is easy to remove any biofilm or necrotic tissue.

The ultrasound delivered through the curette also facilitates cutting much more substantive tissue that needs removing. You use the cutting edge of the curette to cut into the tissue. The robust device design still performs when the head is under significant load (denser tissue).

The QWTS has an integrated fluid wash system that cleanses the wound work area and increases the delivery of ultrasound waves through the fluid wash. Disposable tubing delivers the fluid wash to the tip of the Qoustic Qurette. The design allows for both contact based sharp debridement and non-contact wound therapy.

INDICATIONS FOR USE

The Qoustic Wound Therapy System™, Model AR1000 Series and its variants has been approved by the FDA for the following uses.

Access our FDA 510K approval on the FDA Website, K131096 https://goo.gl/hKLCXk

- **Surgical, excisional, or sharp-edge wound debridement**
- **Non-contact maintenance debridement**
- **Non-contact wound therapy**
- **Cleansing irrigation and lavage of wound tissue**
- **Preparing the wound bed for graft or other procedures**
- **Selective and non-selective contact dissection and fragmentation of soft and / or hard tissue**

CORE TECHNOLOGY CAPABILITIES

Not all ultrasound devices are the same. The QWTS is the only ultrasound wound therapy device that operates at 35 kHz, which is considered the "Sweet Spot" for bioburden control. The patented dome-shaped, sharp-edged Qoustic Qurette probe gives clinicians more control for gentle and selective removal of necrotic tissue. It also provides therapeutic maintenance debridement by targeting the low frequency ultrasonic energy through fluid solution to the wound bed. Our system has had success even with the most difficult wounds.

Stable Cavitation Field

Cavitation is the formation of an empty space within a solid object or body. A cavitation field is a little known phenomenon within ultrasound. It is similar to a magnetic field in that is it invisible but we can see evidence.

You will notice small bubbles, which have been known and used for a long time. Near the end of the video, you will see large bubbles forming in the water untouched by the curette head which come from the cavitation field.

Bactericidal

It has been long understood there can be a bactericidal effect from ultrasound. The frequency plays a critical role in delivering this effect. Similar to a wine glass, when the right frequency is hit, the resonance will cause the target to begin vibrating and then shatter. Bacteria and virus are the same way. University of Winston-Salem in North Carolina conducted research on our equipment using it to eliminate MRSA, (Teresa Conner-Kerr, et al., 2010). Additional studies have also been conducted verifying strong bactericidal effects (Serena T, 2009), (Karau MJ, 2010).

Pain Management

Research conducted at The Regional Medical Center in South Carolina on low frequency ultrasound demonstrated a reduction in pain according to patients with diabetic ulcers. The equipment used in the study was originally developed by Dr. Babaev (Marie L. Gehling & and John H. Samies, 2007). Research later conducted at University of Winston-Salem and Wake Forest in North Carolina by Dr. Conner-Kerr investigated mechanisms behind the pain reduction. Research showed a flattening of the neurons with the potential of rebounded improvement (Teresa Conner-Kerr, Hope Fox, Erik Garland, Angela Handsel, & and Allyn Howlett, 2008). Arobella has replicated these capabilities into the QWTS.

Fluid Wash

Sound travels better through liquids than air, the same goes for ultrasound. The ultrasound energy is transferred through the fluid wash. The wash is able cover the wound more thoroughly and better providing better application to the wound. Arobella has patented this capability (United States of America Patent No. 8050752, 2011).

Graft Bed Preparation

We are the only company with the graft bed preparation indication for use. Because of the bactericidal effects along with the fluid wash the wound bed preparation supports a better taking of the graft by the wound.

CASE STUDY 1

Limb Salvage

Limb was scheduled for amputation. Toes had been removed due to necrotic tissue. QWTS was administered 2x per week until healed.

DAY 0: No Treatment → Day 1: Debrided → Day 5 →

2024 Unadjusted Approximate Medicare National Average 2024 Physician Fee Schedule Rates - Continued					
CPT Code	Description	Physician Payment		Facility and Hospital Based Wound Care	
		Office Non-Facility		Facility	Physician
97598	DEBRIDEMENT (e.g.: HIGH PRESSURE WATERJET WITH/WITHOUT SUCTION, SHARP SELECTIVE DEBRIDEMENT WITH SCISSORS, SCALPEL AND FORCEPS), OPEN WOUND, (e.g.: FIBRIN, DEVITALIZED EPIDERMIS AND/OR DERMIS, EXUDATE, DEBRIS, BIOFILM), INCLUDING TOPICAL APPLICATION(S), WOUND ASSESSMENT, USE OF A WHIRLPOOL, WHEN PERFORMED AND INSTRUCTION(S) FOR ONGOING CARE, PER SESSION, TOTAL WOUND(S) SURFACE AREA; EACH ADDITIONAL 20 SQ CM, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE).	$45		$44	$24
15002	SURGICAL PREPARATION OR CREATION OF RECIPIENT SITE BY EXCISION OF OPEN WOUNDS, BURN ESCHAR, OR SCAR, (INCLUDING SUBCUTANEOUS TISSUES), OR INCISIONAL RELEASE OF SCAR CONTRACTURE, TRUNK, ARMS, LEGS, UP TO 100 SQ CM.	$212		$355	$211
15003	SURGICAL PREPARATION OR CREATION OF RECIPIENT SITE BY EXCISION OF OPEN WOUNDS, BURN ESCHAR, OR SCAR, (INCLUDING SUBCUTANEOUS TISSUES), OR INCISIONAL RELEASE OF SCAR CONTRACTURE, TRUNK, ARMS, LEGS, ADDITIONAL 100 SQ CM.	$66		$67	$27
15004	SURGICAL PREPARATION OR CREATION OF RECIPIENT SITE BY EXCISION OF OPEN WOUNDS, BURN ESCHAR, OR SCAR, {INCLUDING SUBCUTANEOUS TISSUES), OR INCISIONAL RELEASE OF SCAR CONTRACTURE, FACE, SCALP, EYELIDS, MOUTH, NECK, EARS, ORBITS, GENITALIA, HANDS, FEET AND/OR MULTIPLE DIGITS.	$380		$383	$220
16020	DRESSINGS AND/OR DEBRIDEMENT OF PARTIAL-THICKNESS BURNS, INITIAL OR SUBSEQUENT, SMALL, (LESS THAN 5% TOTAL BODY SURFACE AREA).	$85		$83	$54
16025	DRESSINGS AND/OR DEBRIDEMENT OF PARTIAL-THICKNESS BURNS, INITIAL OR SUBSEQUENT, MEDIUM, (WHOLE FACE OR WHOLE EXTREMITY OR 5% TO 10% OF TOTAL BODY SURFACE AREA).	$159		$152	$107
16030	DRESSINGS AND/OR DEBRIDEMENT OF PARTIAL-THICKNESS BURNS, INITIAL OR SUBSEQUENT, LARGE, (MORE THAN ONE EXTREMITY OR MORE THAN 10% TOTAL BODY SURFACE AREA).	$188		$191	$127

Payment amounts shown for Medicare National Average 2024 Physician Fee Schedule are averages and may vary from location to location based on the payer. Please check with the payer for any details, updates or modifications prior to performing the above listed treatments. Current Procedural Terminology is copyright of the American Medical Association, **(AMA),** All Rights Reserved. The reimbursement information provided by Arobella Medical, LLC. is gathered from third-party sources and is presented for illustrative purposes only. It does not guarantee coverage or reimbursement for services performed utilizing the Qoustic Wound Therapy System.

Arobella has made every effort to ensure the completeness and accuracy of the information contained herein; however, no representations or warranties are made regarding the selection of codes for the use of Arabella's products or the services in which the products may be used, or for compliance with any billing protocols or procedures, requirements, or prerequisites.
As with all coverage claims, individual physicians and facilities are responsible for exercising their independent clinical judgment in selecting the codes that most accurately reflect the patient's condition and the services provided to a patient. Healthcare providers are encouraged to contact the individual Medicare contractor, carrier, fiscal intermediary or other third-party payers, as needed.

2024 Medicare National Unadjusted Approximate Average Payment Rates					
CPT Code	Description	Physician Payment		Facility and Hospital Based Wound Care	
		Office Non-Facility		Facility	Physician
97610	LOW FREQUENCY, NON-CONTACT, NON-THERMAL ULTRASOUND, INCLUDING TOPICAL APPLICATION(S), WHEN PERFORMED, WOUND ASSESSMENT, AND INSTRUCTION(S) FOR ONGOING CARE, PER DAY.	$450 per Treatment up to 18 Treatments		$188	$20
11042	DEBRIDEMENT, SUBCUTANEOUS TISSUE (INCLUDES EPIDERMIS AND DERMIS, IF PERFORMED); FIRST 20 SQ CM OR LESS.	$60		$125	$58
11043	DEBRIDEMENT, MUSCLE AND/OR FASCIA (INCLUDES EPIDERMIS, DERMIS, AND SUBCUTANEOUS TISSUE, IF PERFORMED); FIRST 20 SQ CM OR LESS.	$160		$225	$148
11044	DEBRIDEMENT, BONE (INCLUDES EPIDERMIS, DERMIS, SUBCUTANEOUS TISSUE, MUSCLE AND/OR FASCIA, IF PERFORMED); FIRST 20 SQ CM OR LESS.	$340		$301	$217
11045	DEBRIDEMENT, SUBCUTANEOUS TISSUE (INCLUDES EPIDERMIS AND DERMIS, IF PERFORMED); EACH ADDITIONAL 20 SQ CM, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE).	$27		$39	$24
11046	DEBRIDEMENT, MUSCLE AND/OR FASCIA (INCLUDES EPIDERMIS, DERMIS, AND SUBCUTANEOUS TISSUE, IF PERFORMED); EACH ADDITIONAL 20 SQ CM, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE).	$75		$70	$53
11047	DEBRIDEMENT, BONE (INCLUDES EPIDERMIS, DERMIS, SUBCUTANEOUS TISSUE, MUSCLE AND/OR FASCIA, IF PERFORMED); EACH ADDITIONAL 20 SQ CM, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE).	$115		$117	$93
97597	DEBRIDEMENT (e.g.: HIGH PRESSURE WATERJET WITH/WITHOUT SUCTION, SHARP SELECTIVE DEBRIDEMENT WITH SCISSORS, SCALPEL AND FORCEPS), OPEN WOUND, (e.g.: FIBRIN, DEVITALIZED EPIDERMIS AND/OR DERMIS, EXUDATE, DEBRIS, BIOFILM), INCLUDING TOPICAL APPLICATION(S), WOUND ASSESSMENT, USE OF A WHIRLPOOL, WHEN PERFORMED AND INSTRUCTION(S) FOR ONGOING CARE, PER SESSION, TOTAL WOUND(S) SURFACE AREA; EACH ADDITIONAL 20 SQ CM, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE).	$35		$98	$35

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As with all coverage claims, individual physicians and facilities are responsible for exercising their independent clinical judgment in selecting the codes that most accurately reflect the patient's condition and the services provided to a patient. Healthcare providers are encouraged to contact the individual Medicare contractor, carrier, fiscal intermediary or other third-party payers, as needed.

Training and Use of Equipment

The device is easy and intuitive to operate. There are only two main requirements for use of the equipment: (1) the medical professional is authorized by the facility to do wound management and (2) earn Arobella's QWTS Certification which only takes a few hours and is a hands on training with the equipment. Training will cover use of the equipment, proper maintenance, and sterile handling procedures. These should fit within and address your Hospital Acquired Infections Policies. A certificate will be provided. An onsite training program is provided as part of the equipment purchase.

Warranties & Service

Our warranty packages cover all wear and tear of the equipment. If there are any issues with your equipment, you will have a loaner system within two business days of notifying us.

	AR1000 - Extended Warranty
1 Year	$4500 for One Year
2 Year	$3500 per Year for Two Years
3 Year	$3000 per Year for Three Years
Generator	Yes
AC Cord	Yes
Foot Pedal	Yes
Hand Pieces	Yes
Wrenches	Yes
Tips	Yes
Shrouds	Yes

TREATMENT AREA (cm²)	TREATMENT TIME Tx (minutes)
<10	1
10-20	1
20-30	1
30-40	1
40-50	2
50-60	2
60-70	2
70-80	2
80-90	3
90-100	3
100-110	3
110-120	3
120-130	4
130-140	4
140-150	4
150-160	4
160-170	5
170-180	5
180-190	5
190-200	5

Day 37 → Day 96 → Day 183

QWTS was used in a difficult case to aid in the healing process and help the patient salvage the limb.

CASE STUDY 2

Graft Bed Preparation

Demonstration that wound bed can be prepared for Apligraf, resulting in improved taking of the graft.

COST-BENEFIT ANALYSIS

minute off, one minute is returned to the timer. Many treatments are delivered within that eight minute window.

Our financial model is available upon request and can be modified to individual facility needs. Competitor comparison analysis is available upon request.

[2] Approaching it this way, if there is a good ROI under each scenario, then the business model will be seen more quickly.

Arobella's Unrivalled Expertise

We have maintained this position from the beginning, that we understand ultrasound better than anyone else. Dr. Eliaz Babaev has over 45 years of professional experience with ultrasound. Very few if any academic institutions in the USA conduct any exploratory research on Ultrasound. Dr. Babaev has earned a PhD in Biomedical and Mechanical Engineering, focused on ultrasound and the biomechanics of the body. He went on to receive two additional Doctorate of Science Degrees, one in Biomedical Engineering and the other in Biomedical Instrumentations and Biomechanics. With this background, he has developed many unique patented technologies throughout his career.

Best in Ultrasound™

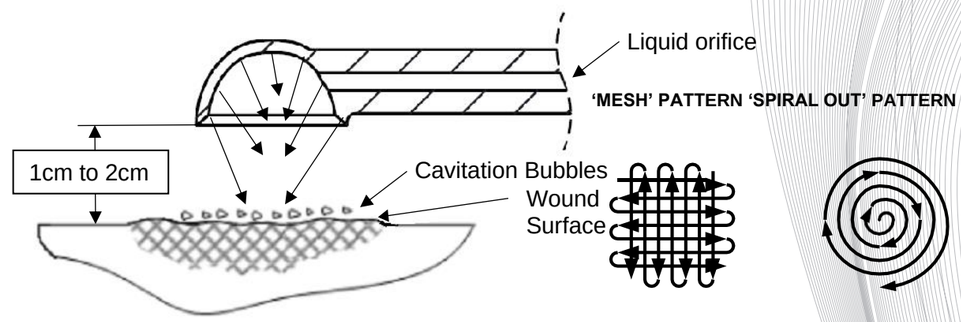
No Comparison

The physics behind ultrasound is a lot more complicated than just sending out a high frequency sound wave. There are lots of not well understood phenomena associated with ultrasound that even researchers and experts in the field may not understand or even know exist. Because of Dr. Eliaz Babaev's lifelong research and pursuit to understand ultrasound, he has cataloged this better and more extensively than anyone else in this space. Because of this, Arobella is delivering results where others are failing.

Arobella Medical, LLC
Sound Touch for Wound Care™
952-345-6840 | www.arobella.com

LIGHT GUIDANCE CONTACT WITH TISSUE OR HOVER (NONCONTACT) OVER TISSUE

KEEP SPACE BETWEEN WOUND/TISSUE AND APPLICATOR TIP ONE cm to TWO cm



CODING & PAYMENT

Coding & Payment Quick Reference Select Wound Care Procedures

The Qoustic Wound Therapy System™ is indicated for producing and delivering low frequency ultrasound used to promote wound healing via:

- Selective and non-selective dissection and fragmentation of soft and/or hard tissue
- Surgical, excisional or sharp-edge wound debridement (acute and chronic wounds, burns) for the removal of nonviable tissue including but not limited to diseased tissue, necrotic tissue, slough and eschar, brin, tissue exudates, bacteria and other matter
- Site cleansing irrigation and lavage of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue)
- Contact and/or non-contact maintenance debridement for the removal of debris, exudates, fragments, bacteria, slough, brin, excised or fragmented tissue, and other matter
- Preparing the wound bed for graft or other subsequent procedures using contact and/or non-contact techniques to achieve wound debridement

It is prescribed for patient population of any age with one or more wounds and/or that may also exhibit Diabetes Mellitus (DM).[1]

[1] FDA 510(k) clearances K062544, dated January 3, 2007 and revised July 2, 2009, and K131096, dated May 16, 2014.

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[3] Payment amounts shown for Medicare National Average 2016 Physician Fee Schedules (MPFS) and Medicare Hospital Outpatient Ambulatory Payment Classification (APC) National Average Benchmarks are not a guarantee of payment.