IMAGE GUIDED PERFORMANCE STUDY OF PEMF TECHNOLOGY EFFECTS WITH HIGH RESOLUTION 3D ULTRASOUND

Clinical performance test report by:

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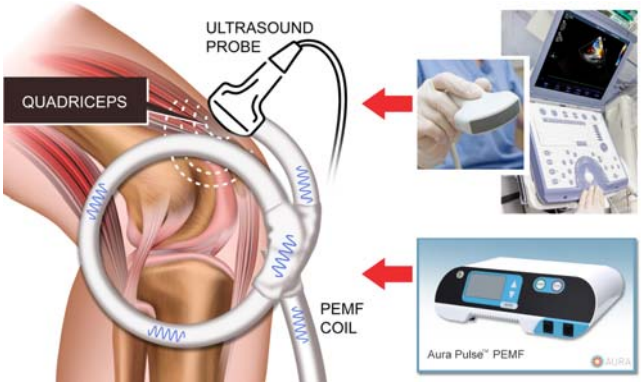
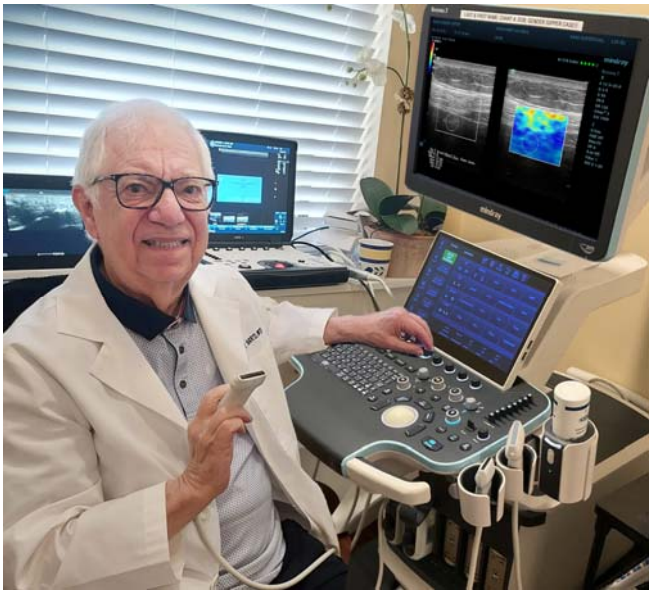
IMAGE GUIDED PERFORMANCE STUDY OF PEMF TECHNOLOGY EFFECTS WITH HIGH-RESOLUTION 3D ULTRASOUND

This report covers a private single study and efficacy review launched on August 18, 2023. The study explores biometric response of PEMF induction through the use of high resolution 3D imaging of the Aurawell PEMF (Aura Pulse model). ONE clinical participant was pre-qualified, then exposed to PEMF treatment to the QUADRICEPS muscle area for a given period of time and under a given frequency. The clinical imaging specialist employed various applications of a medical-grade ultrasound to monitor any visible muscle reaction during the time and area where the bio-energy treatment was applied.



TECHNICAL REVIEW

QUANTITATIVE IMAGING TO MONITOR THERAPEUTIC RESPONSE

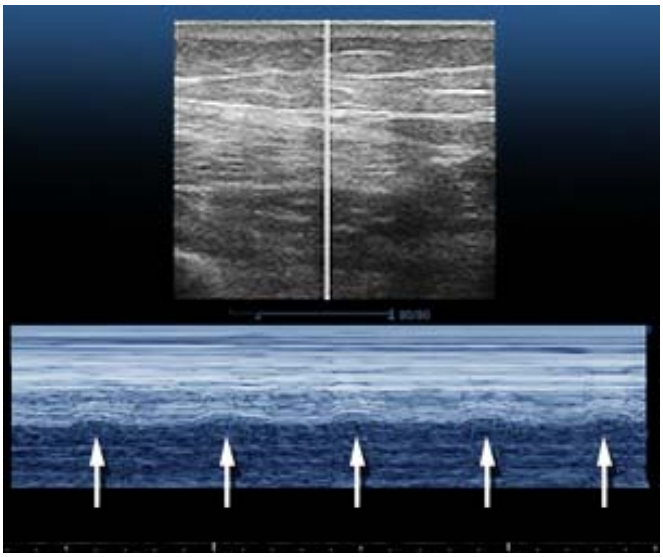


To date, the ultrasound's ability to evaluate abnormalities within the soft tissue such as cysts, tumors and inflammation is used to help identify an expanded set of pathologies in the body. Since the early 1970's, Dr. Robert L. Bard (NYC Cancer Radiologist) has used diagnostic imaging for pre and post procedural guidance. He is also recognized for his use of ultrasound in pharmaceutical research and clinical trials, where his leadership in analytical interpretation is sought after worldwide for identifying markers and therapeutic efficacy.

Dr. Bard has employed this imaging strategy to monitor and confirm the body's reaction to a variety of therapeutic interventions. He has joined in double-blinded, corporate sponsored and private studies as well as non-invasive therapeutic interventions in studies of neuro-stimulation, electrostimulation and electromagnetic field treatments. His approach involves the comparative study of measurable scanning data or quantitative ultrasound (QUS) which aims at recording interactions between the behavior and activity of biological tissue microstructure and ultrasound waves. Dr. Bard applies the use of BLOOD FLOW DETECTION TECHNOLOGY OR HEMODYNAMIC DATA gathering protocols, document specific objective and quantifiable biological responses to therapeutic treatments.

For this study of treating and scanning the quadriceps muscle, diagnostic imaging captures measurable data about the effects of any area (including any inflamed area). Widely preferred scanning modalities include the Doppler Blood Flow Ultrasound (or sonography) and Elastography, both using high-frequency sound waves to view inside the body. Like an internal video camera, these high speed scanning innovations capture actual function of the body's internal organs. The ultrasound's ability to evaluate abnormalities within the soft tissue in research and clinical trials are widely used in recording evidence-based biomarkers to trace therapeutic efficacy.

PHASE 1: PREFLIGHT EXPLORATORY MICRO-TEST



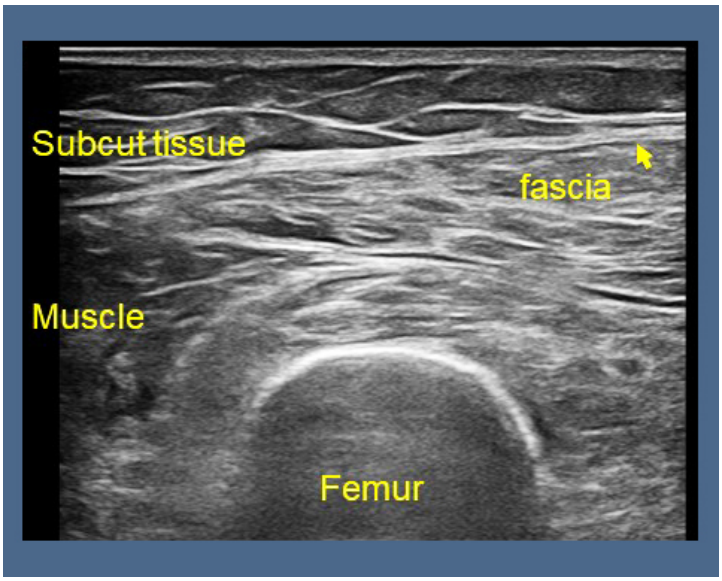
Prior to launching a comprehensive device performance test, Dr. Robert Bard (and his technical team) initiated a standard short term, preflight test phase. This standard, cost-effective one-scan measure is an exploratory pass-fail initiator of the given hypothesis. In this case, the client (AuraWell PEMF) requested recordings of any/all identifiable evidence of muscular activity as a result of the PEMF frequency induction.

Strategically, the research team proceeded by testing a lower-powered PEMF model (first) called the **NOVA-HD** to adequately challenge the sensitivity of the ultrasound scanner(s) used in this energy induction study. Upon treatment, the imaging technician simultaneously scanned the target muscle with B-mode high resolution ultrasound. Adjusting the PEMF device's power level from 1-10, the M-mode echocardiography transducer was activated and recorded the intrinsic contraction timed to the pulse frequency.

To validate results of physiological intervention, this study is designed to detect tissue/muscular motion. This is to be noted as intrinsic to MUSCULAR CONTRACTION and NOT MUSCLE MOTION. The imaging team employed the intrinsic echocardiogram feature called M-mode (or motion mode) to verify that the muscular contraction is occurring in the area under investigation. Echocardiographic technology is widely used to track delicate motion of the heart, muscle and valves. Echocardiographic analysis is recognized as the most delicate way of showing (the slightest) motion. For this, we elected to target the quadriceps muscle that was able to offer visual results when the low-powered electromagnetic pulse was activated. Experience and research indicated the muscle composition of the quadriceps has been widely studied for validating effects of other muscle therapeutic solutions (ie. neurostim, shockwave, cold laser etc).

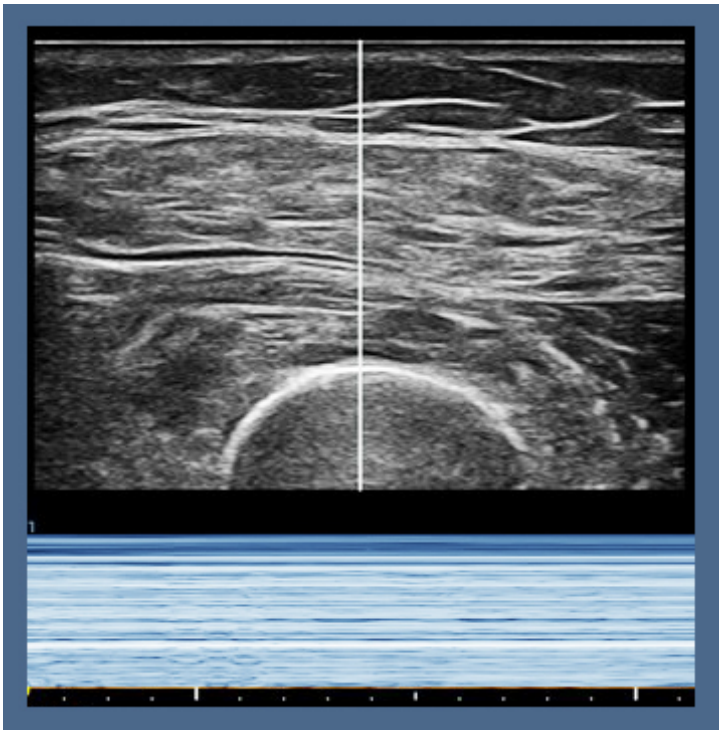
This exploratory phase is the pre-flight test necessary to determine whether or not to deploy a full performance study. Capturing enough evidence such as an indication of response would dictate the execution of a more comprehensive study and clinical review. The response from this initial test showed immediate positive results (see scan diagram above, showing echocardiogram signal irregularity to pulse frequency). Tissue motion is reported as being intrinsic to the pulse stimulus in the quadriceps muscle that was scanned in real time. By this micro-test, we can conclude recordable and visible muscle reaction to the pulse electromagnetic waves from this NOVA HD. This report also extrapolates similar recordable reaction to exposure from the AURA PULSE (same brand with vastly more powerful model) to result in a similar, if not more significant effects.

PHASE 2: COMPREHENSIVE PERFORMANCE REVIEW OF THE AURA PULSE MODEL



Scan #1 of 6: PRE-TREATMENT SONOGRAM (Pre Quad) - Baseline 8/18/2023 12:59:49pm

This is a pre-treatment scan using medical-grade ultrasound probe at 14 MHz frequency with 12 cm penetration and axial resolution of 0.5 mm. Conducted is a transverse scan of the quadriceps muscle. The top set of lines (labeled subcutaneous tissue). Directly underneath this is the fascia located between the subcutaneous fascia and the curved white bony femur outlined on the bottom is the interdigitating muscle fibers that form the four tendons of the quadriceps near the patella.



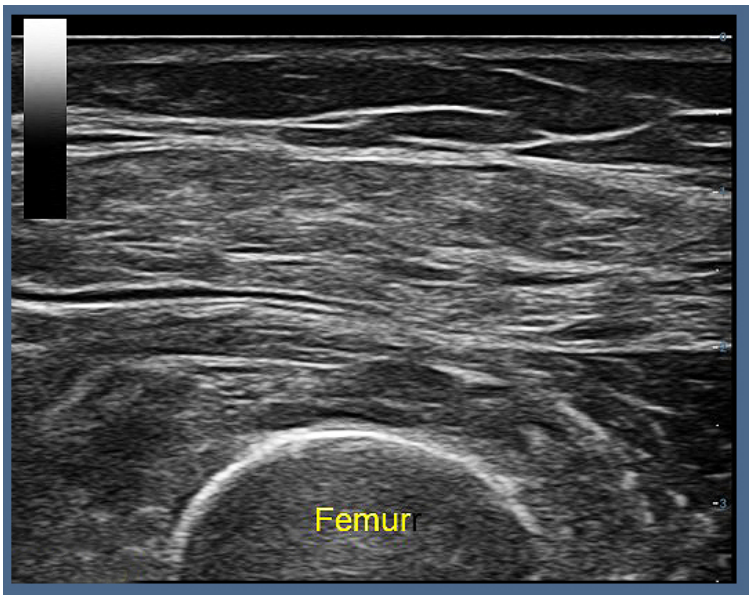
Scan #2 of 6: M-MODE ECHO-CARDIOGRAPHY (Pre Quad) 8/18/2023 1:05:39pm
Real-time scan DURING PEMF exposure

To document motion changes induced by the pulse electromagnetic pulsations, we elected to use the motion mode setting that is originally used for echocardiography to demonstrate the subtlest movements in the muscle tissue inside the heart. The M-Mode line is seen as a white band that goes from the skin surface right down and through the curved bony portion of the femur. The graphic below the scan shows a steady band of horizontal lines without any motion or any change indicating that there is no contractility or motion present in the resting muscle.

- over -

Scan #3 of 6: DOPPLER/ No Flow in Box
8/18/2023 1:01:21 pm

Above the level of the femur, our utility area (box) indicating a flow descriptor where our scanner is looking for arterial or venous blood flow. Notice the color bar on the top left showing directional flow where red is flow towards the probe and blue is flow away from the probe in the box. We see NO indication of color or evidence of any vessels with even the lowest blood flow representing dilation in response to the energy being induced. Hence, we are ruling out using the 3D Doppler Blood Flow feature of the ultrasound (we see NO blood flow or N0 Vessel dilation). This indicates extremely low velocity that is not appearing in hemodynamic readings.



Scan #4 of 6: TREATMENT POWER 10/20
8/18/2023 01:05:39 pm

With the power/frequency setting of 10/20, we employed the circular transducer (probe) around the quadriceps in a 360 degree configuration. The motion of the muscles above this bony femur is seen to have changed from its ovoid appearance into something with a midline central contraction due to the energy transfer to and within the quadriceps muscle.

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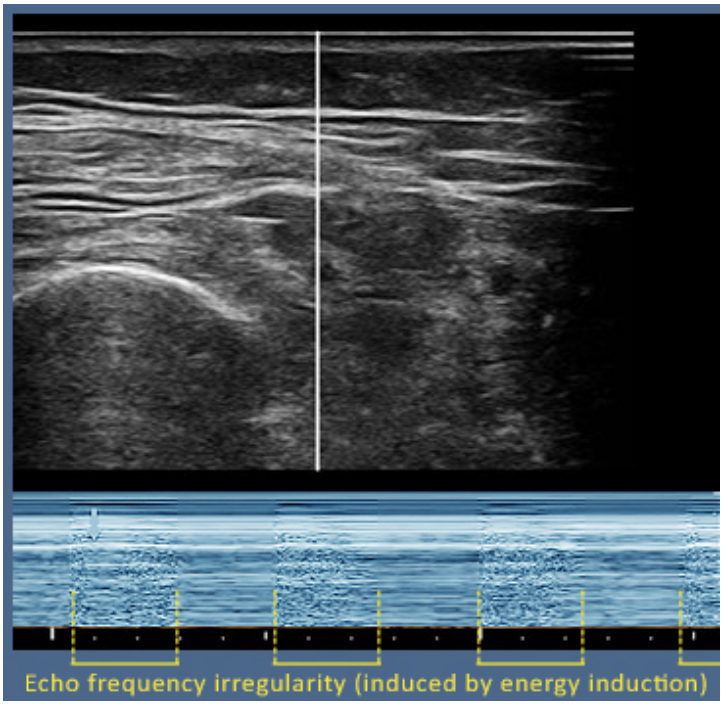
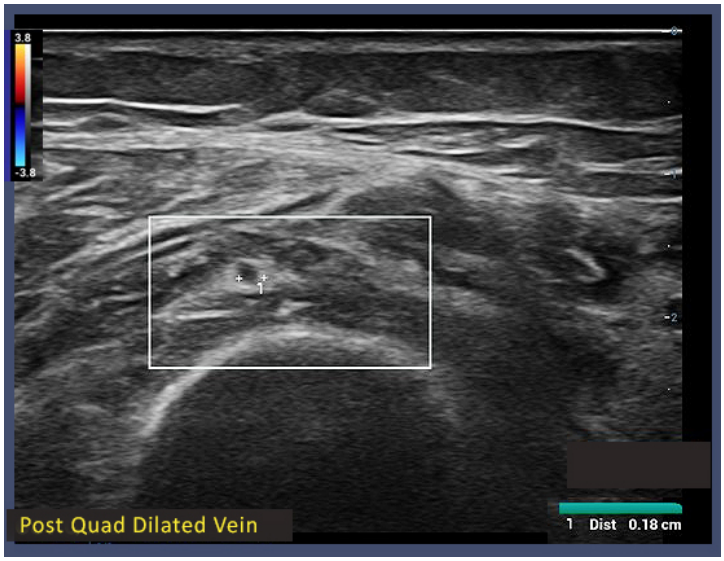


Scan #5 of 6: M-MODE – PHASIC PULSATILITY NOTED
8/18/2023 01:06:56 pm

Notice the white line in the center of the twitching muscle that translates into the transverse linear tissue and contracting muscle fibers as pointed out by the arrow at the initial pulse that reaches the muscle.

Below are brackets of motion artifacts that transform the uniform, linear, horizontal lines into an unrecognized pattern of interrupted lines indicating the energy transfer and motion occurring within the muscle structure. The yellow brackets indicating pattern interruptions of muscle stasis showing visible evidence of the energy frequency induction from the PEMF.



Scan #6 of 6: DOPPLER FLOW BOX
1.8mm VENOUS DILATION 8/18/2023 01:11:46 pm

Measurement of a dilated vein is visually represented in the doppler flow box (center of screen) of the treated area between the fascia and the bone showing a dilated vein that was previously not present during pre-treatment. The vein measures 1.5 by 1.8mm, and the dilatation implies blood flow of such small magnitude that it doesn't appear as a color on the registration index because the blood flow is too low. However, the dilating veins indicate a vascular response to the energy input. The 2 (+) marks are measurement indicators of the vein at 1.8mm. This is the vein that appeared during the PEMF exposure.

CONCLUSION: During the pre-treatment (at-rest) phase, there is no identifiable venous dilatation or blood flow. There was no muscular contractility detected by the ultra-sensitive cardiac motion mode technology. Following a treatment at half power (10 out of 20) we can visibly and quantifiably identify that small veins are beginning to dilate and that the contractility of the tissue being energized is appearing as pulse vibrations in the form of the undulating surface line of the muscle. Measurements of change in the internal motion of the muscle fibers are outlined by the brackets (slide 5) immediately during bioenergy/electromagnetic exposure. This phase 1 test was designed to capture preliminary and evidential data of IMMEDIATE muscle/physiological reaction to energy induction therapy. Upon further review of this quantifiable evidence and the physiological behavior of the musculature, one can extrapolate more venous dilatation and more visible blood flow activity if/when more treatment time is provided.