CURESOUND

Technology Abstract

November 2019

Overview

If sound wave passes through a liquid or solid medium, with a suitable frequency and intensity that fits the impedance of the medium, it will cause an oscillation of the medium.

Therapeutic ultrasound is widely known because it has been used in medicine for over six decades. Despite its widespread use, ultrasound has a significant drawback in terms of therapeutic efficacy - it loses its effectiveness within a few minutes into a treatment session.

The key reason behind the rapid decline and loss of efficacy is that the treated tissue changes its impedance which results in cessation of the vibration effect that renders the penetration efficacy to null.

A comprehensive Review of ineffectiveness of Therapeutic Ultrasound (*Physical Therapy*, Volume 81, Issue 7, 1 July 2001, Pages 1339–1350,) was conducted by Velama J Robertson and Kerry G Baker, which conclusion is provided herein:

> *"… Therapeutic ultrasound is one of the most widely and frequently used electrophysical agents. Despite over 60 years of clinical use, the effectiveness of ultrasound for treating people with pain, musculoskeletal injuries, and soft tissue lesions remains questionable. This article presents a systematic review of randomized controlled trials (RCTs) in which ultrasound was used to treat people with those conditions. Each trial was designed to investigate the contributions of active and placebo ultrasound to the patient outcomes measured. Depending on the condition, ultrasound (active and placebo) was used alone or in conjunction with other interventions in a manner designed to identify its contribution and distinguish it from those of other interventions.* ***Methods.*** *Thirty-five English-language RCTs were published between 1975 and 1999. Each RCT identified was scrutinized for patient outcomes and methodological adequacy. Results. Ten of the 35 RCTs were judged to have acceptable methods using criteria based on those developed by Sackett et al. Of these RCTs, the results of 2 trials suggest that therapeutic ultrasound is more effective in treating some clinical problems (carpal tunnel syndrome and calcific tendinitis of the shoulder) than placebo ultrasound, and the results of 8 trials suggest that it is not.* ***Discussion and Conclusion.*** *There was little evidence that active therapeutic ultrasound is more effective than placebo ultrasound for treating people with pain or a range of musculoskeletal injuries or for promoting soft tissue healing.*

Prior to the introduction of Muscle Stimulator therapy in the mid 1950's, low frequency stimulation was reported to be used for pain relief, muscle re-education and other treatment protocols. These legacy methods have not overcome the barrier of human skin's relatively high impedance to such frequencies. In order to overcome is barrier a larger voltage has to be used resulting in an unacceptable increased patient discomfort. In addition, the legacy methods suffered from poor penetration depth.

At 50 Hz (faradic current) the impedance for a 100 cm2 of human skin is approximately 3,000 ohms. At 4000 Hz (medium frequency) the skin impedance of the same area is around 50 ohms. This means that a much lower voltage current can be used to produce the desired effect resulting in reduced skin sensitization and a far more comfortable treatment.

CureSound is the first and only treatment technology (to the best of our knowledge) that solves the penetration problem. Ultrasound is the therapeutic component used by CureSound, but we have made it effective

We discovered that specific application of electric field stimulation (EFS) to the ultrasound treatment area creates complete effectiveness of the ultrasonic energy for the entire duration of a treatment session.

Impedance is the lock; Electrical field stimulation is the key

The electric field manages the bio-impedance which keeps the gateways open, allowing the full ultrasonic energy to reach the affected tissue. The complex algorithms in our patented software automatically adjusts the electric field, keeping the gateways clear even as the impedance changes

Synchronization solves the penetration problem

The electrical field in the treatment area, which counteracts the body's bio-impedance and "packing" of the tissue by the ultrasonic waves, keeps the gateways open, allowing full penetration and effectiveness of the ultrasound therapy.

CureSound has developed a sustainable solution overcoming legacy barriers to efficacy of the ultrasound treatments.

With CureSound, we significantly increase the amount of ultrasound energy reaching the target area. As a result, the sound wave travelling through the medium causes excitation of the target tissue molecules (increased vibration patterns) which in turn vibrates the tissue to the resonance range which increases blood flow and enhances tissue fluid interchange which is the primary cause of the CureSound therapeutic effect.

We incorporated into our patented Algorithm an integrated Software for Patient management and Measurement as well an advanced software and data saving solution. The system includes an integrated camera, which can efficiently store patient data and results. The touch screen application enables the input of detailed patient data, including specific details. All data is saved for improved patient management and is secured using advanced privacy tools.

Our Standards Compliance and Technical Specifications

ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text) “Medical electrical equipment. Part 1: General requirements for safety and essential performance”

IEC 60601-2-5:2009 Medical electrical equipment. Part 2-5: Particular requirements for the safety of ultrasonic-physiotherapy equipment” 21 CFR 1050.10

IEC 60601-2-10 Edition 2.0 2012-06 “Medical electrical equipment. Part 2-10 Particular requirements for the safety and essential performance of nerve and muscle stimulators.

ISO 14971:2007 “Medical devices – Application of risk management to medical devices” including residual risks evaluation.

IEC 60601-1-6 Edition 3.1 2013-10 “Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability”

IEC 60601-1-8:2006 & A1:2012 “Medical electrical equipment. Part 1-8: General requirements for basic safety and essential performance– Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems”

IEC 60601-1-2: 2007 /AC: 2010 “Medical electrical equipment. Part 1-2: Electromagnetic compatibility – Requirements and tests”

IEC 62304 Edition 1.1 2015-06 “Medical Device Software Development”

ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes

Power source	AC Line
Power input	90-264 VAC, 50-60 Hz
Method Line current isolation	Yes
Operating temperature	+50^{o}F to +104^{o}F
Humidity	Operating, 30% to 75% RH (not condensed) Storage, 20% to 80% RH (not condensed)
Storage temperature	40^{o}F to 167^{o}F
Indicator display On/off status	Yes
Treatment timer	Treatment time counts down to zero when time is set
Timer Accuracy	± 0.5 seconds for all times range

Number of electric field channels	2
Software control	Yes
Automatic overload trip	Yes
Insulation	BF
Patient override control	Yes
Maximum Treatment Time	30 minutes - ultrasound or combination therapy 30 minutes – electric field
Treatment Timer	Treatment time counts down to zero when time is set, or up to 30 minutes when no time is set. The digital timer indicates the remaining or elapsed treatment time during the 'Hold' period.
Power indicator	Yes
Operational indicator	Yes
Transducer	4 cm^2 transducer
Frequencies	1.0 MHz to 3.0 MHz
Modes	Continuous
Maximum output power	8 W with at 4 cm^2 applicator
Maximum intensity	2.0 W/cm^2 Cavitation occurs above 2.2 W/cm^2
Indication Accuracy	±20% (for any level above 10% of maximum
Treatment head dimensions	D4.5x 15.5cm
Transducer contact face Biological evaluation	303 stainless steel
Contact Monitor	Light on transducer
Frequency	1.0 MHz to 3.0 MHz
Beam type	Collimated
Effective Radiating Area ERA	4 cm^2±10%

Maximum Beam Non Uniformity Ratio BNR	<5
Maximum patient contact surface temperature of treatment head under simulated	Continually operated for maximum treatment time - 32.1°C Under simulated use conditions
Ultrasound Timer range	0 - 30 min
Automatic shut off	Yes
power level indicator display	Yes
Contact Monitor	Yes
Output waveforms	Electric Field 2 channels
Treatment timer	1-30 minutes±1%
Automatic shut off	Yes
Current level indicator display	Yes
Channel(s)	2
Synchronous or alternating output channels	Synchronous
Electric Field Max Output Current (mA)	0-65±10% mA RMS, max 1Kohm load
Electric Field Max output Voltage (V)	0-65v ±10% volts RMS, 1Kohm load
Electrode size	Round, 2 inch diameter
Maximum current density (2 inch dia)	3.2 mA/cm^2 at 500Ω 3.2 mA/cm^2 at 1kΩ 1.33 mA/cm^2 at 2kΩ 0.08 mA/cm^2 at 10kΩ
Maximum power density	0.195 W/cm2 at 500kΩ ≤ 0.25 W/cm^2 0.208 W/cm2 at 1kΩ ≤ 0.25 W/cm^2 0.074 W/cm2 at 2kΩ ≤ 0.25 W/cm^2 0.0012 W/cm2 at 10kΩ ≤ 0.25 W/cm^2
Compliance with 21 CFR 898	Yes
Electrode Housing materials and construction	No
Beat frequency PPS	1 – 250 Hz in 5Hz increments

Output Displays	Two simultaneously, amber channel active indicators
Channel Isolation	Yes Transformer isolated
Automatic No Load Trip	Yes
Control Method	On/Off
Max Leakage Current (µA)	Chassis <100 Electrodes <100
Patient leakage current (µA)	Normal condition – 0.004 µA Single fault condition – 0.014 µA
Indicator Display Unit Functioning	Yes
Net charge	No
Maximum phase charge (µC)	8.9 µC