

# CAVITAT™ Ultrasonograph

Received.....1/30/04 Scientific Review.....2/8/04 IAOMT Board Review.....3/25/04 Reevaluation..... 7/24/05	<b>Scientific Review                  Root Canals &amp;                  Cavitations</b>	<b>Approval.....3/25/04</b> Provisional Approval No Opinion No Approval
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**Explanation of IAOMT position:** In the next paragraph the applicant request that the Cavitat Ultrasonograph be also approved as an IAOMT Standard of Care. The IAOMT fully appreciates the true value of the Cavitat Ultrasonograph. However IAOMT Approval as a Standard of Care in addition to the Scientific Review could place the membership in legal jeopardy if the Cavitat Ultrasonograph is **not** used below by a member for those purposes. With this in mind, the IAOMT fully supports the use of this technology for the reasons described below. The IAOMT encourages anyone doing these procedures to seriously consider using the Cavitat Ultrasonograph but at this time the IAOMT must be cautious in defining this as a Standard of Care.

**Applicant’s Request:** It is recommended that the CAVITAT™ Ultrasonograph be an approved **Scientific Review and Standard of Care of the IAOMT** for the following reasons:

1. The device is used to determine the general health of the jawbone before any dental procedure is done.
2. The incidence of necrotic bone lesions is estimated in the general population to be from 40% to 80%. Utilization of this technology would reduce the failure rate of dental procedures performed on ischemic bone, which is currently estimated to be 40%. Necrotic bone tissue is reported to give off toxins that can affect the general health as well as the integrity of dental health. When used in conjunction with a panograph, detection and diagnosis of jawbone lesions approaches 98 to 100% in accuracy. X-rays alone show 27% at best and only when 60% or more of the cortical bone is destroyed.
3. The results of Cavitat™ testing should be evaluated with the panograph as this provides a higher percentage of accurate diagnosis than either procedure alone. The dental professional can now accurately select or rule out appropriateness of certain dental procedures for patients seeking restorative or reconstructive dental procedures.
4. Diagnosis of necrotic jawbone can also benefit the medical professional as this diagnosis provides the potential cause of chronic illness whose etiology is unknown and the illness cannot otherwise be explained. It opens a new avenue of investigation for the physician and the opportunity to work with the dental professional to assist the patient in recovery of health.

1. The CAVITAT™ Ultrasonograph provides:

- A) An ultrasound-based 3-D color image of the alveolar process of the maxilla and mandible.
- B) An extremely accurate quantitative analysis of the alveolar process.
- C) Real-time and 3-D image of each tooth site that can be moved vertically or mesial/distal to scan a larger area while in use, and the image can also be rotated, zoomed in or zoomed out to better evaluate the total condition of the bone.
- D) Detection and precise measuring of low bone density to aid medical professionals in diagnosing areas of possible concern before a dental procedure such as an implant or root canal.
- E) Color coded images that distinguish the intensity of destruction:
  1. Red = significant bone loss and density
  2. Yellow = moderate bone loss and density
  3. Green = no bone loss.
- F) Capable of detecting jawbone defects from 1 millimeter and up in size

2. Benefits:

- A) Information can be read and interpreted immediately
- B) Quick and thorough scanning of the entire jawbone
- C) Real time digital scanning
- D) No radiation
- E) Very user-friendly
- F) Low cost operation, uses no chemicals or film
- G) Mobile

No other imaging device has been able to match the accuracy of Cavitat™. X-rays show 27% at best and only when 60% or more of the cortical bone is destroyed. The CAVITAT™ Ultrasonograph when used in conjunction with a panograph will provide 98 to 100% of the information needed for an accurate clinical diagnosis allowing the practitioner to confirm or rule out suspect areas that cannot be clearly imaged by x-ray alone.

It is the only instrument designed exclusively for quantitative bone analysis.

<b>Name of Scientific Review:</b> CAVITAT™ Ultrasonograph
<b>Alternative name(s) of Scientific Review:</b> Ultrasonographic imaging of jawbone to detect low jawbone bone density
<b>This Scientific Review is related to</b> Medicine & Dentistry
<b>This Scientific Review is</b> Equipment
<p><b>Purpose of the Scientific Review:</b> This equipment is used for:</p> <ol style="list-style-type: none"> <li>1. Detection of low bone density in the jawbone. It provides an ultrasound-based 3-D image of the alveolar process of the maxilla and mandible. It performs a quantitative analysis of the alveolar process.</li> <li>2. To better evaluate the total condition of the jawbone by precisely measuring necrosis of the jawbone to aid medical professionals in diagnosing Bone Marrow Edema Syndrome, Neuralgia Inducing Cavitational Osteo-necrosis, Osteomyelitis and Periodontal Pockets of the Buccal Bone.</li> </ol> <p>The latest scientific studies have proven these lesions to be highly neurotoxic (reference website: <a href="http://www.testfoundation.org">www.testfoundation.org</a>). These toxins inhibit protein and enzyme absorption essential for all cellular functions contributing to or inducing systemic cellular disease.</p>
<p><b>Scientific Review History:</b> The CAVITAT™ was developed by Bob Jones, a former pilot, who suffered from an extremely severe, debilitating osteonecrosis of multiples sites in his jawbone.</p> <p>Initially, the inventor developed a transducer, a device that sends sound waves through the jawbone at an ultrasound wave strength determined to be effective and then a digitized array was developed that is capable of interpreting the strength of the signal after it has passed through the bone.</p> <p>Once the signal data is acquired, it is sent to a computer that converts the signal to a digital perspective 3-D color image. User-friendly software was developed to operate and convert the signals from analog to digital (WIN/CAV) in order to project the color image to the computer screen. All components of the Cavitat™ are patented by the inventor</p>
<p><b>A brief description of the Scientific Review</b> Initial research was done at New Mexico Institute of Mining &amp; Technology, Socorro, New Mexico, on pigs' jaws and confirmed that the ultrasound wave strength frequency was the proper setting to image accurately and safely. Following this research, CAVITAT™ Medical Technologies, Inc. was established to take this revolutionary imaging system through testing and into production. The Generation 3 field model of the CAVITAT™ Ultrasonograph was built and used for several years by doctors who participated in independent clinical trials under the administration of Dr. Jerry Bouquot of The Maxillofacial Center for Diagnostics &amp; Research, Morgantown, West Virginia. Using the data obtained from clinical trials, a Generation 4 production model was built and sold to doctors as a custom built system.</p> <p>Data from clinical trials and Dr. Bouquot's study was presented to the FDA for full review with the 510(k) application. Although not normally required in the FDA 510(k) process, CAVITAT™ Medical Technologies, Inc., prepared and submitted in excess of 12,000 scans, biopsies and panos to the FDA as supporting evidence. Dr. Bouquot personally took in excess of 900 scans and supporting data to the FDA where 392 were randomly selected and reviewed by the FDA committee. The CAVITAT™ legal team commented that this was the largest amount of research data ever presented to the FDA, to their knowledge, for a dental device for a 510(k) clearance.</p> <p>The FDA requires the scan be a prescription item. The FDA designated the instrument as an Ultrasonograph and listed it as a Class II device with no restrictions on marketing.</p>
<p><b>A specific description of this Scientific Review:</b> Contact the manufacturer for specific directions of use which would be part of training with the equipment purchase</p>
<p><b>Manufacturer(s) &amp; Distributer(s):</b> CAVITAT™ Medical Technologies, Inc. is the manufacturer/distributor, 10730 E. Bethany Drive, Ste. 112, Aurora, Colorado 80014, (303) 755-2688, FAX (303) 755-2699 <b>Website:</b> <a href="http://www.cavitat.com">www.cavitat.com</a>.</p>

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**Scientific Literature:** *Medullary and Odontogenic Disease in the Painful Jaw: Clinicopathologic Review of 500 Consecutive Lesions*, The Journal of Craniomandibular Practice, October 2002, volume 20, Number 4.

Published abstracts relative to Through-transmission Alveolar Ultrasonography (TAU) as of September 19, 2002.  
More information at [www.maxillofacialcenter.com](http://www.maxillofacialcenter.com), (click osteonecrosis), as follows:

1. Bouquot, W, Martin, G, Wroblewski. Computer-based thru-transmission sonography (CTS) imaging of ischemic osteonecrosis of the jaws – a preliminary investigation of 6 cadaver jaws and 15 pain patients. Oral Surg Oral Med Oral Pathol Oral Radiol Endo 2001; 92:550. Presented orally to the American Academy of Oral & Maxillofacial Pathology, Chicago, Illinois, April, 2001.
2. Bouquot J, Margolis M, Shankland W, Imbeau J. Through-transmission Alveolar Ultrasonography (TAU) – A new technology for evaluation of medullary diseases. Correlation with histopathology of 285 scanned jaw sites. Oral Surg, Oral Med Oral Pathol, Oral Radiol Endod 2002; 94:210. Presented orally to the American Academy of Oral & Maxillofacial Pathology, New Orleans, April, 2002.
3. Bouquot JE, Shankland WE II, Margolis M. Through-transmission alveolar ultrasonography (TAU) – new technology for evaluation of bone density and desiccation. Comparison with radiology of 170 biopsied alveolar sites of osteoporotic and ischemic disease. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2002; 93:214-215. Presented orally to the American Academy of Oral Medicine, Ft. Lauderdale, April, 2002.
4. Bouquot JE, Shankland WE II, Margolis M, Glaros W. Through-transmission Alveolar Ultrasonography (TAU) – new technology for detection of low bone density of the jaws. Comparison with radiology for 92 osteoporotic alveolar sites with histopathologic confirmation. J Oral Pathol Med 2002; 31:289-290. Presented orally to the 11<sup>th</sup> Biennial Congress of the International Association of Oral Pathologists, Singapore, August, 2002.
5. Bouquot, JE, Through-transmission alveolar sonography (TAU) – new technology for the evaluation of low bone density and ischemic disease. Correlation with histopathology of 339 scanned alveolar sites. This paper was presented to the American Academy of Oral and Maxillofacial Pathology, New Orleans, Louisiana, April, 2002.

*Jawbone Cavitations: Infarction, Infection & Systemic Disease*, Susan Stockton, MA; Townsend Letter for DOCTORS & PATIENTS – April 2002.

Margolis, Michael D. DDS, Candidate, Doctor of Integrative Medicine, Daniel F. Farrier, MD, CCN, Doctor of Integrative Medicine (CUIM), David S. Margolis, B.S., - Doctoral Thesis: *Accurate Detection of Jawbone Lesions and Osteolytic Abnormalities Using the CAVITAT™ Ultrasonogram Imaging System: A clinical Study Utilizing Photoaffinity Labeling and Histological Assessments*

**Legal Aspects of this Scientific Review:** The CAVITAT™ Ultrasonograph has the following clearances and certifications:

**Food and Drug Administration:** FDA Clearance #K011147 was granted February 15, 2002 with the following indication for use:

“Indications for Use: the CAVITAT™ Ultrasonograph CAV 40000-1 or CAV 40000-3 with WIN/CAV software (Release 1.05) provides an ultrasound-based, three dimensional image of the alveolar process of the maxilla and mandible as an adjunct to standard radiographic evaluation and clinical diagnostic procedures.”

Prior to review of data by the FDA, a third party designee of the FDA in California cleared the CAVITAT™ Ultrasonograph for its complete safety and efficacy – February 16, 2001.

**Health Canada:** CSA #37968; approved 5/17/02

**Federal Communications Commission:** FCC – 3/27/02

**Commission of Europe:** CE – 3/27/02

**Commission of Medical Europe:** CME –3/27/02

**Applicant Name:** CAVITAT™ Medical Technologies, Inc.

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