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PRINCIPAL INVESTIGATOR: Richard J. Littlefield

CONTRACTING ORGANIZATION: Battelle Pacific Northwest Laboratory
Richland, Washington 99352

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13. ABSTRACT (<i>Maximum 200 Words</i>) This report documents the fourth and fifth years of an ongoing project to develop a prototype 3-D ultrasound telemedicine imaging system. During the first year of the reporting period (FY98), development of a motor driven linear-scan version of the MUSTPAC-2 ultrasound system was completed. One unit of this type has been placed at the National Naval Medical Center (Bethesda, MD) for evaluation in a clinical environment, and a second (ruggedized) unit was sent with the NASA/Yale Everest Extreme Expedition for testing at Mt. Everest Base Camp (elev 17,500 ft). In addition, research and development was performed leading toward a freehand scan capability. In the second year of the reporting period (FY99), freehand scan capability was developed to a usable prototype level, and one unit of this type was placed at Georgetown University for evaluation. Efforts continued toward commercialization and routine use, resulting in a new project (at Mercy Hospital, Darby, PA), funded outside DARPA, to complete development of the freehand scan capability and obtain FDA 510(k) approval for MUSTPAC. Project DAMD17-94-C-4127 is essentially complete at this time, but is formally continuing under a no-cost time extension to allow NNMC further opportunity for their evaluation.				
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FOREWORD

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NA In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

N/A For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

NA In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

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NA In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Richard J. Littlefield 10/27/99
PI - Signature Date

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1. INTRODUCTION

The primary focus of this project is development of the MUSTPAC™ (Medical UltraSound, Three-dimensional, Portable, with Advanced Communications).

MUSTPAC™ is an ultrasound telemedicine system using 3-D volumetric data acquisition that allows a patient to be scanned at any convenient location by an operator with limited training and no ultrasound diagnostic skills, then have those scans analyzed by a diagnostic expert at a center of excellence at any location. This technology may have widespread application in both military and civilian rural and emergency healthcare, resulting in both improved quality of care and reduced costs.

2. BACKGROUND

Inexpensive, portable diagnostic imaging systems can play a key role in decreasing battlefield fatalities and reducing the cost of military health care. Ultrasound imaging is a particularly promising modality because it does not use ionizing radiation (unlike X-rays), does not require large heavy equipment (unlike magnetic resonance imaging), and has been shown through long use to be safe and effective when used by highly trained practitioners.

However, in current practice, ultrasound is basically an online two-dimensional (2-D) scanning procedure that produces a sequence of images under interactive hands-on control by the diagnostician. Each image represents a slice through the body at the corresponding ultrasound probe position. These images typically are difficult to interpret, requiring a trained ultrasonographer with years of experience to make more than the simplest diagnoses. This need for an expert interpreter makes it attractive to use ultrasound in a telemedicine setting, sending images from the patient's location to a skilled diagnostician somewhere else. However, with conventional 2-D ultrasound, considerable skill is required even to position the sensor probe, since this must be done interactively as diagnosis progresses. Thus it is problematic to use conventional 2-D ultrasound in a telemedicine setting, due to the need for a highly skilled operator to scan the patient.

Three-dimensional (3-D) ultrasound imaging offers the potential to overcome these difficulties, thus providing a diagnostically valuable, low-cost, real-time imaging modality suitable for operation and use under emergency conditions by non-specialists. Because 3-D volumes show more context than 2-D slices, it becomes easier for users to understand spatial relationships and detect abnormal conditions. Positioning the sensor so as to acquire useful images is also easier with 3-D, because volumetric data can readily be rotated and realigned to good viewing positions, largely independent of the original sensor position. This potentially allows useful 3-D ultrasound data to be taken by an inexperienced operator, then transmitted to and interpreted by a remote expert.

While 3-D ultrasound imaging has been investigated periodically for over 20 years, its adoption into routine use has been hindered by clumsy equipment, long image acquisition times, and the difficulties of visualizing the 3-D clouds of relatively noisy data produced by speckle and directional effects of ultrasound. However, recent advances in transducer array technology, computational hardware speed, and improved image reconstruction and visualization methods now appear sufficient to permit these obstacles to be overcome.

3. HISTORY OF THE PROJECT (FY95-97)

In early 1994, the above considerations prompted Battelle to submit to DARPA, in response to solicitation BAA94-14, a proposal titled "Real-Time High Resolution 3-D Ultrasonic Imaging for Physiological Monitoring". This proposal laid out the vision of a three stage effort, roughly 8 years in length, leading to the development of an imaging "bed", roughly 10,000 square centimeters in size, containing an array of high resolution ultrasonic transducers and providing real-time 3-D visualization of many physiological and anatomical structures.

The first stage of this vision, and the focus of the proposal, was a 3-year project to develop a field prototype Advanced IMaging System (AIMS). This prototype would consist of a lightweight, portable ultrasonic imaging system envisioned as containing a 5 cm by 5 cm two-dimensional transducer array, computer hardware and software for real-time 3-D holographic image reconstruction and visualization, and a stereovision headset

for 3-D image display. The system was envisioned as being used to rapidly detect foreign objects and bleeding in the body cavity, lungs, or extremities.

The Battelle proposal to develop an AIMS prototype was accepted by DARPA, and the project began in September 1994 with two major components:

- Research and develop advanced sensor technology, in particular, 2-D transducer arrays utilizing computational holographic focusing to acquire 3-D images in real time.
- Research and develop one or more fully functional prototype systems, suitable for clinical and/or field use, to investigate and demonstrate the utility of 3-D ultrasound as a medical imaging tool for use by non-specialist operators.

In early stages of the projects, it was planned that these two components would proceed sequentially, with the prototype system(s) being based on newly developed 2-D array transducers and thus appearing late in the project.

However, as the project progressed, it became apparent that a more productive strategy was to pursue both components in parallel, with prototype systems being based on currently available 1-D array transducer technology. This strategy was adopted in FY95, and research and development continued along both lines of research for the next three years.

In FY95, the primary activities and results were as follows:

- Sensor technology: Laboratory research using mechanically scanned simulations of 2-D transducer arrays confirmed that high quality images, fully focused everywhere in the 3-D field of view, could be obtained by using computational holographic focusing techniques in conjunction with large dense arrays (128x128) of high-frequency (5 MHz) transducers. However, the supporting electronics and computational requirements to use such large arrays appeared beyond the reach of current technology. These requirements could be met with smaller, lower frequency arrays, such as 32x32 at 1MHz, and these become the focus for investigation in FY96.
- Prototype systems: a clinically usable 3-D ultrasound system based on "sequential B-scan" technology (mechanical sweep of a conventional ultrasound probe) was

developed. This system was displayed at the October 1995 annual meeting of the AUSA (Association of the U.S. Army) in Washington DC, where it was favorably reviewed by many Army personnel. More importantly, the system was placed into use in the clinic of Dr. Christian Macedonia at Madigan Army Medical Center in Tacoma, Washington, for an extended evaluation to occur in FY96.

In FY96, research and development continued in both of these areas, but with a further shift of emphasis toward the development of field-usable systems.

- The most important product from FY96 was a second-generation prototype system, called MUSTPAC-1 (Medical [or Military] UltraSound, Three-dimensional and Portable, with Advanced Communications), implemented using a Silicon Graphics Indy™ computer. (See Appendix C for further details of the MUSTPAC-1.) Delivery and field demonstration of the MUSTPAC-1 was accomplished during July-September 1996. On July 8, Battelle delivered a MUSTPAC-1 system to the U.S. Army at Ft. Detrick. Following compatibility testing under supervision of the Center for Total Access (CTA, Ft. Gordon, Georgia), the MUSTPAC-1 was shipped to Landstuhl, Germany, for further evaluation. On August 7, it was deployed to the 212th Mobile Army Surgical Hospital in Tuzla, Bosnia, while a second MUSTPAC-1 remained at LRMC (Landstuhl Regional Medical Center) to serve as a receiving station. Additional secondary receiving stations were established and used at Madigan Army Medical Center (Tacoma, WA, USA), Fraunhofer Center for Research in Computer Graphics (Providence, RI, USA), and Georgetown University Medical Center (Washington, DC, USA). The MUSTPAC-1 remained in Bosnia until it was redeployed to Georgetown on Sept. 8.

As a result of the success of MUSTPAC-1, a change within scope was negotiated in late FY96 that adjusted the project's priorities to reduce the level of effort on 2-D array development, emphasizing instead further development of field-usable systems based on sequential B-scan technology.

In FY97, the principle activities and accomplishments under these refocused priorities were as follows:

1. further demonstration and publication of the prototype MUSTPAC-1 telemedicine system, including acceptance of one national award for Technology Innovation;
2. patent application for the MUSTPAC-1 architecture and system concept;
3. technical development of a third-generation prototype MUSTPAC-2 system;
4. laying groundwork for technology transfer of MUSTPAC-2; and
5. continued research on sensor technology.

Further details on FY97 accomplishments are provided as follows:

1. Further demonstration and publication of MUSTPAC-1.

On May 31, 1997, largely as a result of the Germany/Bosnia field demonstration, MUSTPAC-1 won the Discover Award for Technology Innovation in Computer Hardware and Electronics (Discover Magazine, July 97).

Demonstrations and discussions about MUSTPAC™ were invited and given — mostly with funding from other organizations — at the AUSA Annual Meeting (Washington, DC, 14-16 Oct 96), the AUSA Telemedicine Conference (Tysons Corner, VA, 4-6 Mar 97), the Military Medical Capabilities Conference (Knoxville, TN, 30 May 97), Grand Rounds at Walter Reed Army Medical Center and Georgetown University Medical Center (Feb 97 and May 97), the Spanish Society of OB/GYN meeting (Spain, Jun 1997), the Society of Minimally Invasive Therapeutics Meeting (Japan, Jul 97), the MMVR-5 conference (San Diego, CA, Jan 97), NASA Johnson Space Center (Houston, TX, Sep 96 and Jan 97), the Tribal Healthcare 2000 Conference (San Diego, CA, 15-17 Jul 97), and the AMEDD Center and School Conference on Force Structure and Requirements in Telemedicine (Jul 1997).

During this period, the MUSTPAC-1 received a high level of attention and support from the public news media. Technical articles about MUSTPAC™, written by magazine staff, appeared in Jane's International Defense Review (Feb 97, pg.15) and Portable Design Magazine (cover article, Jun 97). A non-technical article, associated with the Discover Award, appeared in Discover Magazine (Jul 1997, pp.74-75.

(Copies of these articles were provided in the FY97 annual report.) In addition many

non-technical articles appeared in AP newspapers and on broadcast television, including CBS, CNBC, and The Discover Channel.

2. Patent application.

On June 25, 1997, a patent application titled "Ultrasound Telemedicine System with Virtual Reality" was filed in support of the U.S. Department of Defense, covering the system concept and certain details of the MUSTPAC-1 system. A copy of this patent application was provided in the FY97 annual report.

3. Technical development of MUSTPAC-2.

As of October 1997, technical development of the MUSTPAC-2 was estimated as being approximately 70% complete, with the following major actions accomplished:

- Redesigned the 3-D Paddle electromechanical scanner to provide a fully sealed operating mechanism capable of immersion cleaning in standard disinfectant solutions. This was accomplished through the use of magnetic coupling of physical force from the internal drive mechanism, through an impermeable aluminum shell, to an external probe carrier.
- Replaced the Silicon Graphics computer, display, and keyboard with a Pentium laptop (Toshiba Tecra 740CDT) augmented with a separate video capture card (Osprey 100).
- Converted all software to run under the Solaris operating system. (Solaris was an interim step, chosen to produce an operational prototype MUSTPAC-2 on the shortest possible schedule. The operating system for the final version of MUSTPAC™ was targeted as Windows/NT.)

Although these changes were conceptually straightforward, some of them proved surprisingly difficult to accomplish. Video capture was an important example. Based on discussions with vendors in 1995 and 1996, MUSTPAC™ development staff believed that adequate video capture capability (640x480 pixels at 15 fps or better) would be conveniently available in Pentium laptops, either built-in or as a CardBus module. However, it turned out that neither capability was developed by industry according to the projected schedule, and after several false starts, the MUSTPAC™

project was eventually forced to use a PCI-bus video capture card. This in turn required adding an external PCI-bus capability to MUSTPAC-2, with attendant increase in size, weight, and complexity of packaging. In addition, a significant amount of programmer effort was required to adapt vendor-supplied video capture device driver software to the special needs of the MUSTPAC project.

In retrospect, it could be seen that rapid development of the high quality MUSTPAC-1 prototype was in large part due to the availability and selection of a particularly well suited computer platform. The Silicon Graphics Indy computer used in the MUSTPAC-1 provided an integrated system, fully supported by a single vendor, encompassing all of the required capabilities in video capture, display, computational speed, and communication software. It was a noticeable setback to the project that Silicon Graphics chose to discontinue the Indy, replacing it only with systems that were perceived as being too large and heavy to be viable for continued MUSTPAC™ development.

As of October 1997, however, many of the difficulties of platform conversion were overcome and a prototype MUSTPAC-2 system was operational. Further evaluation and development were planned for FY98, leading to completion of the MUSTPAC-2 final version in September 1998.

4. Technical transfer of MUSTPAC-2.

Business discussions were held with 4 established ultrasound companies, leading to one agreement-in-principle for manufacture of MUSTPAC™ systems.

5. Development of sensor technology.

An improved method was developed for computational holographic reconstruction of data obtained from a 2-D array sensor using off-axis illumination. This work was a small (3% of project expenditures) computational feasibility study designed to complement other DARPA-funded research exploring the possibility of using a receive-only dense array to achieve true real-time (e.g. 20 fps) high resolution 3-D acquisition.

In summary, at the end of FY97, project resources were focused almost completely on development of MUSTPAC™, with the goals of 1) having a Windows NT version completed by September 1998, and 2) further demonstrations and evaluations of the MUSTPAC™ technology.

4. CURRENT REPORTING PERIOD (FY98-99)

4.1. APPROVED STATEMENT OF WORK

During FY98 and FY99, the MUSTPAC™ technology was developed along the general lines planned in FY97, with refinements and redirections as determined by intermediate results such as those identified in the MUSTPAC™ presentation at the DARPA Ultrasound Workshop (Feb 11-13, 1998, Lansdowne, VA) [see Appendix A].

In March 1998, a contract modification and time extension was negotiated that formalized three deliverables for the remainder of the contract. Quoting from email communications dated 20 Mar 1998 with Dr. Wally Smith, the DARPA program manager for this project, these deliverables were as follows. (Specific progress against these deliverables is described in the following section.)

1. Mt. Everest expedition field test.

Field-test MUSTPAC™ as part of the NASA/Yale Everest Extreme Expedition. One MUSTPAC™ unit will be ruggedized for cold and high altitude conditions. That unit and one MUSTPAC™ project team member will accompany the Everest Extreme Expedition to Base Camp, 17600 ft.

At Base Camp and in transit, the MUSTPAC™ will be tested for its ability to collect medical ultrasound datasets and transmit those datasets over satellite links back to consulting sites in the U.S. for interpretation. This capability will also be demonstrated at the TEDMED2 conference in Charleston, SC, on May 15, 1998.

2. Military demonstration and evaluation.

Summary description (as submitted by Dr. Wally Smith for DARPA internal "highlights" list, 18 Feb 1998):

“Ultrasound Telepresence to be Demonstrated At Sea.

The MUSTPAC development team led by Battelle is currently working with the U.S. Navy to place a MUSTPAC ultrasound telepresence system for at-sea testing on the aircraft carrier Enterprise when it deploys in Oct/Nov 1998, probably to the Mediterranean. Prior to deployment on the Enterprise, the MUSTPAC will reside at the National Naval Medical Center, Bethesda MD, for a period of 3-6 months, for evaluation, development, and vetting in the Navy's operational environment. NNMC, an integrated medical team composed of radiologists, surgeons, nurses, and other medical providers will develop protocols, collect and evaluate clinical data, and train the intended users. During deployment, ultrasound scans will be performed on the Enterprise by non-radiologists trained NNMC to use the equipment, and will be transmitted to NNMC evaluation by radiologists there. This effort was initiated and is being coordinated by CAPT Rick Bakalar, MD, USN, Head of Telemedicine Department at NNMC, as requested by VADM Koenig. Clinical studies are being coordinated by CAPT Chuck Macri, MD, USN."

The target schedule for this activity was:

Apr 3, 1998 Installation of 1 MUSTPAC system at National Naval Medical Center (NNMC)

Sep 31, 1998 Report on outcome of clinical evaluation at NNMC.

Oct 15, 1998 (est) Installation of 1 MUSTPAC system on Navy ship
(date to be determined by Navy schedule)

Jan 31, 1998 Report on outcome of shipboard tests.

3. Demonstration at IEEE Ultrasonics Symposium (Sendai Japan).

The MUSTPAC, accompanied by one project team member, will be demonstrated as an "invited poster" at the 1998 international IEEE Ultrasonics Symposium.

4.2. KEY RESEARCH ACCOMPLISHMENTS

In FY98 and FY99, progress against the deliverables described above was as follows:

1. The Everest Extreme Expedition test and associated TEDMED2 Conference presentation were highly successful, despite a formidable collection of technical, administrative, and logistic hurdles to be overcome. In the end, a ruggedized MUSTPAC™ configuration based on a Fieldworks FW7666P rugged laptop and an Ausonics Impact VFI ultrasound scanner were taken to Mt. Everest Base Camp by Dr. Chris Macedonia (MAJ, US Army MC), co-inventor of the MUSTPAC™ system. At Base Camp Dr. Macedonia performed a total of 32 volumetric (3-D) scans and transmitted these to MUSTPAC™ diagnostic workstations positioned at Yale University and Walter Reed Army Medical Center (WRAMC). Communications were accomplished using a sat-com based electronic mail facility provided by Jim Bruton, the expedition logistics leader. In addition to the 3-D scans, Dr. Macedonia also collected a total of 292 still images (JPEG format) containing Doppler blood flow information relating to physiological adaptation to altitude. These results were discussed on May 15, 1998, during a real-time video conference between Base Camp, WRAMC, and the TEDMED2 conference in Charleston, SC. See Appendix B for pictures of the Everest configuration. (Medical scientific results from the Everest mission will be published separately by Dr. Macedonia.)
2. The NNMC demonstration and evaluation was repeatedly delayed due to a combination of administrative and staff availability factors. From a technical standpoint, progress was acceptable, with an initial installation at NNMC on May 15, 1998, followed by upgrades for increased functionality on June 5 and July 16. However, NNMC's clinical investigation protocol was not approved by the Institutional Review Board (IRB) at NNMC until 3 Mar 1999, over a year after the study was first discussed and agreed upon in principle. As a result of these administrative delays, there was no progress on the actual clinical investigation during FY98. The clinical evaluation is not yet complete as of this writing (October 1999), and a further no-cost time extension on the project has been negotiated to enable its completion. The relevance of this study to future MUSTPAC™ applications is unclear, since the study is being performed using only the motor-driven linear scanner instead of the more recent freehand capability (see item #5, below). However, the very long time required for initial approval of the protocol

argues against changing it at this point, and in any case the medical personnel involved are more comfortable with the concept of parallel scanning and prefer, at this point, to have that constraint enforced by the motor-driven scanner.

3. Demonstration at the 1998 IEEE International Ultrasonics Symposium, and subsequent publication of results was accomplished on schedule. See Appendix C, R.J. Littlefield, C.R. Macedonia, J.R. Coleman, *MUSTPAC™ 3-D Ultrasound Telemedicine System*, 1998 IEEE International Ultrasonics Symposium, Sendai, Japan, Oct.5-8, 1998.

4.3. OTHER REPORTABLE OUTCOMES

Other notable activities and results (some negative) are as follows:

4. Conversion of the MUSTPAC™ system to Windows NT is now complete.
5. MUSTPAC™ now includes a high quality freehand scan capability, utilizing a high precision mechanical arm as a 6-degree-of-freedom position sensor. This was accomplished by integrating into MUSTPAC™ a new acquisition and display software package called 3D FreeScan, a product of EchoTech 3D Imaging Systems GmbH (Hallbergmoos, Germany), then convincing EchoTech to modify their software to acquire positioning information using a high precision mechanical arm (MicroScribe arm from Immersion Corp., San Jose, CA) instead of a lower precision free-space magnetic sensor. In addition to greatly improving data quality, use of the mechanical arm also obviates earlier concerns about the impact on MUSTPAC™ of the active EMF cancellation used by Navy ships. Freehand scan capability using the mechanical arm was delivered to Dr. Chris Macedonia at Georgetown University in mid-November 1998, for use in Dr. Macedonia's study on amniotic fluid and cervical length measurements.
6. The TeleInViVo software from Fraunhofer CRCG has been replaced as the software of choice by the 3D FreeScan software from EchoTech (see previous item). At some future time, it is expected that TeleInViVo will be removed altogether from MUSTPAC™.

7. The MUSTPAC™ and Dr. Christian Macedonia appeared before the House Commerce Committee, Subcommittee on Health and Environment, June 5, 1998.
8. A possible application of MUSTPAC™ for prostate cancer detection & monitoring was identified. Dr. Chris Macedonia presented the MUSTPAC™ at the 70th Semiannual Meeting of the Japanese Society of Ultrasonics in Medicine (Sendai, Japan, Nov.1997). While in Sendai, Dr. Macedonia collaborated with Dr. Yoshikatsu Tanahashi to utilize the MUSTPAC™ to reprocess video data recorded during an intraurethral prostate examination, producing a 3-D reconstruction and enabling subsequent reslicing at arbitrary angles. This resulted in a second presentation, by Dr. Tanahashi, at the 71st Semiannual Meeting of JSUM, highlighting MUSTPAC™ images generated by Richard J. (Rik) Littlefield of Battelle / Pacific Northwest National Laboratory (PNNL) from videotapes sent to him by Dr. Tanahashi. On this same topic, Rik Littlefield attended the workshop "Transperineal Brachytherapy for Early Stage Prostate Cancer" held by Northwest Hospital (Seattle, WA, Jan.12-13, 1998).
9. A possible application for MUSTPAC™ in screening for thyroid nodules among Chernobyl victims was identified by Dr. Richard Satava, previously with DARPA and currently at Yale. This application was not pursued due to lack of funding.
10. The MUSTPAC™ patent application, filed June 25, 1997, was rejected on the grounds of obviousness compared against patent #5,609,485, "Medical Reproduction System", by Mark Bergman et.al., granted Mar.11, 1997 and assigned to MedSim, Ltd. of Israel. This patent was unknown to the project team at the time of the MUSTPAC™ filing (and, obviously, MUSTPAC's earlier development). Fortunately, the MedSim patent specifically restricts its claims to the application domain of training, so the existence of this patent apparently does not create any issues for use of MUSTPAC™ in medical practice.
11. No commercialization partner has been identified, although several letters of interest were received in response to a CBDNet notice published in March 1999.
12. Several individual technology improvements developed or identified by this project have been transferred into the commercial domain. These include:

- The “virtual ultrasound probe” user interface specification, adopted by EchoTech for their 3D FreeScan product.
 - Use of the high precision mechanical arm (Immersion MicroScribe™) for 3D data acquisition, also adopted by EchoTech for 3D FreeScan.
 - Medical quality video capture by a PCMCIA-format interface card, adopted by EchoTech for 3D FreeScan.
13. Under separate travel funding, but utilizing MUSTPAC™ equipment, presentations were given at the following conferences / workshops:
- Pacific Medical Technology Symposium (PacMedTek), Honolulu, HI, August 18-21, 1998, presented by Larry Skelly, PNNL and Dr. Chris Macedonia, US Army Medical Corps.
 - U.S. Dept of Energy (DOE) Biomedical Technologies Exposition, Washington DC, April 20, 1999, presented by Richard J. (Rik) Littlefield, PNNL.
 - Advanced Technology Applications to Combat Casualty Care (ATACCC-98), Fort Walton Beach, FL, November 17-19, 1998, presented by Laura Curtis, PNNL.
14. Project review meetings were held or attended as follows:
- Advanced Medical Technologies Workshop, San Diego, CA, Jan 28-29, 1998.
 - MUSTPAC Expert Panel Review, ISIS Center, Georgetown University, Washington, DC, Feb 10, 1998.
 - DARPA 40th anniversary celebration, Arlington, VA, April 6, 1998.
 - Image Conference, Scottsdale, AZ, Aug 6, 1998.
15. Discussions regarding potential follow-on projects (separately funded) were held as follows:
- McKennan Hospital (Sioux Falls, SD): Aug.25, 1998; Nov 16, 1998; Dec 4, 1998; April 14, 1999.

- South Dakota Congressional briefing, regarding McKennan Hospital proposal, Georgetown University ISIS Center, Washington DC, Dec.9, 1997.
- Mercy Hospital (Darby, PA): Aug 31, 1998; June 8, 1998; Feb.17, 1999.

16. Two follow-on projects for MUSTPAC™ have been developed:

- For McKennan Hospital in Sioux Falls, South Dakota, using a mix of U.S. Department of Agriculture and non-government matching funds arranged by McKennan, Battelle will develop and place several MUSTPAC™ systems into McKennan's existing telemedicine system. This project is expected to be finalized in November 1999.
- For Mercy Hospital in Philadelphia, using government funding coordinated through TATRC, Battelle will place one unit for clinical evaluation, with follow-on phases to place and evaluate additional units for emergency care. This project officially began on June 14, 1999. See Appendix D for a more complete description of this project.

4.4. PUBLICATIONS / PRESENTATIONS

- Yoshikatsu Tanahashi, M.D., Ph.D. Christian Macedonia, M.D., *Formatted and Retrievable Imaging Evaluation for Neoplasm and Disease Screening High-resolution Intraurethral Prostagams (FRIENDSHIP)*, presented at the 71st Semiannual Meeting of the Japanese Society of Ultrasonics in Medicine, Yokohama Japan, May 1998.
- Christian Macedonia, Seong Ki Mun, Rik Littlefield, *Telemedicine and Ultrasound: A Comparison of Two-dimensional and Three-dimensional Imaging Techniques*. 70th Semiannual Meeting of the Japanese Society of Ultrasonics in Medicine, Sendai Japan, November 1997.
- Macedonia C, Littlefield R, Collea J, Landy H, McClaren R., Lewis K, Zalud I, Bartholomew L, Pezzullo JC, Eglinton G, *A comparison of standard endovaginal cervical length sonography to free-hand acquired three-dimensional endovaginal*

sonography. Abstract to the Society of Maternal Fetal Medicine (formerly SPO), San Francisco CA, Jan 1999.

- C R Macedonia, R J Littlefield, J Coleman, R M Satava, T Cramer, G Mogel and G Eglinton. *Three-dimensional ultrasonographic telepresence*, Journal of Telemedicine and Telecare 1998, 4:4,224-230.
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- Dr. Christian R. Macedonia, testimony before the House Commerce Committee, Subcommittee on Health and Environment, June 5, 1998.
- Richard J. Littlefield, *MUSTPAC™ 3-D Ultrasound Telemedicine Imaging System*, DOE Biomedical Technologies Exposition, Washington DC, April 20, 1999.
- Christian Macedonia, *Telemedicine and ultrasonography: making waves*, Ultrasound Obstet Gynecol 1998;12:1-2.

4.5. IRB REFERENCES

All investigations involving human subjects in this project have been performed in adherence to applicable policies of Federal Law 45 CFR 46, approved and monitored by Institutional Review Boards at the Pacific Northwest National Laboratory (PNNL) and other participating organizations as follows:

- Everest Extreme Expedition: Georgetown University Medical Center (GUMC) IRB approval #98-113; PNNL IRB approval #94-6.
- National Naval Medical Center, IRB approval #B98-070; PNNL IRB approval #94-6-5.

- Amniotic fluid and cervical length measurements: GUMC IRB approval #179-97; PNNL IRB approval #94-6.

5. CONCLUSIONS

The MUSTPAC™ technology continues to be a promising mechanism to utilize ultrasound in the telemedicine setting, by allowing a non-specialist operator in the field to obtain high quality scans that can be interpreted by a remote expert. In FY98 and FY99, MUSTPAC™ has been significantly improved by conversion to the Windows NT / Pentium platform and by incorporation of a freehand scan mechanism, augmenting or replacing the older motor-driven linear scanner. Further evaluation and experience by the medical community is required to determine the conditions where MUSTPAC™ is effective.

APPENDIX A

**APPENDIX A: “3-D Ultrasound for Physiological Monitoring”, Presentation
Slide Set from the DARPA Ultrasound Workshop, Lansdowne, VA,
Feb 11-13, 1998.**

Real Time 3-D Ultrasound For Physiological Monitoring

Project # DAMD17-94-C-4127

Richard J. (Rik) Littlefield, Battelle, P.I.

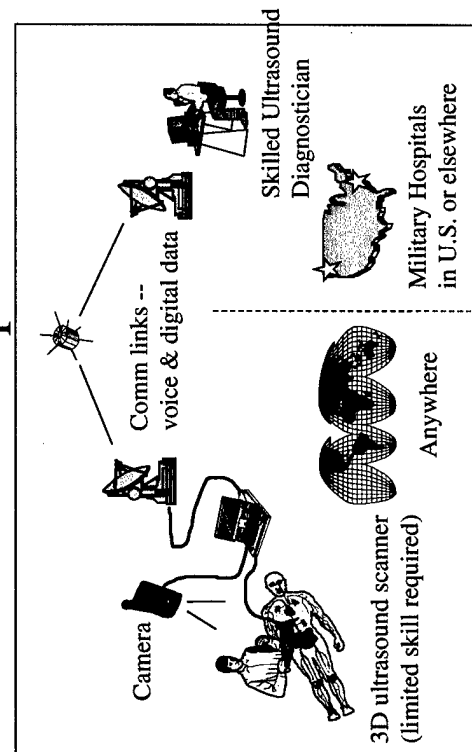
DARPA Ultrasound Workshop, Lansdowne, VA
Feb. 11-13, 1998

A-2

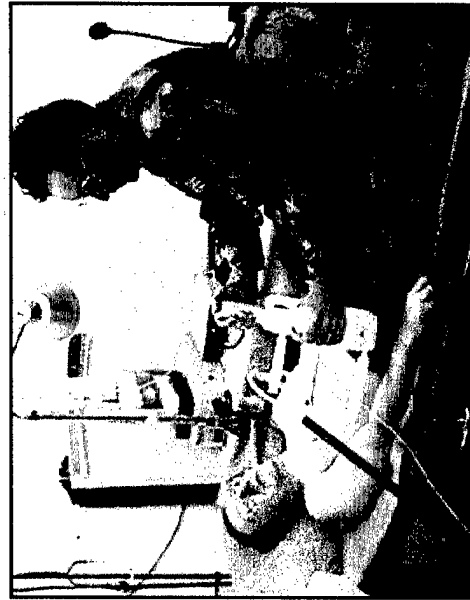
•Project Focus

- ◆ 3-D ultrasound telemedicine (tolerating limited connectivity, exploiting store-and-forward)
- ◆ Integrated system development and technology demonstration.

3-D Ultrasound Telemedicine Concept



Scanning

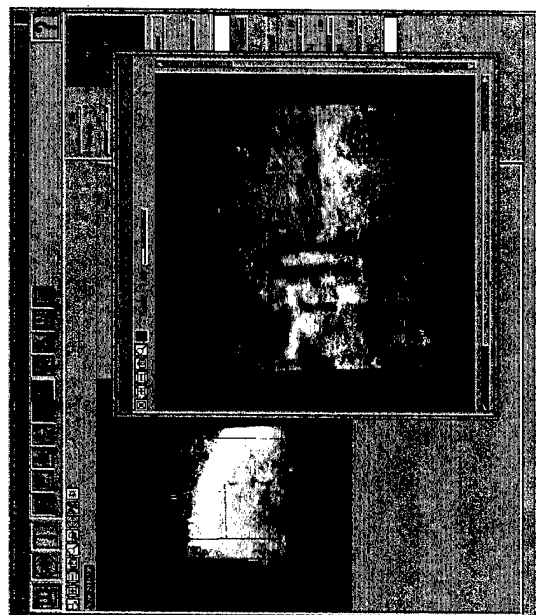


Diagnosing

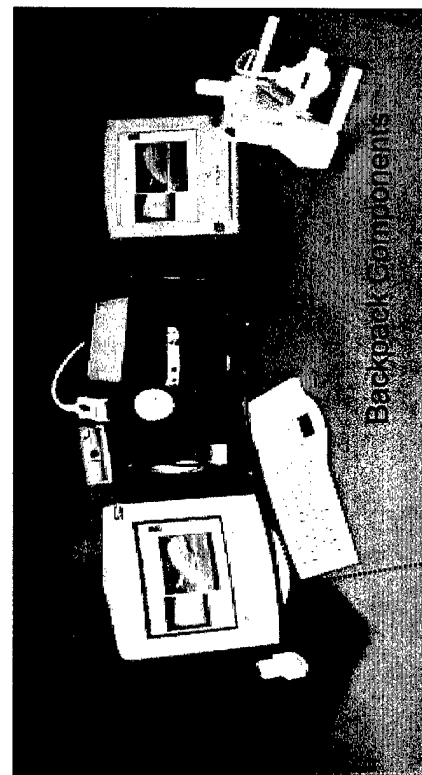


A-3

Diagnostic Screen (human liver)



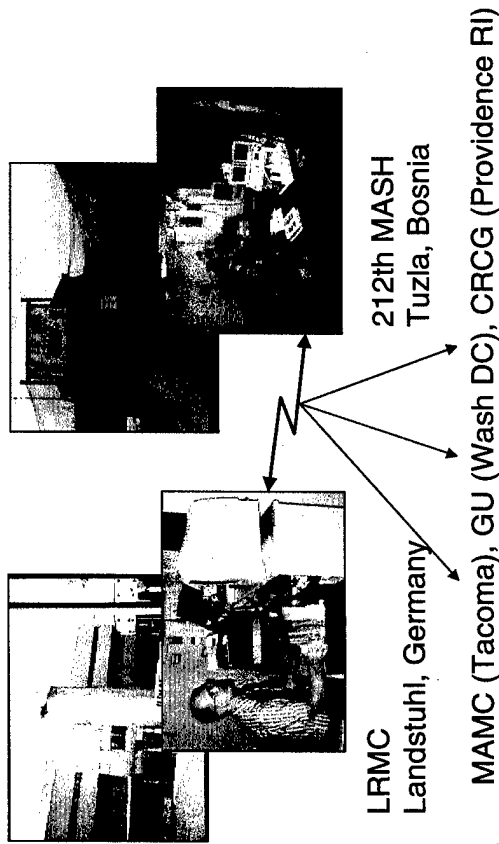
MUSTPAC-1 System



MUSTPAC-1 Main Points

- ◆ Medical UltraSound, Three dimensional, Portable, Advanced Communications
- ◆ Telemedicine focus
- ◆ Effective remote ultrasound exams
- ◆ No diagnostic expertise needed to scan
- ◆ Familiar diagnostic interface
- ◆ Prototype units fielded in August 1996

Field Trial



A-4

Results

- ◆ Focused on usability in field environment
- ◆ Informal evaluation
 - 75 scans, 10 diagnosticians, 20 scan operators
- ◆ Ease of use: very good
 - Diagnostician trainup times: 5 minutes typical (due to virtual ultrasound probe)
 - Scanner training: operational only (1/2 hour typical)
- ◆ Acceptance:
 - very good, improving with hands-on experience

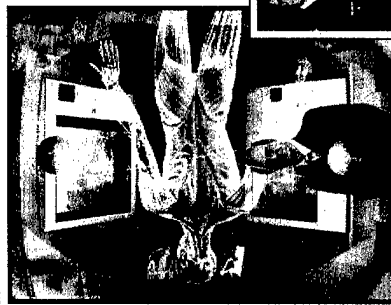
• More Results

- ◆ Versatility: very good
 - network connectivity
 - image transfer
 - text messaging
- ◆ Robustness:
 - surprisingly good

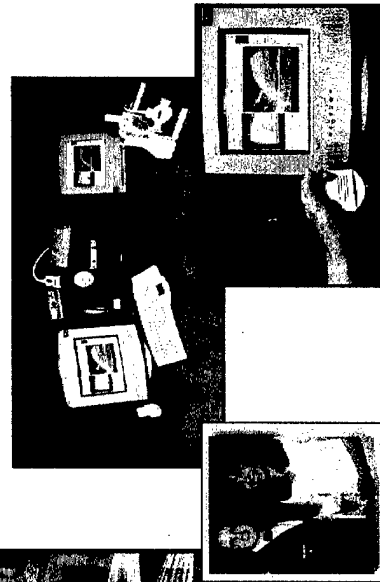


• Arrival in Tuzla -- bounced upside down on Crater Alley

8th ANNUAL TECHNOLOGY AWARDS
Discover



1997 Discover Award
Computer Hardware and Electronics
MUSTPAC 3-D Ultrasound System

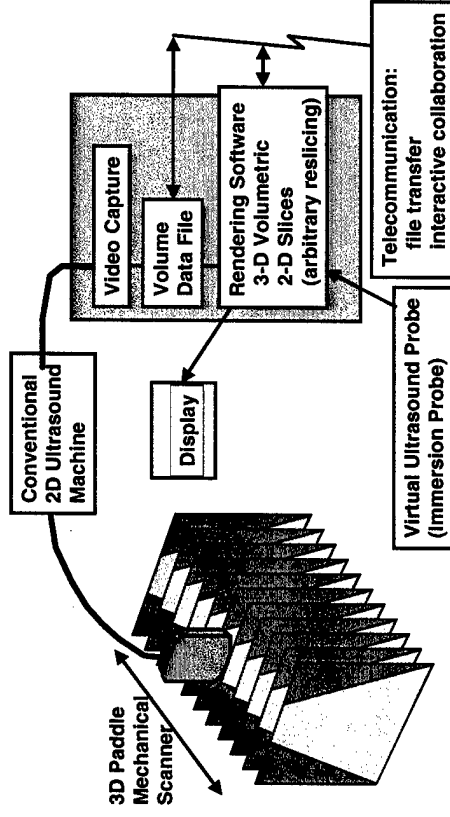


•Application Targets

- ◆ **Military**
 - Navy [Bakalar, committed]
 - MRMCT/TATRC
- ◆ **Civilian**
 - McKennan Hospital (South Dakota) [Heimbrecht, proposed]
- ◆ **International**
 - Ukraine/Chernobyl thyroid screening [Satawa/Cheban, proposed]
 - prostate screening/monitoring [Macedonia/Tanahashi, investigating]
- ◆ **Special situations**
 - Everest expedition [Satawa/Bruton, committed]

A-5

MUSTPAC-1 Principles of Operation



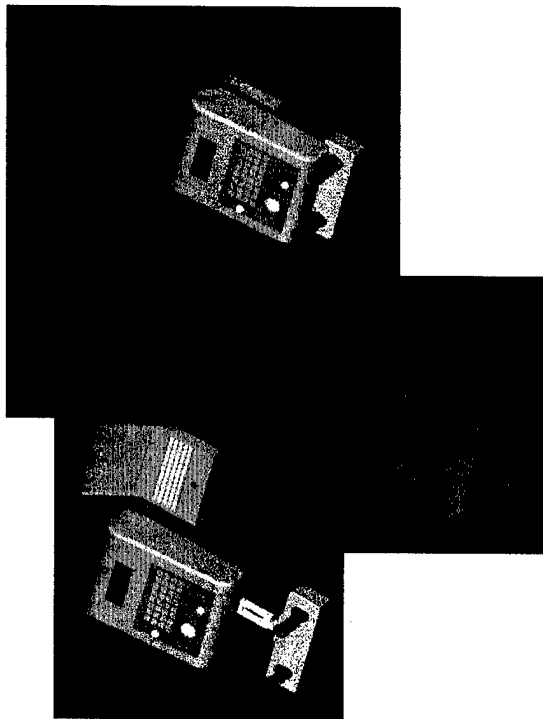
•Major Components of MUSTPAC-1

- ◆ **Silicon Graphics Indy & Presenter**
 - (computer & display)
- ◆ **“3D Paddle” scanner**
- ◆ **Virtual Ultrasound Probe**
- ◆ **TeleInViVo software (Fraunhofer CRCG)**
- ◆ **Data capture, transfer, and UI software**
- ◆ **Hitachi 905 ultrasound engine**

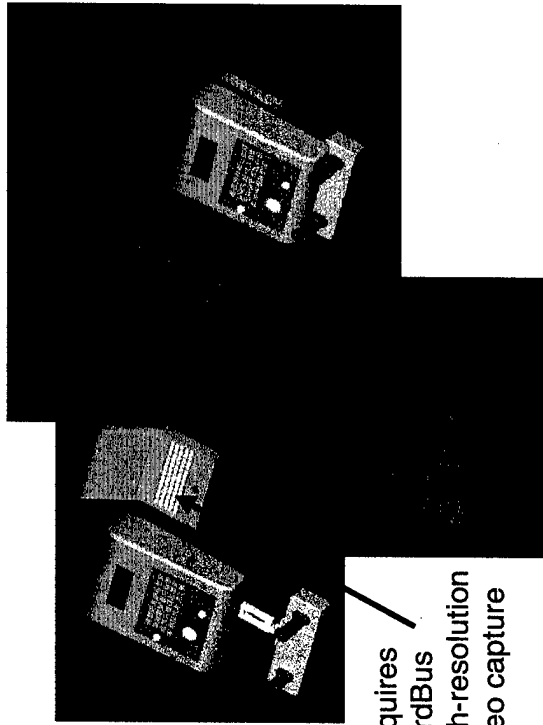
•Modifications Needed For MUSTPAC-2

- ◆ **Pentium computer replaces SGI**
- ◆ **“3D Paddle” scanner**
- ◆ **Virtual Ultrasound Probe**
- ◆ **TeleInViVo software (Fraunhofer CRCG)**
- ◆ **Data capture, transfer, and UI software**
- ◆ **Hitachi 905 ultrasound engine**

Early 1997 Packaging Concept

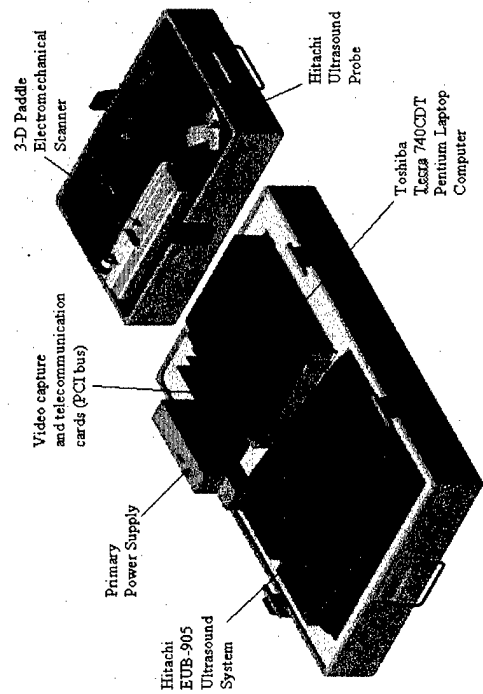


Early 1997 Packaging Concept

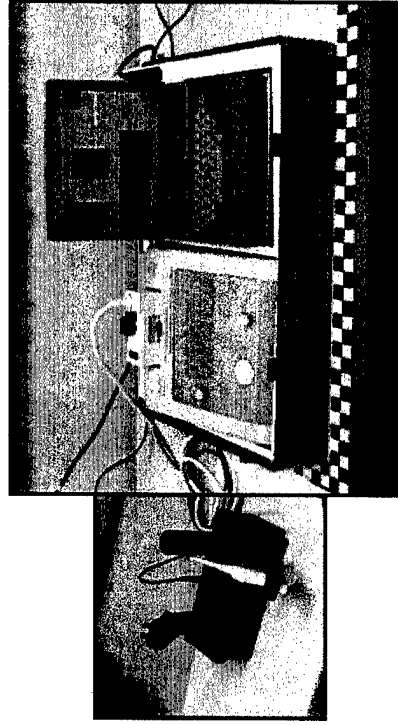


A-6

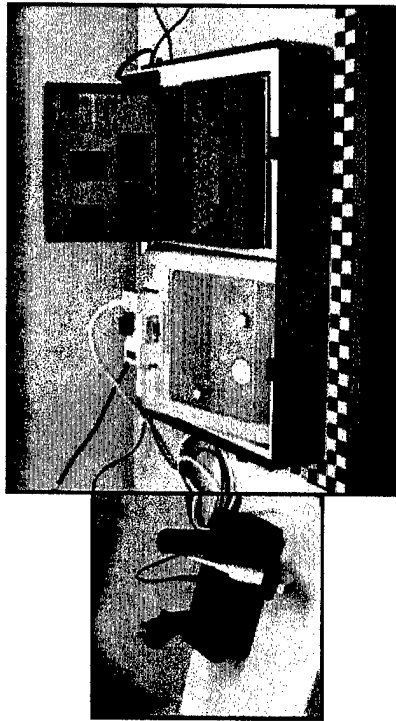
Mid 1997 Packaging Plan



Prototype System -- October 1997



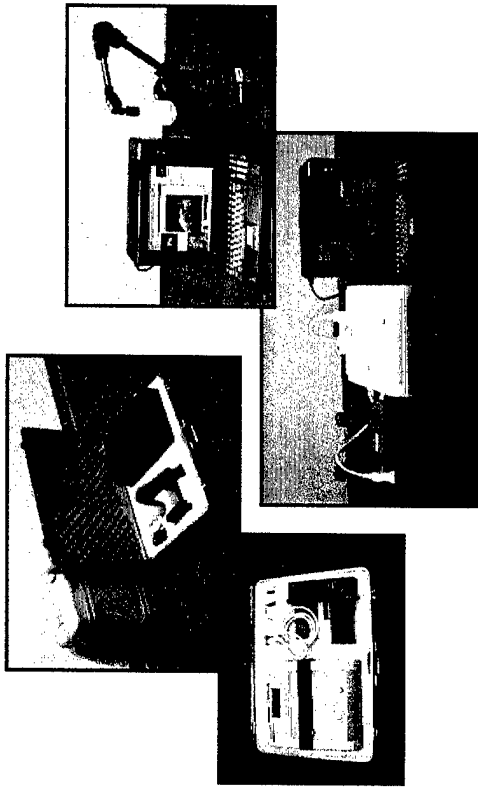
Prototype System -- October 1997



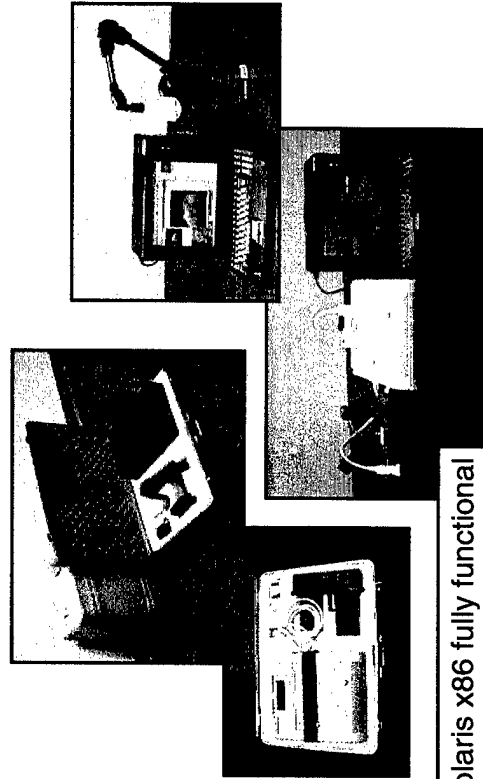
Too heavy to justify expense of custom packaging.

A-7

Revised Prototype -- February 1998



Revised Prototype -- February 1998



Solaris x86 fully functional
Windows/NT in unit test

•Military Demo 1998

- ◆ Phase 2: Navy carrier deployment, 4Q98
- ◆ Phase 1: Develop and evaluate at National Naval Medical Center, Bethesda
 - integrated team of physicians (radiologists, surgeons, OB/GYN) and technicians
 - evaluate usefulness
 - develop and package scanning procedures
 - identify and train users on both ends
 - extend system as needed (RadCom and communications compatibility, dataset compression, freehand scan)

3-D Dataset Compression



7.58 MB lossless
(12.6 MB raw)

At 56 KB: 18 minutes



1.26 MB, JPEG

3 minutes

•Summary

- ◆ MUSTPAC development proceeding
- ◆ Military demo scheduled
- ◆ Significant interest by several applications

APPENDIX B

APPENDIX B: “*MUSTPAC 3-D Ultrasound Telemedicine – The MUSTPAC™ System*”, Web site <http://aims.pnl.gov:2080/MUSTPAC-2/index.html>, as of Oct.26, 1999.

MUSTPAC

3-D Ultrasound Telemedicine -- The MUSTPAC™ System

Summary

MUSTPAC™ (Medical UltraSound, Three-dimensional and Portable, with Advanced Communications) is a telemedicine system based on 3-D ultrasound data acquisition.

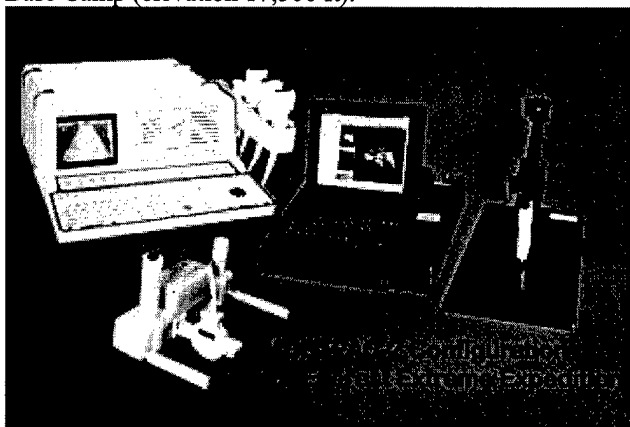
MUSTPAC™ provides the unique capability of allowing an effective ultrasound examination to be performed remotely -- with no diagnostic skills needed by the operator at the patient's location, and no need for a dedicated videoconference link.

The MUSTPAC™ technology is being developed at the Pacific Northwest National Laboratory in support of the Advanced Biomedical Technologies program at the Defense Advanced Research Projects Agency (DARPA)

Currently, the MUSTPAC-2 system is an investigational device being evaluated in both clinical and field environments.

Highlights as of May 1998 include:

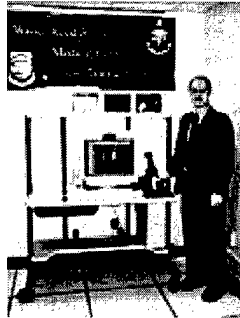
- A ruggedized MUSTPAC-2 system is being used by the Everest Extreme Expedition to collect scientific data on physiological adaptations to high altitude. The system on Everest incorporates a Fieldworks FW7666P rugged laptop and an Ausonics Impact VFI portable ultrasound scanner with Doppler capability. This system MUSTPAC-2 configuration accompanying the Everest Extreme Expedition to Base Camp (elevation 17,500 ft).



(Bigger picture)

is supported by diagnostic workstations located at Walter Reed Army Medical Center and Yale University.

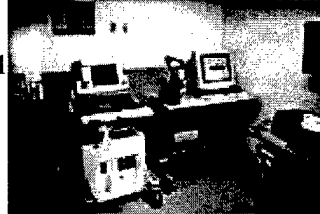
MUSTPAC-2 diagnostic workstation at Walter Reed Army Medical Center Telemedicine.



[\(Bigger picture\)](#)

- A standard MUSTPAC-2 system has been installed at the National Naval Medical Center (Bethesda), where it will undergo clinical evaluation in preparation for shipboard testing later this year.

MUSTPAC-2 system in Radiology Department of National Naval Medical Center. (Shown in evaluation configuration with ATL HDI ultrasound scanner.)



[\(Bigger picture\)](#)

For more information...

Several detailed documents are available describing the current MUSTPAC-2 system and its predecessor MUSTPAC-1:

- System design and experiences of the MUSTPAC™ family of systems are described in a 7-page paper titled "MUSTPAC™ 3-D Ultrasound Telemedicine / Telepresence System", presented at the 1998 IEEE International Ultrasonics Symposium, Sendai, Japan (Oct.6-8). This paper is available as a [Microsoft Word file](#).
- A two-page summary handout, from the DOE Biomedical Technologies Exposition, March 21, 1999, is available as a [Microsoft Word file](#).
- A large photomontage marketing graphic is available as a [JPEG file](#).
- System design and field experiences of the MUSTPAC-1 are described in a 5-page report titled "MUSTPAC-1: 3-D Ultrasound Telemedicine Tool for Deployment Situations in Bosnia and the European Theater". This report is available in [HTML](#) and with higher quality graphics as a [Microsoft Word file](#).
- An earlier description of the MUSTPAC-1, dated December 1996, is also [available](#).
- A December 1997 briefing presentation, describing the MUSTPAC-2 system with application to civilian health care, is available as a [Microsoft PowerPoint file](#).
- A February 1998 presentation given at the DARPA ultrasonics workshop also is available as a [PowerPoint File](#).

APPENDIX C

APPENDIX C: “*MUSTPAC™ 3-D Ultrasound Telemedicine / Telepresence System*”, 1998 IEEE International Ultrasonics Symposium, Sendai, Japan, Oct.5-8, 1998.

MUSTPAC™ 3-D Ultrasound Telemedicine / Telepresence System

Richard J. Littlefield

Pacific Northwest National Laboratory, P.O.Box 999, Richland, WA 99352

Email: rj_littlefield@pnl.gov

MAJ Christian R. Macedonia, MD[†]

Dr. John D. Coleman[‡]

Abstract — MUSTPAC™ is a family of ultrasound telemedicine systems based on the use of 3-D (volumetric) data acquisition. Diagnostically useful scans can be taken by an operator with limited training and no ultrasound diagnostic skills, using a simple “point-and-shoot” procedure. For diagnosis, volumetric datasets are transmitted to a remote radiologist, who uses a “virtual ultrasound probe” to reslice the datasets along arbitrary planes, using familiar hand movements and seeing 2-D (planar) displays similar to those of a conventional real-time hands-on examination. Prototype MUSTPAC™ systems have operated in a military field hospital and on a Mt. Everest climbing expedition, and are currently being evaluated for clinical application in rural and remote environments.

INTRODUCTION

Health-policy experts have become increasingly concerned about the uneven distribution of physicians. The lack of widespread availability of expertise in diagnostic ultrasound has been a particular problem, causing some to advocate the creation of ultrasound “centres of excellence”.[1] Recently, a number of groups have pioneered realtime remote ultrasound examination and have shown the value of teleconsultations for ultrasound technicians in rural areas.[2,3, 4]

However, conventional realtime 2-D (two-dimensional) ultrasound imaging has the significant drawback that a highly skilled operator must be physically present at the patient’s location. This is because conventional 2-D ultrasound imaging uses a hands-on interactive procedure that requires the operator to make diagnostic decisions simply in order to position the image acquisition probe at the correct location and orientation.

For example, to allow a diagnosis of gallstones using conventional 2-D ultrasound, the operator must interactively manipulate the image acquisition probe to locate the

gall bladder, image the bile duct at the correct angle to measure its diameter, and finally locate the stones within the bladder. A positioning error of only two or three millimeters, relative to the patient’s internal anatomy, can make the difference between diagnostic images and useless ones. This need for precision pointing introduces some difficulties in using conventional 2-D ultrasound in a telemedicine setting, where the diagnostic expert does not have direct control over the probe positioning.

In contrast, using 3-D (three-dimensional) ultrasound potentially allows diagnostically useful scans to be taken by an operator with limited training, no diagnostic skills, and no real-time expert assistance. This is accomplished by having the system scan a fairly large volume of the subject’s anatomy at one time, without interpretation, so that the operator can use a simple “point-and-shoot” strategy for data acquisition.

For example, to scan for gallstones using 3-D ultrasound, the operator has to know only enough anatomy to scan a volume that includes the gall bladder. Measuring the bile duct and locating individual stones is still required, but this analysis and diagnosis can be done later by an ultrasound expert located elsewhere.

Beginning in 1996, a series of prototype 3-D ultrasound telemedicine systems has been developed to demonstrate and evaluate this telemedicine concept. These systems, called MUSTPAC™ (Medical UltraSound, Three dimensional, Portable, with Advanced Communications), have been tested in a variety of environments, including a U.S. Army telemedicine network in Europe[5], a Mt. Everest climbing expedition, and several medical institutions in the U.S. Clinical studies are currently underway to evaluate MUSTPAC™ for routine application in rural and remote settings.

This report discusses the design, implementation, and use of several MUSTPAC™ systems.

[†] U.S. Army Medical Corps, Georgetown University Medical Center, 3800 Reservoir Road, Washington, DC 20007

[‡] Fraunhofer Center for Research in Computer Graphics (CRCG), 321 S. Main Street, Providence, RI 02903

OVERVIEW

MUSTPAC™ is an ultrasound medical imaging system that can scan patients to generate 3-D volumetric digital datasets, interactively generate 3-D and 2-D images for use by diagnosticians, and optionally transfer datasets over standard communication links to facilitate remote diagnosis and consultation. It is designed to work in a telemedicine framework, enabling diagnostically useful ultrasound scans to be taken by an operator with no diagnostic skills, modest training, and no online connection to an expert.

Typically a MUSTPAC™ system is used as follows. First, the patient is scanned by placing an ultrasound probe on the patient and mechanically sweeping it across his/her skin over the area of interest (Figure 1). During the scan, the system records ultrasound data from a sizable 3D volume of the patient's anatomy, producing a 3D volumetric dataset of ultrasound reflectivity. The scanning process requires no interpretation of the ultrasound images, other than possibly to confirm that the intended anatomy is covered.



Figure 1. Acquiring a 3-D abdominal scan using a linear scanning device and conventional ultrasound transducer.

Scans in the form of 3D volumetric datasets are then transmitted over any standard digital network to a qualified diagnostician.

Finally, a diagnostician interprets each 3-D scan using a Virtual Ultrasound Probe that simulates a conventional real-time hands-on examination procedure. This allows the diagnostician to display arbitrary 2D slices from the 3D dataset simply by moving the probe as if he/she were interactively examining the patient. The Virtual Ultrasound Probe and corresponding screen displays are very natural to diagnosticians, leading to rapid acceptance and productivity (Figures 2-4).

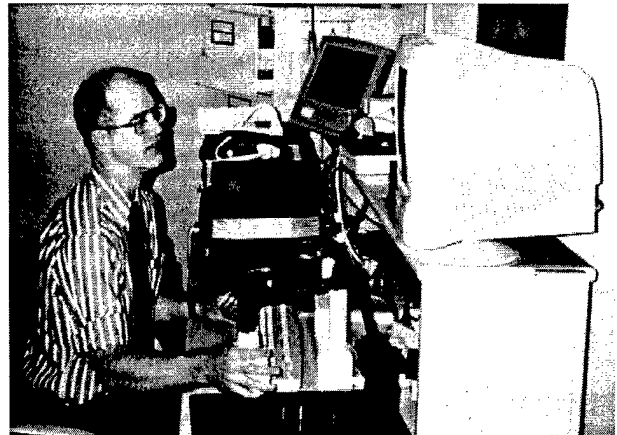


Figure 2. Interpreting a 3-D scan using the Virtual Ultrasound Probe at a diagnostic workstation.

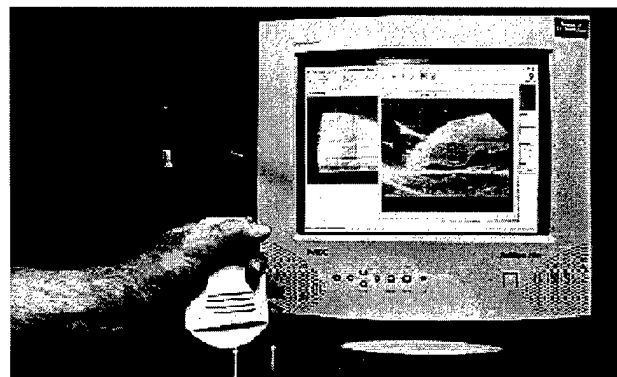


Figure 3. Closeup of the Virtual Ultrasound Probe and diagnostic workstation display. Image on the screen is of a plastic phantom.

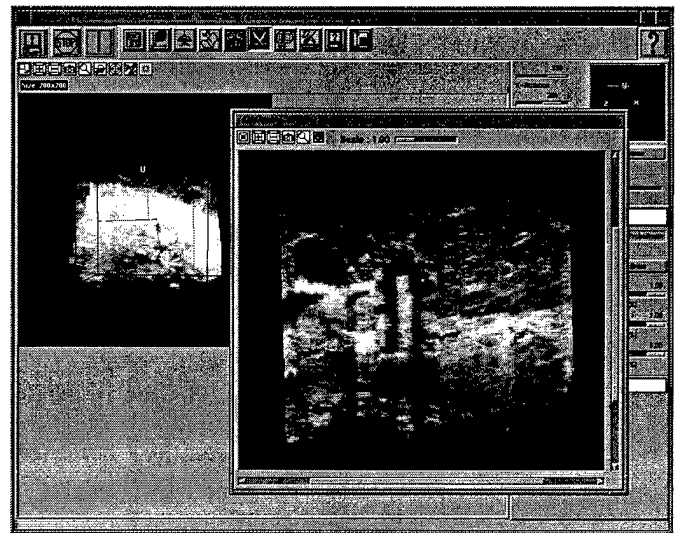


Figure 4. Actual diagnostic display (human liver with clotting in major vessels).

PRINCIPLES OF OPERATION

All versions of the MUSTPAC™ system developed to date have used a similar high level design (Figure 5). There are two primary operations — scanning and visualization — typically separated by a data transmission step.

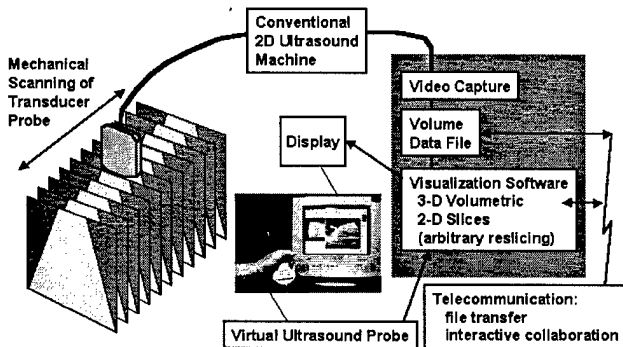


Figure 5. Major aspects of the MUSTPAC™ architecture. In this diagram, scanning and visualization are shown on the same system. In practice, these two functions would normally be done on two systems.

Scanning

Volumetric scanning in MUSTPAC™ is done using the well-known approach[6] of mechanically moving the transducer probe of a conventional off-the-shelf ultrasound machine. As the probe moves, the ultrasound machine generates a sequence of video images, called B-scans, showing 2-D slices of the subject under the probe. A computer digitizes the sequence of B-scan images and corresponding spatial positions of the transducer probe, then assembles the B-scans to form a 3-D volumetric dataset that represents a sort of "snapshot" of the subject's anatomy. Anatomical movement is not captured, except in the form of motion artifacts that the diagnostician must learn to ignore.

MUSTPAC™ supports two types of volumetric scanning: linear and freehand. In linear scanning, a hand-held motor-driven device is used to move the transducer in a straight line, at a constant speed, keeping the transducer oriented perpendicular to the direction of movement. This generates a set of parallel registered images that naturally assemble to form a dense rectangular 3-D dataset. Linear scanning is fairly restrictive in what anatomy it can be used with. However, the technique generates very high quality datasets because tightly controlling the transducer position essentially eliminates the possibility of position error and gaps in the image data.

In freehand scanning, the transducer is hand-held and moved by the operator. A 6-degree-of-freedom sensor attached to the ultrasound transducer records its position and orientation. Software in the MUSTPAC™ system then reconstructs a dense 3-D volumetric dataset by interpolating as necessary between the somewhat random planes of acquired image data. This procedure generates somewhat lower quality datasets, primarily due to inaccuracies in sensing the probe position. The quality of freehand datasets depends to a considerable degree on properties of the position sensor and its interaction with the operating environment. The MUSTPAC™ development group is currently evaluating the tradeoffs between free-space magnetic sensors (such as the Ascension¹ pcBIRD™) and mechanical articulated arms (such as the Immersion² MicroScribe-3D™).

Scans are usually taken at 15 fps (frames per second) at a scanning rate of 1 cm/sec, using a 3.5 MHz or 5 MHz convex-face sector-scan probe. With typical penetration depths, this results in scanning a region 4-6 cm wide at the skin surface and 20 cm wide at 15 cm deep, with a voxel (volume element) size of roughly 0.7mm on each axis. The resulting 3D rectangular dataset contains about 13 million voxels.

Visualization for Analysis and Diagnosis

The primary function of visualization in MUSTPAC™ is to allow experienced sonologists to make diagnostic decisions. Thus, the emphasis is on providing to those diagnosticians a user interface that is familiar, easy to learn, and productive.

Screen displays. The primary visualization tool in MUSTPAC™ is TeleInViVo™³. TeleInViVo™ can generate several kinds of images:

- 2-D slices at arbitrary positions and orientations.
- 3-D volumes using "maximum intensity projection" (MIP) and similar techniques for combining the values of dataset volume elements (voxels).
- 3-D surfaces defined by threshold values and rendered using one of several shading techniques

In MUSTPAC™, the most common practice is to combine a large 2-D slice image with a small 3-D volumetric image (Figure 4). The 2-D slice shows detail that is diagnostically useful, while the 3-D volumetric image provides context by showing location of the 2-D slice within the volume.

Virtual Ultrasound Probe. To provide diagnosticians with a familiar, convenient user interface, the MUSTPAC™ version of TeleInViVo™ has been extended by the addition

¹ Ascension Technology Corp., Burlington, VT, <http://www.ascension-tech.com>

² Immersion Corp, San Jose, CA, <http://www.immerse.com>

³ Fraunhofer CREG, Providence, RI, <http://www.creg.edu>

of a Virtual Ultrasound Probe (Figure 3). This is a hand-held 6-D input device combined with software to control 2-D slicing of volumetric datasets in the same way that a real ultrasound probe controls 2-D imaging of patients. That is, the Virtual Ultrasound Probe looks, feels, and acts like a real ultrasound probe in that the on-screen image is constantly updated in real time (typically 5-10 times per second) to reflect the position and orientation of the probe. (Again, this real time updating does not reflect anatomical movement, which is not captured in the datasets.)

Data Transmission

The MUSTPAC™ system provides two major methods of data communication: batch mode file transmission and TeleInViVo™ incremental transmission.

In batch mode file transmission, 3-D datasets and associated files are transferred using the Internet standard "ftp" protocol. If bandwidth is limited, then the 3-D datasets are compressed before transmission, using standard JPEG⁴ methods. On typical datasets, this achieves approximately 10X compression without visible effect on the images.

Incremental communication capabilities are also built into the TeleInViVo™ visualization program. These capabilities allow all or part of the full dataset to be transferred quickly at reduced resolution, while the user interactively evaluates the images. This feature has not been used extensively to date, but is expected to become more frequent as MUSTPAC™ systems are incorporated into consulting practices. Typical use is envisioned to be transfer of the entire dataset with resolution reduced by 4X per axis (64X overall), followed by transmission of an identified region of interest at the full resolution of the dataset.

IMPLEMENTATIONS

MUSTPAC-1

In the summer of 1996, the first prototype system was developed for testing by the U.S. Army under field conditions. This system, called the MUSTPAC-1, was designed to demonstrate an ultrasound telemedicine system in a backpack.[7,8]

System components and packaging. Major components of the MUSTPAC-1 are shown in Figure 5. These components include (right-to-left):

- Battery-powered linear scanner (at extreme right)
- Silicon Graphics Presenter™ flat panel display.
- Hitachi EUB-905™ ultrasound machine (in backpack, top section, with cord)
- Silicon Graphics Indy™ computer (in backpack bottom section)
- Teleconferencing camera (on backpack, top left)

- Keyboard with integral touchpad.
- High-resolution color monitor.
- Virtual Ultrasound Probe
- TeleInViVo™ visualization software.
- Other custom data acquisition and control software.

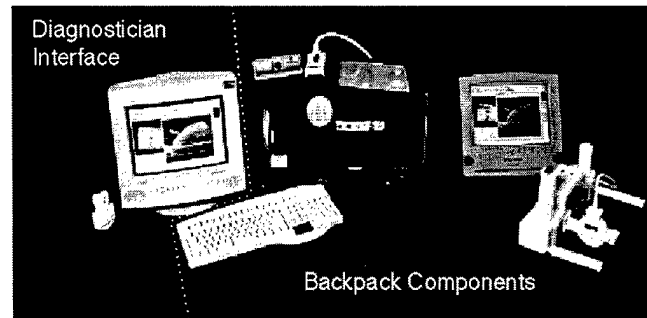


Figure 5. MUSTPAC-1 system components as packaged for military field evaluation.

Field Experiences. In August, 1996, the MUSTPAC-1 system was deployed by the U.S. Army to the 212th Mobile Army Surgical Hospital in Tuzla, Bosnia. A second MUSTPAC-1 placed at the Army's Landstuhl Regional Medical Center in Germany served as the primary receiving station.

Scanning. During the deployment, a total of 72 scans were performed. Most of these scans were taken by operators with no ultrasound diagnostic skills and minimal MUSTPAC-1 training (typically 10 minutes). No formal evaluation of the image quality was performed; informal evaluation by a variety of experienced ultrasound users suggested that the quality of the scans was largely independent of an operator's level of training and generally ranged from adequate to good.

Communications. Most transfers between Bosnia and Germany were performed using ftp over a roughly 1 megabit/second geosynchronous satellite link leased by the Army. Despite a round-trip packet delay of 580-600 ms, net transfer rates of roughly 50 Kbytes/second were routinely achieved. Thus typical 3-D datasets of 6-12 Mbytes required only a few minutes to transfer even without compression.

As exercises, 3-D datasets were also transferred over two slower communication links. One of these links was between Germany and Washington DC (USA) at 56 Kbits/sec using the International Maritime Satellite System (INMARSAT) and its associated telephone system ISDN link. The other was between Bosnia and Germany using the Army's Tactical Packet Network (TACNET) at 9.6 Kbits/sec. These transfers were also successful, but would have been too slow for routine use. (Data compression was added to the MUSTPAC-2 to address this deficiency.)

Diagnostic Usability. During the Bosnia deployment and in the 6 months after its completion, the MUSTPAC-1

⁴ Joint Photographic Experts Group, <ftp://ftp.uu.net/graphics/jpeg>

system was operated by approximately 20 experienced ultrasound users. Again, informal evaluation suggested that the system was very easily learned. One striking observation was that no experienced ultrasound user required more than 5 minutes practice with the Virtual Ultrasound Probe to begin making medical interpretations of 3-D scans that he/she had not previously seen.

MUSTPAC-2

MUSTPAC-2 is actually a family of MUSTPAC™ systems implemented on a common base of Intel Pentium processors using the Windows/NT operating system. The principles of operation are similar to MUSTPAC-1. However, MUSTPAC-2 incorporates several significant improvements from the user's standpoint. These include:

- Simplified and more robust user interface
- Wider range of packaging options (e.g. lightweight and rugged data acquisition system versus high performance diagnostic workstation)
- Increased network compatibility.
- Faster transmission and reduced data volume (through JPEG data compression).
- DICOM v3.0 import/export capability⁵.
- Freehand scan (research quality – still under development for routine clinical use).

Several configurations of MUSTPAC-2 systems have been developed for specific purposes. These purposes include:

- Everest Extreme Expedition
- Hospital clinical evaluation
- Remote clinic consultation

Everest Extreme Expedition. An unusually rugged portable configuration of MUSTPAC-2 (Figure 6) accompanied the Yale/NASA telemedicine team on the May 1998 Everest Extreme Expedition⁶ to Base Camp (elev. 17,500 ft). 3-D ultrasound datasets were transmitted back to MUSTPAC™ diagnostic workstations at Yale University (New Haven, CT) and Walter Reed Army Medical Center (Washington, DC) for interpretation. In addition, the MUSTPAC™ system acquired a series of 2-D images containing spectral Doppler data characterizing blood flow in major arteries, as part of a scientific study of climber adaptations to high altitude.

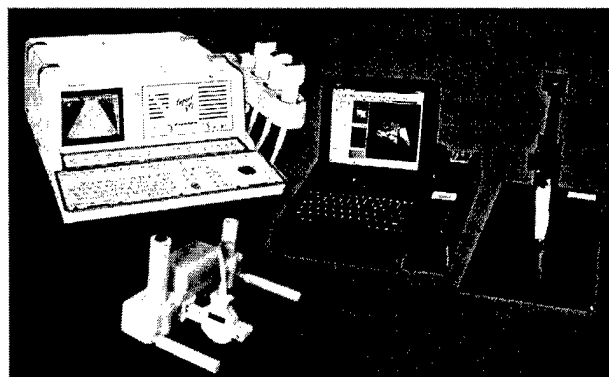


Figure 6. MUSTPAC-2 Everest Extreme configuration. This system incorporated a 166 MHz FieldWorks FW-7666P computer⁷ (center), Ausonics Impact VFI ultrasound machine⁸ (upper left), MUSTPAC-1 battery powered linear scanner, and MUSTPAC-1 Virtual Ultrasound Probe.

Hospital clinical evaluation. A deskside system (Figure 7) equipped for both scanning and visualization has been installed at the National Naval Medical Center (NNMC) in Bethesda, MD. This system is being evaluated for use in a clinical setting, prior to possible shipboard deployment.

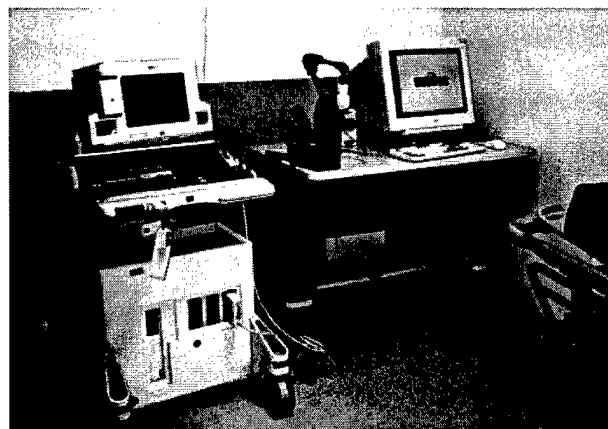


Figure 7. MUSTPAC-2 clinical evaluation system at NNMC. This unit incorporates a 333 MHz Dell Dimension XPS computer⁹ (under desk), MUSTPAC-2 Virtual Ultrasound Probe based on the Microscribe 3D articulated arm¹⁰ (on table), MUSTPAC-2 linear scanner (on table), and NNMC's existing ATL HDI-3000 ultrasound machine¹¹ (console and cabinet at left).

⁵ Merge Technologies, Milwaukee, WI, <http://www.merge.com>

⁶ <http://www.explorers.org/newsfiles/e3.html>

⁷ Fieldworks Inc., Eden Prairie, MN, <http://www.field-works.com>

⁸ Universal Medical Systems, Bedford Hills, NY, <http://www.u-m-s.com>

⁹ Dell Computer Corporation, Round Rock, TX, <http://www.dell.com>

¹⁰ Immersion Corporation, San Jose, CA, <http://www.immerse.com>

¹¹ ATL Ultrasound, Bothell, WA, <http://www.atl.com>

Remote clinic consultation. The "lunchbox" configuration (Figure 8) focuses on data acquisition, with limited capability for visualization. This demonstration/evaluation unit represents a configuration being considered for installation in a network of telemedicine clinics in rural northern U.S.



Figure 8. This portable "lunchbox" configuration incorporates a 166 MHz BSI LCD V8 computer¹², MUSTPAC-2 linear scanner (not shown), MUSTPAC-2 Virtual Ultrasound Probe, and any of several existing ultrasound machines (also not shown).

DISCUSSION

Experience to date suggests that MUSTPAC™ is a promising approach for extending the application of ultrasound in telemedicine. Further studies are needed, however, to determine its usefulness in clinical practice. In addition, MUSTPAC™ has a number of recognized limitations that need to be addressed. These include:

- *No Doppler imaging.* At present, MUSTPAC™ has no specific capability to capture or visualize Doppler information in 3-D datasets, suitable for later reslicing.
- *No anatomic motion.* Conventional real-time 2-D ultrasound shows anatomic motion, such as pulsing arteries, as a moving image on screen. This is diagnostically useful. However, the 3-D scans captured by MUSTPAC™ are static snapshots. Generally speaking, anatomic motion produces image artifacts that the diagnostician must learn to recognize and ignore. In extreme cases, such as scanning an active fetus, anatomic movement can render a dataset unusable. This condition must be recognized by the scanner operator, and the scan repeated.
- *Static shadowing artifacts.* With conventional real-time ultrasound, the image is produced by insonification from the current transducer position, so shadow

and posterior enhancement artifacts always look radial and shift location if the transducer moves. With MUSTPAC™, these artifacts are captured statically as they appeared during data acquisition. When the 3-D dataset is resliced on a different plane, shadows and enhancements can have an unusual appearance. Again, diagnosticians must learn to recognize and deal with these artifacts, typically by reviewing the data in the original plane of insonification to clarify the interpretation.

- *Data quality bounded by the original B-scans.* In the conventional clinical setting, skilled ultrasound technicians interactively adjust power, gain, TGC (time gain compensation), patient position, and other parameters to optimize images on a case-by-case basis. At present, the MUSTPAC™ system cannot make such adjustments by itself (since it has no direct control over the ultrasound machine), nor does it actively help the scanner operator to make them. Carefully chosen presets help to alleviate this problem. In the long run, we anticipate that automated image analysis will enable further improvements.

SUMMARY

3-D ultrasound data acquisition potentially can expand the use of ultrasound imaging in a telemedicine setting, by allowing an operator with no diagnostic skills to collect high quality scans that can be interpreted by a remote expert. This potential is illustrated by the MUSTPAC™ series of ultrasound telemedicine systems. Several prototype MUSTPAC™ systems have been developed and evaluated in a variety of operational environments. While the MUSTPAC™ approach is promising, significant further work remains before its clinical applicability is fully determined.

ACKNOWLEDGMENTS

Development and testing of MUSTPAC™ systems was funded by the Defense Advanced Research Projects Agency (DARPA) under contract number DAMD-17-94-C-4127. We are grateful to our program managers Dr. Rick Satava and Dr. Wally Smith for their support and guidance.

The Pacific Northwest National Laboratory is operated by Battelle Memorial Institute for the U.S. Department of Energy under Contract DE-AC06-76RLO 1831.

¹² Broadax Systems Inc., El Monte, CA, <http://www.bsicomputer.com>

DISCLAIMERS

The opinions expressed in this article are those of the primary authors and do not necessarily reflect official policy of the United States Department of Defense, Department of Energy, Battelle, or Fraunhofer.

Reference to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the authors or their associated organizations.

MUSTPAC™ is a trademark of Battelle Memorial Institute. TeleInViVo™ is a trademark of Fraunhofer CRCG. All other trademarks are property of their respective owners.

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- [7] Mayer JH, "Ultrasound marches to the front", *Portable Design*, June 1997:43-48.
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APPENDIX D

APPENDIX D: “*MUSTPAC™ 3-D Ultrasound Teleradiology / Telepresence System*”, Project #30681 with Mercy Health System.

MUSTPAC™ 3-D Ultrasound Teleradiology/ Telepresence System

Project # 30681

Richard J. Littlefield
Laura M. Curtis
Heinz J. Roye
Lawrence E. Skelly

December 1998

Prepared for
Mercy Health System
One Bala Plaza, Suite 402
Bala Cynwyd, PA 19004

Information Sciences & Engineering Resources
Battelle Pacific Northwest Division
P.O. Box 999
Richland, Washington 99352

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1.0 Summary

Problem Statement

Mercy Health System has proposed to the Department of Defense to conduct a study showing how the use of telemedicine devices will expedite the triage and treatment process in emergency situations for patients in remote areas, thereby improving timeliness, quality of care and patient outcomes. Data generated from this study will be compared to other telemedicine devices with the goal of establishing cost effective telemedicine devices for use in the remote and austere battlefield environment with technology transfer to the civilian at-home or assisted-living environments.

Mercy Health System proposes to include the MUSTPAC™ 3-D Ultrasound System in its study to determine if sonographic data acquired in volumetric fashion can be used by a physician at a site remote from where the data was obtained for a diagnosis with accuracy equal to that of the "gold standard" in-hospital real-time protocol.

Project Objective Statement

Deliver one MUSTPAC-3 prototype five months after contract award to Battelle Pacific Northwest Division (Battelle) for test and evaluation by Mercy Health System, and provide assistance for three months to Mercy Health System in performing that evaluation, for \$372,609. MUSTPAC-3 will consist of engineering improvements that incorporate free-hand scan for gray scale into the MUSTPAC-2 system delivered under DOD Contract DAMD17-94-C-4127. Battelle also will pursue FDA 510(k) approval for the MUSTPAC-3 prototype using data resulting from the Mercy Health System study.

Project Benefits

Mercy Health System is a major provider of the medical and health services used by residents of Delaware County, Pennsylvania. The proposed collaborative research endeavor will generate data relative to the improvement in acceptance and delivery of telemedicine applications through the development of systems, policies, protocols, procedures, and educational products applicable to medical services management efforts both in the military and civilian health delivery sectors. Mercy Health System plans to use the MUSTPAC™ system as part of its state-of-the-art telemedicine network to improve the care provided in both emergency and non-emergency environments.

Mercy plans to conduct its study in two phases. Phase 1 will consist of an in-house clinical trial that will compare MUSTPAC-3 to the current "Gold Standard" ultrasound methodology. If Phase 1 successfully demonstrates the usefulness of the MUSTPAC system, then Phase 2 will take MUSTPAC-3 into the remote environment. Mercy will extend the use of the system to nursing homes, external health clinics and ambulance services. Data will be collected at the remote sites and transmitted to diagnostic experts centrally located in the major Mercy facilities for interpretation and analysis.

2.0 Deliverables

Deliverable	Description
MUSTPAC-3 Prototype, 1 each, to support Phase 1 of the Mercy study	MUSTPAC system with free-hand scan capability: • 3-D Free hand scanner device for data collection • Virtual Probe for data interpretation • Integrated MUSTPAC software
System Installation	Install MUSTPAC –3 Prototype on a Mercy computer and calibrate the system for use with a Mercy ultrasound instrument in a clinical environment
Monthly Project Status Report	Monthly status report

3.0 Scope

Execution of this project is dependent on support from two sponsors: Mercy Health System, Bala Cynwyd, Pennsylvania, and McKennan Medical System, Sioux Falls, South Dakota. The earlier versions of MUSTPAC™ were developed under a research project of the Defense Advanced Research Projects Agency (DARPA). DARPA's research objectives have been met and the project has moved into the technology transfer stage which is not being funded by DARPA. By jointly sponsoring the continuation of MUSTPAC research, Mercy Health System and McKennan Medical System will benefit, since they share a common desire to significantly improve the quality of healthcare provided to their patients through the application of emerging telemedicine systems like MUSTPAC™.

A single version of the MUSTPAC-3 prototype will be developed for both sponsors and delivered in the quantities specified in the individual project proposals of each sponsor. By sponsoring the continuation of the research each sponsor will receive an exclusive use license for its respective patient care region.

Battelle will deliver the MUSTPAC-3 software, the 3-D free hand scanner for data collection, the virtual probe for data analysis, and the computing platform to run these. Mercy Health System will provide the ultrasound instrument that will be used with the MUSTPAC-3 system. Battelle will calibrate the Mercy MUSTPAC system for use with the Mercy ultrasound instrument. Battelle also will provide user training concurrently with MUSTPAC installation and setup. A duplicate MUSTPAC-3 system will be placed at Battelle to support continued development and to serve as a "hot spare" in the event of equipment failure at Mercy.

Since MUSTPAC is an experimental medical device, it can be used only within the scope of a medical research protocol approved by appropriate IRBs (Institutional Review Boards). Mercy is responsible for preparing the protocol as well as submitting the protocol to the Mercy IRB. Federal regulations relating to Battelle's government contracts require that the protocol also be approved by the IRB at the Pacific Northwest National Laboratory (PNNL) in Richland, WA. Battelle will assist Mercy staff in the preparation of the protocol, to facilitate its acceptance by both IRBs. During the clinical trial Battelle will provide telephonic technical support to the Mercy staff.

Battelle will prepare and submit a device approval application to the U.S. Food and Drug Administration using the clinical trial data collected by Mercy and McKennan (FDA 510k application).

4.0 Background

Introduction

MUSTPAC™ is a family of ultrasound telemedicine systems based on the use of 3-D (volumetric) data acquisition. An operator with limited training and no ultrasound diagnostic skills, using a simple “point-and-shoot” procedure, can take diagnostically useful scans. For diagnosis, volumetric datasets are transmitted to a remote radiologist, who uses a “virtual ultrasound probe” to reslice the datasets along arbitrary planes, using familiar hand movements and seeing 2-D (planar) displays similar to those of a conventional real-time hands-on examination.

Health-care policy experts have become increasingly concerned about the uneven distribution of physicians. The lack of widespread availability of expertise in diagnostic ultrasound has been a particular problem. Recently, a number of groups have pioneered real-time remote ultrasound examination and have shown the value of tele-consultations for ultrasound technicians in rural areas.

However, conventional real-time 2-D (two-dimensional) ultrasound imaging has the significant drawback that a highly skilled operator must be physically present at the patient’s location. This is because conventional 2-D ultrasound imaging uses a hands-on interactive procedure that requires the operator to make diagnostic decisions simply in order to position the image acquisition probe at the correct location and orientation.

For example, to allow a diagnosis of gallstones using conventional 2-D ultrasound, the operator must interactively manipulate the image acquisition probe to locate the gall bladder, image the bile duct at the correct angle to measure its diameter, and finally locate the stones within the bladder. A positioning error of only two or three millimeters, relative to the patient’s internal anatomy, can make the difference between diagnostic images and useless ones. This need for precision pointing introduces some difficulties in using conventional 2-D ultrasound in a telemedicine setting, where the diagnostic expert does not have direct control over the probe positioning.

In contrast, using 3-D (three-dimensional) ultrasound potentially allows diagnostically useful scans to be taken by an operator with limited training, no diagnostic skills, and no real-time expert assistance. This is accomplished by having the system scan a fairly large volume of the subject’s anatomy at one time, without interpretation, so that the operator can use a simple “point-and-shoot” strategy for data acquisition.

For example, to scan for gallstones using 3-D ultrasound, the operator has to know only enough anatomy to scan a volume that includes the gall bladder. Measuring the bile duct and locating individual stones is still required, but this analysis and diagnosis can be done later by an ultrasound expert located elsewhere.

System Overview

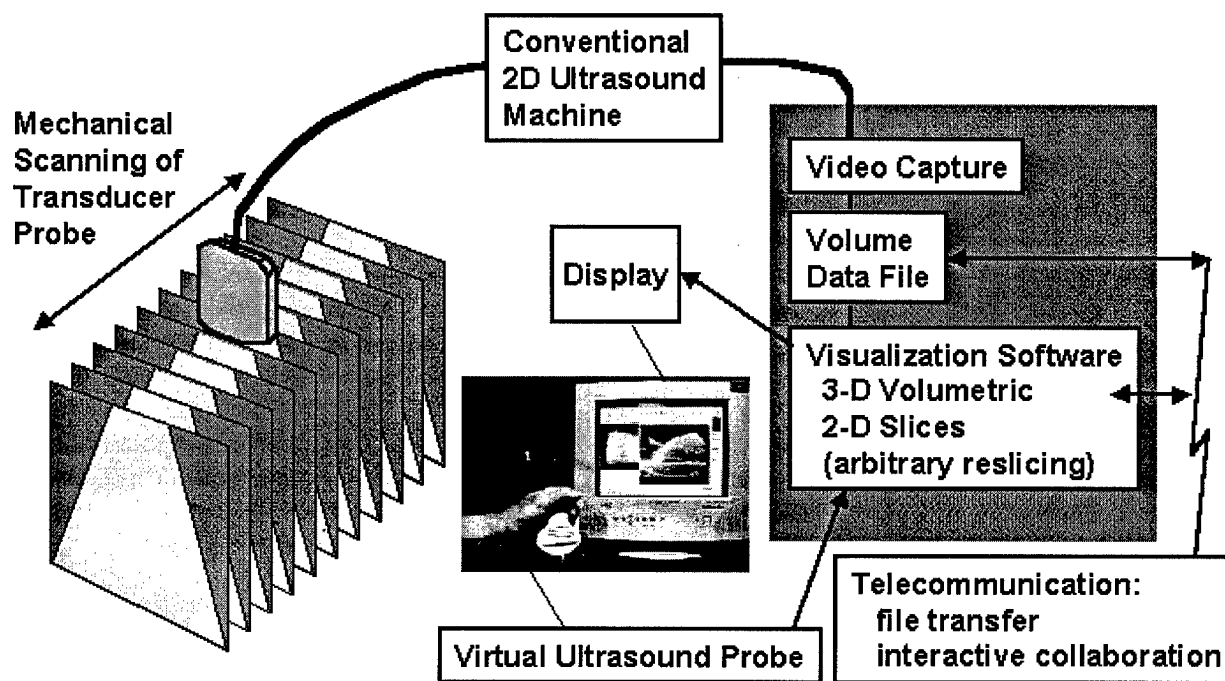
MUSTPAC™ is an ultrasound medical imaging system that can scan patients to generate 3-D volumetric digital datasets, interactively generate 3-D and 2-D images for use by diagnosticians, and optionally transfer datasets over standard communication links to facilitate remote diagnosis and consultation. It is

designed to work in a telemedicine framework, enabling diagnostically useful ultrasound scans to be taken by an operator with no diagnostic skills, modest training, and no online connection to an expert.

Typically a MUSTPAC™ system is used as follows. First, the patient is scanned by placing an ultrasound probe on the patient and mechanically sweeping it across his/her skin over the area of interest. During the scan, the system records ultrasound data from a sizable 3D volume of the patient's anatomy, producing a 3D volumetric data set of ultrasound reflectivity. The scanning process requires no interpretation of the ultrasound images, other than possibly to confirm that the intended anatomy is covered.

Scans in the form of 3D volumetric datasets are then transmitted over any standard digital network to a qualified diagnostician. Finally, a diagnostician interprets each 3-D scan using a Virtual Ultrasound Probe that simulates a conventional real-time hands-on examination procedure. This allows the diagnostician to display arbitrary 2D slices from the 3D data set simply by moving the probe as if he/she were interactively examining the patient. The Virtual Ultrasound Probe and corresponding screen displays are very natural to diagnosticians, leading to rapid acceptance and productivity.

All versions of the MUSTPAC™ system developed to date have used a similar high level design. There are two primary operations — scanning and visualization — typically separated by a data transmission step.

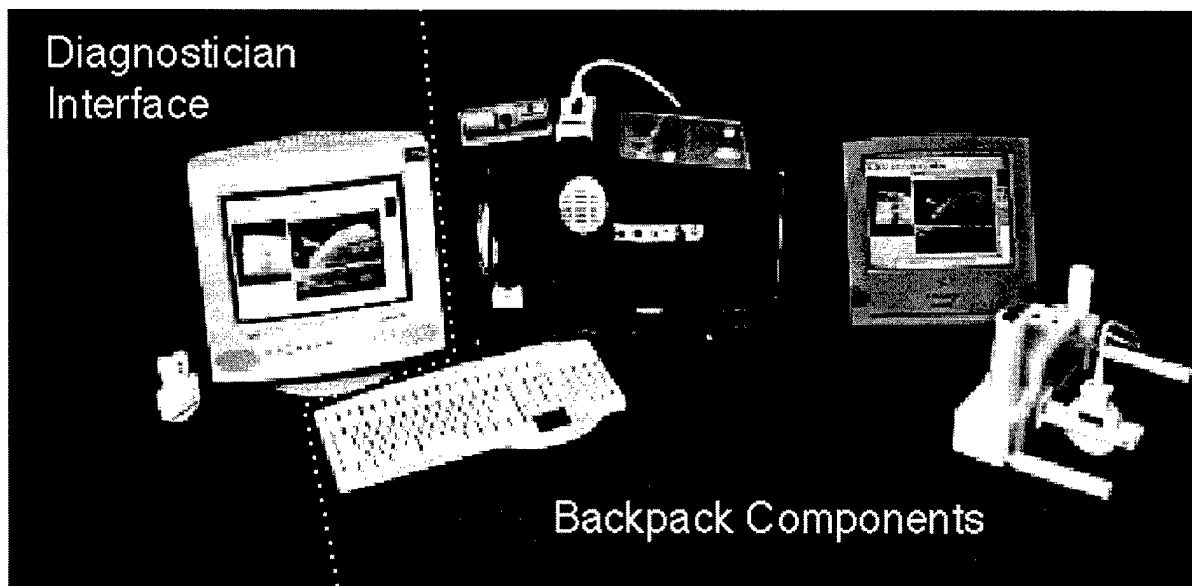


MUSTPAC-1

In the summer of 1996, the first prototype system was developed for testing by the U.S. Army under field conditions. This system, called the MUSTPAC-1, was designed to demonstrate an ultrasound telemedicine system in a backpack.

System components and packaging. Major components of the MUSTPAC-1 are shown below. These components include (right-to-left):

- Battery-powered linear scanner (at extreme right)
- Silicon Graphics Presenter™ flat panel display.
- Hitachi EUB-905™ ultrasound machine (in backpack, top section, with cord)
- Silicon Graphics Indy™ computer (in backpack bottom section)
- Teleconferencing camera (on backpack, top left)
- Keyboard with integral touchpad.
- High-resolution color monitor.
- Virtual Ultrasound Probe
- TeleInViVo™ visualization software.
- Other custom data acquisition and control software.



MUSTPAC-2

MUSTPAC-2 is actually a family of MUSTPAC™ systems implemented on a common base of Intel Pentium processors using the Windows/NT operating system. The principles of operation are similar to MUSTPAC-1. However, MUSTPAC-2 incorporates several significant improvements from the user's standpoint. These include:

- Simplified and more robust user interface
- Wider range of packaging options (e.g. lightweight and rugged data acquisition system versus high performance diagnostic workstation)
- Increased network compatibility.
- Faster transmission and reduced data volume (through JPEG data compression).
- DICOM v3.0 import/export capability.

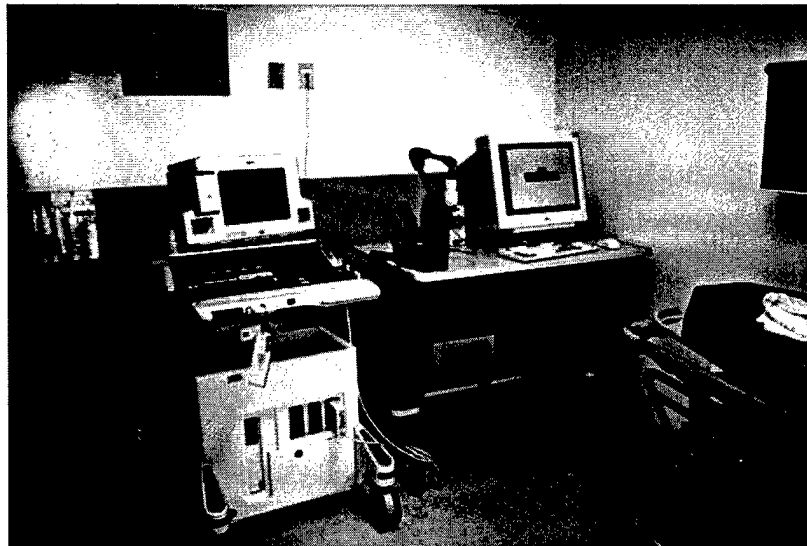
- Freehand scan (research quality– still under development for routine clinical use).

Several configurations of MUSTPAC-2 systems have been developed for specific purposes. These purposes include:

- Everest Extreme Expedition
- Hospital clinical evaluation
- Remote clinic consultation

For the purposes of this proposal, two of the configurations will be further developed for delivery to Mercy Health System as MUSTPAC-3. They are the hospital and remote clinic versions.

Hospital clinical evaluation. A bedside system equipped for both scanning and visualization has been installed at the National Naval Medical Center (NNMC) in Bethesda, MD. This system is being evaluated for use in a clinical setting, prior to possible shipboard deployment.



This unit incorporates a 333 MHz Dell Dimension XPS computer (under desk), MUSTPAC-2 Virtual Ultrasound Probe based on the Microscribe 3D articulated arm (on table), MUSTPAC-2 linear scanner (on table), and NNMC's existing ATL HDI-3000 ultrasound machine (console and cabinet at left).

Remote clinic consultation. The "lunchbox" configuration focuses on data acquisition, with limited capability for visualization. This demonstration/evaluation unit represents a configuration being considered for installation in a network of telemedicine clinics in rural northern U.S.



This portable "lunchbox" configuration incorporates a 200 MHz BSI LCD V8 computer, MUSTPAC-2 linear scanner (not shown), MUSTPAC-2 Virtual Ultrasound Probe, and any of several existing ultrasound machines (also not shown).

5.0 Technical Approach

As outlined above, current MUSTPAC-2 systems (like the one installed at NNMC) are based on the use of a motor-driven linear scanning device, TeleInViVo™ visualization software, and communication protocols used at sites where installations have been done to date. These features are not sufficient to meet the requirements of Mercy Hospital's intended usage of MUSTPAC.

To support Mercy Hospital, Battelle proposes to extend and refine MUSTPAC-2, thereby producing a next-generation system called MUSTPAC-3, and to specialize MUSTPAC-3 for Mercy Hospital's operational environment.

In particular, from the standpoint of delivered functionality, Battelle proposes to:

- Replace the motor-driven linear scanning device with a free-hand scanning capability, where the ultrasound probe is hand-held and its position and orientation are sensed instead of controlled. This will allow the ultrasound probe to follow body contours and be tilted to scan around obstructions (such as looking upward under the rib cage). It will also allow performing scans in many special situations, such as collecting images for cervical length measurements by using a vaginal probe with a side-to-side tilting/sweeping movement.
- Implement the free-hand scanning capability using state-of-the-art electro-optical and mechanical technology that is highly accurate and reliable even in the presence of metal, variable magnetic fields, etc.
- Extend the range of measurements provided by the visualization software to include angles and volumes, and to view the original (non-parallel) freehand scan images, in addition to the arbitrary reslicing that is currently provided.
- Provide file conversion and communication software as needed to make MUSTPAC-3 interoperate with Mercy Hospital's existing system for radiology image storage and retrieval.

The following actions are planned to provide the above functionality:

- Replace the current visualization software (TeleInViVo™) with a different software package (3D FreeScan™) that integrates free-hand scanning capability and visualization.
- Utilize the MicroScribe™ high resolution mechanical arm as a 6-D spatial positioning input device for both data acquisition (scanning) and visualization (reslicing, using the virtual probe). There are two major parts to this work:
 - Extend the 3D FreeScan™ software to support the MicroScribe™ arm.
 - Design and fabricate mechanical mounting devices to attach real and virtual ultrasound probes to the MicroScribe™ arm, and to hold the arm in comfortable positions for clinical use.
- Extend MUSTPAC™ communication hardware and software as needed to operate in the Mercy Hospital environment.
- Extend MUSTPAC™ file conversion software for compatibility with Mercy Hospital's image storage and retrieval system.
- Procure hardware and software licenses for MUSTPAC™ installation at Mercy Hospital and a development / hot spare system at Battelle, including two each computer systems, MicroScribe™ arms, video capture cards, FreeScan™ licenses, digital cameras, communication interfaces, and routinely required commercial utility software such as Microsoft Office, disk defragmenter, WSFTP, PKZIP.
- Develop new end-user training and documentation materials covering Mercy Hospital's targeted applications for MUSTPAC™.
- Visit Mercy Hospital to install MUSTPAC™ equipment, calibrate the MUSTPAC™ system for use with the ultrasound system to be provided by Mercy Hospital, and train Mercy personnel on MUSTPAC™ use.

6.0 Task Descriptions/Statement of Work

Task 1. Develop free-hand gray scale scan capability for the MUSTPAC system that enables the collection of diagnostically useful ultrasound data by an operator with limited training and no ultrasound diagnostic skills, using a simple "point and shoot" procedure.

Task 2. Develop the software to support: calibration of the MUSTPAC-3 for use with the Mercy ultrasound instrument; interface of the MUSTPAC-3 with the Mercy computer network, the Mercy PACS, and the DICOM standard in use.

Task 3. Install free-hand scan prototype on the Mercy computing platform. Installation will include a free-hand scanner, a diagnostic virtual probe and the MUSTPAC-3 software. The installation will be calibrated to the ultrasound instrument provided by Mercy. Network communications interface, PACS and DICOM support and data compression will be confirmed during the installation. Document the setup. Provide user training during the MUSTPAC-3 installation. Provide telephonic "help" support for 90 days after the installation.

7.0 Schedule

Milestone	Date
Task 1. Complete MUSTPAC-3 prototype free-hand scan development	5 months after award of contract
Task 2. Complete software development to support MUSTPAC-3 installation at Mercy facility	4 months after award of contract
Task 3. Install MUSTPAC-3 prototype at Mercy facility	Within 30 days after completion of Task 1
Monthly Project Report	By 10 th of each month

8.0 Budget

[deleted from project DAMD17-94-C-4127 report]

APPENDIX E

***APPENDIX E: "MUSTPAC™ 3-D Ultrasound Telemedicine Imaging System",
flyer distributed at the DOE Biomedical Technologies Exposition,
Washington DC, April 20, 1999.***



U.S. Department
of Energy

MUSTPAC™ 3-D Ultrasound Telemedicine Imaging System

MUSTPAC



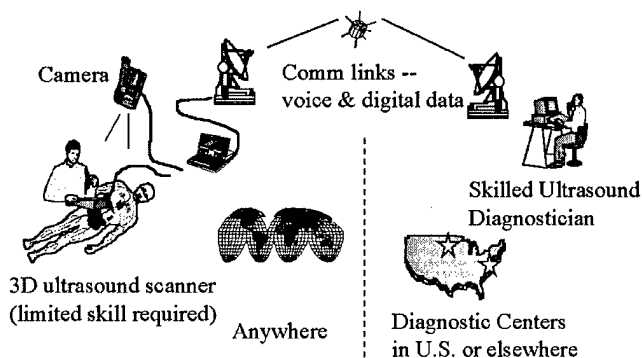
ultrasound imaging has one significant drawback: it requires a highly skilled operator at the patient's location. This is because conventional ultrasound imaging requires the operator to very precisely point a scanner probe based on diagnostic decisions while the scan is being done.

MUSTPAC™, in contrast, allows diagnostically useful scans to be taken by an operator with limited training, no diagnostic skills, and no expert assistance. This is accomplished by providing the operator with a simple "point-and-shoot" method for data acquisition. Using this method, the system scans a fairly large 3-D (three-dimensional) volume of the patient's anatomy at one time, without interpretation.

Introduction

Researchers at the Pacific Northwest National Laboratory have developed the world's first ultrasound imaging system designed specifically for telemedicine. The MUSTPAC™ system (Medical UltraSound, Three-dimensional, Portable, with Advanced Communication) allows a patient to be scanned at any convenient location, then be diagnosed by an expert at a center of excellence. This technology may have widespread application in rural and emergency healthcare, resulting in both improved quality of care and reduced costs.

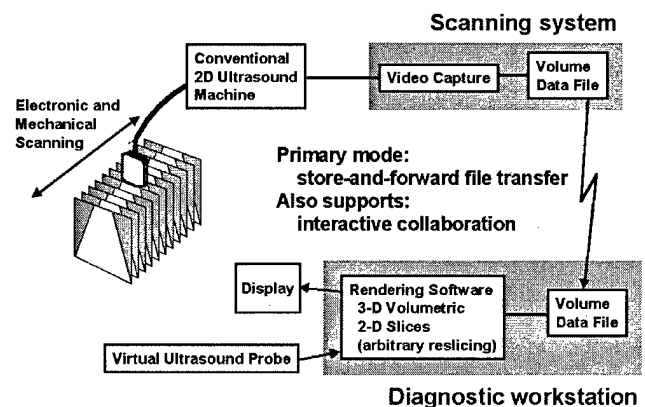
Scans in the form of 3-D volumetric datasets are sent over any standard digital network to a qualified diagnostician. The diagnostician then interprets each 3-D scan using a Virtual Ultrasound Probe that simulates a conventional real-time hands-on examination procedure. This allows the diagnostician to display arbitrary 2-D slices from the 3-D dataset simply by moving the probe as if he/she were interactively examining the patient. The Virtual Ultrasound Probe and corresponding screen displays are very natural to diagnosticians, leading to rapid acceptance and productivity.



MUSTPAC™ allows a patient to be diagnosed from far away.

MUSTPAC™ Technology

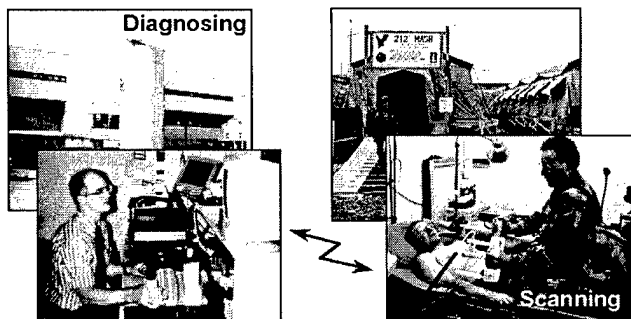
Ultrasound is a commonly used method for medical imaging of soft tissues. It is safe, inexpensive, and quick. However, conventional 2-D (two-dimensional)



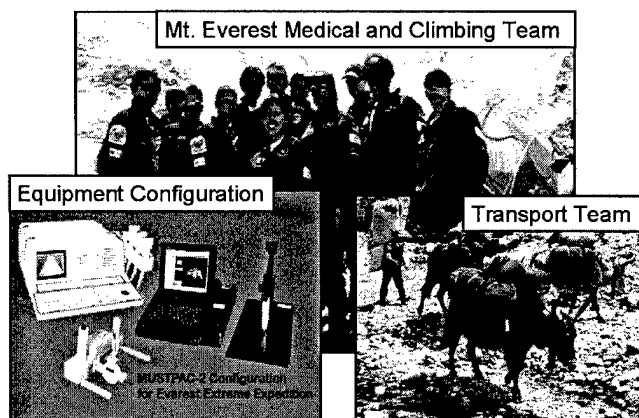
MUSTPAC™ is a leading-edge practical technology based on custom software and off-the-shelf hardware.

Applications

Beginning in 1996, a series of prototype MUSTPAC™ systems have been developed to demonstrate and evaluate the concept of 3-D ultrasound telemedicine. These systems have been tested in a variety of environments, including a U.S. Army telemedicine network in Europe, a Mt. Everest climbing expedition, and several medical institutions in the U.S. Clinical studies will soon be underway to evaluate MUSTPAC™ for routine application in rural and remote settings.



MUSTPAC™ field trials have been carried out in several unconventional settings.



Discover Award

The MUSTPAC™ system was named winner of the prestigious 1997 Discover Award for Technological Innovation in the category of Computer Hardware and Electronics.

Contacts

Rik Littlefield
MUSTPAC Project Manager
Pacific Northwest National Laboratory
MSIN K7-15
P.O. Box 999
Richland, WA 99352
voice: 509-375-3927
email: Rik.Littlefield@pnl.gov

Heinz Roye
Program Manager
Medical Technologies and Systems
Battelle Seattle Research Center
4000 NE 41st St.
P.O. Box 5395
Seattle, WA 98105
voice: 206-528-3102
email: Heinz.Roye@pnl.gov

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**Pacific Northwest
National Laboratory**
Operated by Battelle for the
U.S. Department of Energy

Visit our web sites:
<http://www.pnl.gov/>
<http://aims.pnl.gov:2080/MUSTPAC-2>



APPENDIX F

APPENDIX F: “*Three-dimensional ultrasonographic telepresence*”, Journal of Telemedicine and Telecare 1998, 4:4,224-230

► Three-dimensional ultrasonographic telepresence

Christian R Macedonia*, Richard J Littlefield†, John Coleman, Richard M Satava‡, Timothy Cramer§, Greg Mogel§ and Gary Eglinton*

*Department of Obstetrics and Gynecology, Georgetown University Medical Center, Washington, DC; †Pacific Northwest National Laboratory, Battelle Memorial Institute, Hanford, Washington; ‡Department of Surgery, Yale University School of Medicine, New Haven, Connecticut; §Telemedicine Research Laboratory, Fort Detrick, Maryland, USA

Summary

We have developed a three-dimensional ultrasound telepresence system for remote consultation. Three-dimensional ultrasound data-sets can be acquired by relatively unskilled operators. The data are stored in the remote unit and then transmitted to a consultant equipped with a similar unit. A telepresence pointing device enables the consultant to re-slice that data-set in any plane. During the study period, 72 volumetric scans of male and female volunteers aged 18–45 years were performed in Bosnia. Field users of limited ultrasound experience (most with less than 30 min of training) were able to acquire volumetric scans, send volume data and interact with remote consultants over standard communications lines at distances of up to 20,000 km. Communications links from 9.6 to 1500 kbit/s were used. Technical limitations included lack of motion data, lack of colour data, scan artefacts and increased scan-to-diagnosis time. However, our preliminary experience indicates that this technique may eventually prove to be a useful adjunct to teleultrasonography. Further studies of the technique are needed to determine its value in the broader clinical setting.

Introduction

Health-policy experts have become increasingly concerned about the uneven distribution of physicians¹. Isolated populations need access to diagnostic expertise and until recently this could be achieved only by patients or doctors travelling, or by telephone consultation. The lack of widespread availability of expertise in diagnostic ultrasound has been a particular problem, causing some to advocate the creation of ultrasound 'centres of excellence'². Recently, a number of groups have pioneered realtime remote ultrasound examination and have shown the value of teleconsultations for ultrasound technicians in rural areas^{3–5}.

They reported that examinations performed by experienced ultrasound technicians, remotely supervised by experienced sonologists, have produced similar diagnostic results to bedside examinations. Success depended on the use of image compression, coordination of users at both ends of the communications link and a robust telemedicine infrastructure^{6,7}.

We have approached the remote ultrasonography problem in a different way, using 'telepresence'. Telepresence is a subset of the field of virtual reality, which uses computer graphics (usually three dimensional) to produce computer-generated representations of real objects in distant places. Telepresence should not be confused with computer gaming technology (another subset of virtual reality), where objects presented by the computer are not real. Telepresence systems give the user the illusion of being present at a real location somewhere distant in space or time⁸.

Typically, telepresence has been described by medical researchers in the context of taking the physician to the patient^{9,10}. We view telepresence as bi-directional

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Correspondence: Dr Christian Macedonia, Department of Obstetrics and Gynecology, Georgetown University Medical Center, 3800 Reservoir Road NW, Washington, DC 20007, USA (Fax: +1 202 687 7752; Email: cmacedonia@aol.com)

when dealing with ultrasound. That is, patients can be brought to the consultant or the consultant can be brought to the patient. We became interested in telepresence because we were disappointed with the occasional awkwardness of traditional telemedicine systems for supervising sonography. These systems work quite well if a skilled sonographer is located at the remote site and are further improved if the sonographer has had some collaborative experience with the consulting sonologist. We saw ultrasound telepresence as the natural merger of three-dimensional ultrasound imaging with telemedicine networks.

We have therefore developed a system in which a three-dimensional ultrasound data-set can be acquired by a relatively unskilled sonographer. The data are stored in the remote unit and then transmitted to a consultant. The consultant can then re-slice the previously acquired data as though scanning the patient. Based on previous experience with telemedicine in remote environments, we established the following objectives for an ideal ultrasound telepresence system:

- (1) the remote system should be portable, so that it can be carried by a single person;
- (2) ultrasound scanning at the remote sites should be possible by people with little ultrasonography training (combat medics, relief workers and rural health practitioners);
- (3) the ultrasound data should be acquired quickly, in three dimensions, to limit motion artefacts;
- (4) the data transmission should follow standard Internet protocols and be capable of operating at a wide range of available telecommunications bandwidths;
- (5) the user interface for the consultant should be easy to learn and intuitive to use.

The system created to meet these objectives was called MUSTPAC (Medical UltraSound, Three-dimensional and Portable with Advanced Communications). We carried out a feasibility study and proof-of-concept trial. Our preliminary experience is described in this report.

Methods

The telepresence ultrasonography units (Fig 1) were developed and tested at the Pacific Northwest National Laboratories in Hanford, Washington. Laboratory testing was performed at the US Army Medical Research and Materiel Command in Frederick, Maryland, and

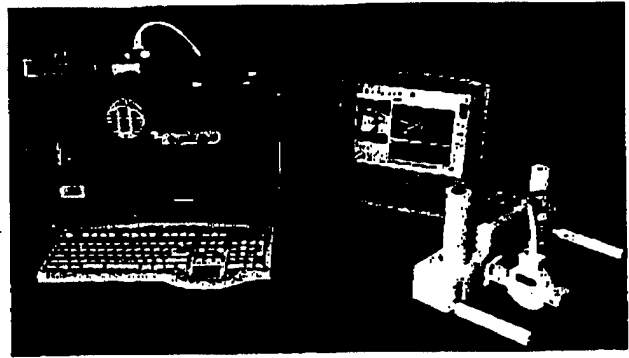


Fig 1 The MUSTPAC series of telepresence ultrasonography units.

the Georgetown University Medical Center in Washington, DC. Field tests were carried out in Bosnia.

Method of use

The normal method of use was to scan the patient, transmit the data, then break the connection between the two computers. The remote consultant could then examine the volumetric data at leisure. Results were usually reported by telephone.

In addition to the normal mode of operation, the software could link two units together in a tele-session. This gave the two users the impression that they were having a realtime interactive B-mode scanning session. These tele-sessions were simply 'conversations' between the two graphics computers. They shared position information from the telepresence pointing devices (immersion probes equipped with sham ultrasound probe heads). The units at each end displayed the two-dimensional slice generated from the three-dimensional data-set, according to the coordinates given by the immersion probe.

System architecture

The telepresence ultrasonography system comprised an acquisition unit and a consulting unit, connected by various telecommunications media. The units were similar and were composed of commercially available subsystems (Fig 2).

- (1) The ultrasound subsystem was a portable ultrasound scanner (EUB 90S, Hitachi Medical Corporation, New York) with a 3.5 MHz curved-array transducer. The ultrasound probe was attached to a linear translation device to generate volumetric scan data. The ultrasound scanner was also used as a stand-alone B-mode imager during field tests to validate the volumetric scan interpretations. The video output from the scanner

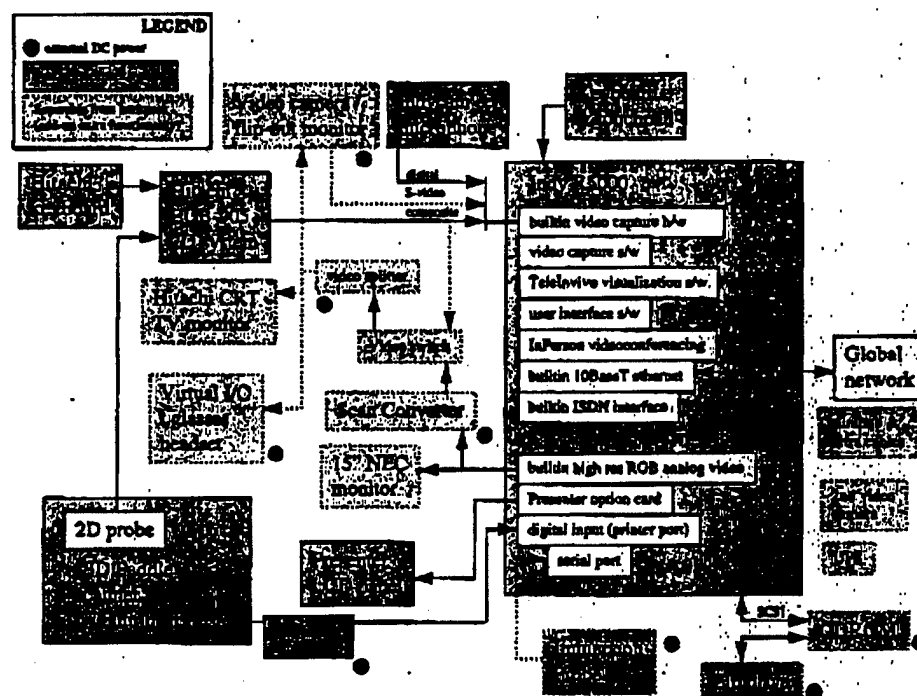


Fig 2 Connections and components of the 38 kg backpack telepresence workstation.

was connected to a video frame-grabbing board in the graphics subsystem (see Fig 2).

- (2) The graphics subsystem was a Unix workstation with a flat panel display (Indy, Silicon Graphics, California).
- (3) The volumetric scan subsystem was a battery-operated linear translation device specially built by the Battelle Memorial Institute (Hanford, Washington). The hand-held ultrasound probe could snap in and out of the linear translation device for easy conversion from volumetric mode to B-mode. We used a volumetric scanning technique that we previously reported in 1993¹¹, which was a minor modification of the method described by Robinson in 1972¹² and Halliwell *et al.* in 1989¹³.
- (4) The telepresence user interface had a probe (Immersion Corporation, California) with a milled plastic head shaped like the ultrasound probe. This gave the consulting sonologists the illusion of B-mode scanning when they interacted with the transmitted volumetric scan data (Fig 3).
- (5) The graphics software was volume-visualization software (Tele-InVivo, version 2.51, Fraunhofer Center for Research in Computer Graphics, Darmstadt, Germany), modified to create the simulated B-mode environment.

Calibration

The MUSTPAC units were calibrated in the laboratory against a standard American Institute for Ultrasound in Medicine 100 mm pin phantom comparing orthogonal-slice three-dimensional registration to the native ultrasound system measurements. They were also qualitatively calibrated with breast and liver phantoms. After synthetic image registration was confirmed to approximate native probe measurements, the units were shipped to remote sites.

Data acquisition

Images were acquired in a 256×256 , 8-bit pixel matrix by linear translation of the ultrasound transducer at a speed of 1.00 cm/s. Acquisition of the video-signal was continuous and required no special synchronization to the frame-grabber card. In each examination, up to 450 frames (1 frame every 0.3 mm) were acquired in sequence to complete the data volume. Volumetric data-sets were 4–20 MByte in size, depending on the length of acquisition and any frame averaging employed.

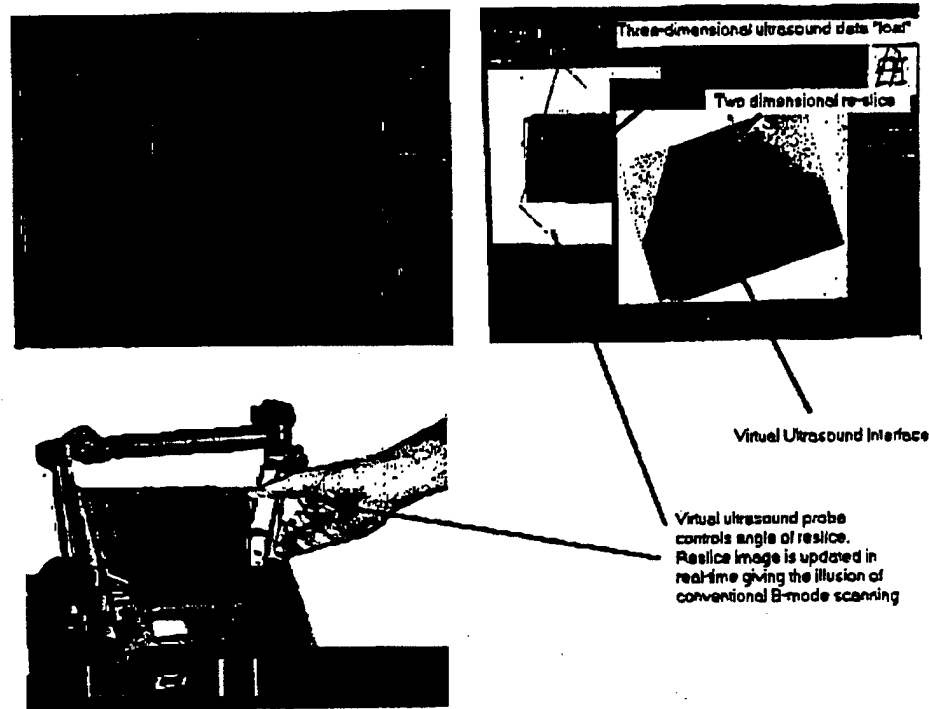


Fig 3 The telepresence user interface subsystem with the immersion probe. The virtual tele-ultrasound interface is shown on the left; on the right is a reverse greyscale image of the same interface, labelled.

Data transmission

Volumetric scan image sets were transferred to consulting units as far as 20,000 km away through a simple 'drag and drop' operation using a standard FTP protocol. Communications links from 9.6 to 1500 kbit/s were used.

Data display

The image data were displayed on a 21 inch (53 cm) X VGA monitor on the consulting unit. Control of the re-slicing of the data volume was accomplished with the immersion probe.

The telepresence interface combined the ability to analyse the volumetric scan data with full capability, including magnify and measure, while simultaneously viewing still-image re-slices of diagnostic quality. The re-slices were updated at 24 frames/s from the volumetric data-sets, giving the illusion of realtime ultrasonography of static structures. This rescanning was done entirely from the volumetric data files. Direct connection with the sending site was not required to perform the remote consultation. The consulting sonologists also had the ability to create their own set of still images for viewing. If the consulting sonologist found the scan lacked the essential data required to make an evaluation, a new scan data-set had to be

acquired and sent using the same file transmission process.

Field testing

A portable acquisition unit weighing 38 kg was tested in a US hospital in Tuzla, Bosnia, for five weeks; scan data were transmitted to a display unit in Germany. Subsequently the units were used in the USA, mainly for image quality analysis.

Scans were performed by a variety of medical personnel, including ultrasound-trained physicians and surgeons, ultrasound-naïve physicians and surgeons, nurses and paramedics. The 'sonographers' in the remote sites performed the scans using pre-formatted regions of interest with easily recognizable anatomical markers. For example, one set of instructions for a trans-abdominal study of the pelvis was: 'Place the unit transversely above the pubic symphysis resting the carrier on the anterior-superior iliac spines. Have the patient take a deep breath and hold for 15 s, press trigger and hold down until the beep sound.' The effective sonar window was typically 15 cm × 3 cm.

Obtaining the virtual scans involved a standard sequence of events (Fig 4). The study was explained and written consent was obtained from the volunteer. The machine was placed into standard two-dimensional mode at transducer frequencies of 3.5–5 MHz and the

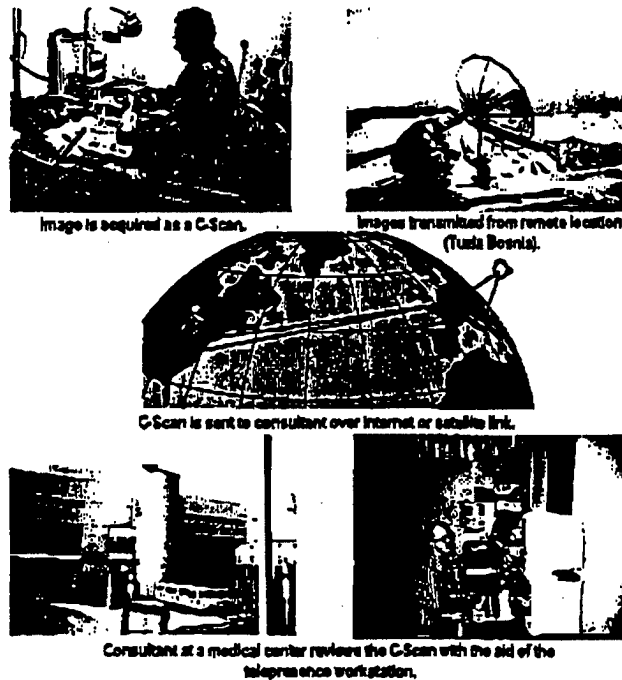


Fig 4 The normal method of use involved a standard sequence of events.

region of interest was scanned using conventional techniques by an experienced sonologist. The conventional ultrasound probe was then placed into the linear translation device. The controls of the MUSTPAC were then handed to a medical professional (paramedic, physician or nurse) with limited ultrasonography experience. The MUSTPAC was set to 'three-dimensional capture and visualize' mode. After the calibration screen was checked, the linear translation device was placed over the patient's abdomen and a sweep was performed. Normally two or three sweeps were made.

Upon completion of an individual volumetric acquisition scan, the local MUSTPAC unit automatically presented the user with a three-dimensional reconstruction of the sweep. The acquisition unit was also fitted with an immersion probe so that the local operator could produce two-dimensional slice images.

Primary diagnoses were made by interpreting soft-copy images. Images were archived in a lossless compression format after primary interpretation.

Results

Each frame of the resultant three-dimensional image was processed and displayed in a conventional B-mode manner. Therefore, the typical properties of each frame

of the image were very similar to standard B-mode acquired images. Blur, resolution, unsharpness, contrast sensitivity and image detail remained the same, and the diagnostic quality of each individual frame was unchanged from a conventional two-dimensional scan.

The overall quality of the three-dimensional images was comparable to those produced by similar two-dimensional ultrasound scanners. The images acquired by individuals with less than 30 min of training were clearly superior to what would be expected were they to attempt to perform unaided two-dimensional sonography.

Typical image artefacts occurred on the three-dimensional imaging system. These are useful in making a sonographic diagnosis; for example, posterior enhancement of fluid-filled structures occurs. Posterior shadowing of some tissue interfaces was the same as with conventional ultrasound imaging. These artefacts were unchanged by altering the angle of insonation when using the virtual probe to interrogate the data block from a different orientation. This gave the image an unconventional appearance when viewing from the other angles, with the posterior enhancement or shadowing appearing to come toward the transducer.

During the study period, 72 volumetric scans of male and female volunteers aged 18–45 years were performed in Bosnia. The subjects were healthy medical staff and patients seen at hospital for a variety of medical complaints including: pregnancies, pelvic pain, abdominal pain, postoperative fever and abdominal trauma. Transmission times depended on the communications bandwidth available. In Bosnia for instance, a 5 MByte file sent over the dedicated telemedicine network using E-1 satellite links took less than 1 min to transmit to Germany. The same data-set was sent over the much slower but more widely available Tactical Packet Network (TACNET), taking 228 min.

Figs 5–8 illustrate some of the field findings. Each image shows a screen shot of the MUSTPAC user interface, including the volumetric image (seen on the left-hand side of each screen) and the two-dimensional re-slice (seen on the right-hand side of each screen). The slicing plane can be seen transecting the volume image. Figs 5 and 6 show the consulting sonologist's hand as he 'scans' the data.

Discussion

Ian Donald wrote in 1958, 'To be of any use at all to the clinician, the echo patterns obtained by pulsed ultrasound must be not only intelligible but also consistently reproducible at the same level in the same

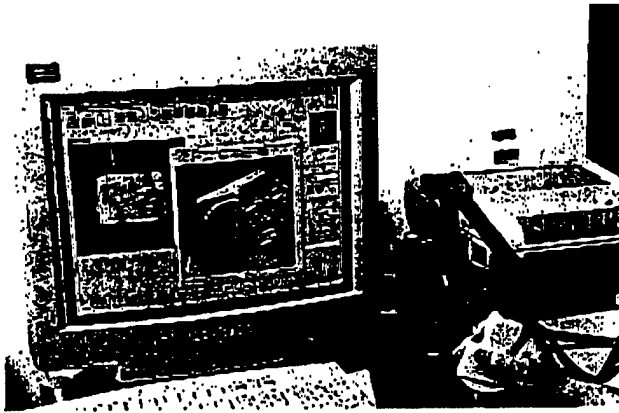


Fig 5 The consulting user has angled the cutting plane of the virtual ultrasound probe through the face of a 24-week fetus. He has highlighted the philtrum to document normal anatomy.

case.¹⁴ This applies to telepresence ultrasound as much as it does to bedside sonography. Getting intelligible and reproducible images of important anatomical structures is an essential step in sonographic diagnosis. How one makes the ultrasound probe point in the correct plane is what determines the utility of any individual image.

Currently, the only proven way to ensure that proper ultrasound image angles are obtained at remote examination centres is to have a skilled sonographer at each end of the communications link. However, this is not a practical solution for rural or underdeveloped parts of the world. Many of these areas have nearly the same difficulty in attracting trained ultrasonographers as they do in attracting consulting sonologists.

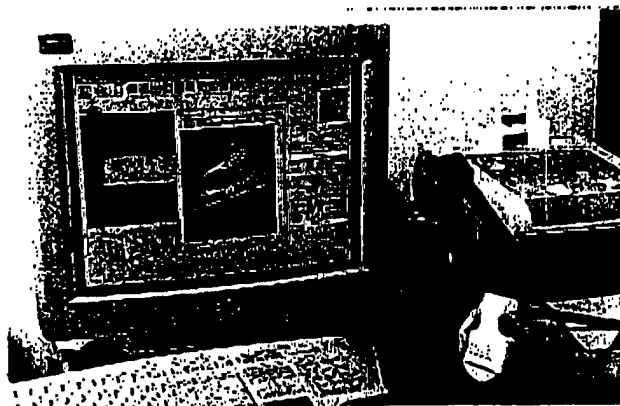


Fig 6 A 32-year-old female soldier developed fever, rigors and localized tenderness over the region of a recent low transverse abdominal incision. The evaluating surgeons suspected a post-operative abscess or seroma formation. They requested a sonographic evaluation to determine the point of deepest pocket for fluid aspiration. B-mode ultrasound and remote volumetric scan ultrasound measurements of lateral fluid pockets were identical. The fluid samples were consistent with seroma.

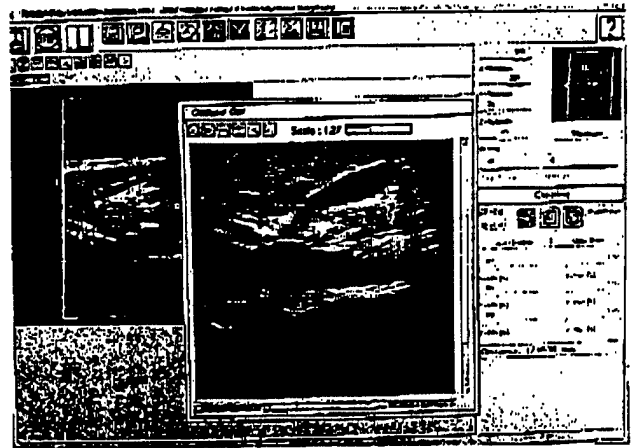


Fig 7 A 32-year-old male soldier presented with symptoms of colic in the right upper quadrant, fat intolerance and a family history of cholelithiasis. Urine analysis was normal. A complete blood count was normal. A hepatitis screen was negative. This image shows the gallbladder, without evidence of cholelithiasis or wall thickening. The negative findings meant that the patient could return to his unit rather than being transferred to the nearest fixed US medical centre with ultrasonography (800 km away). This image shows that distance measurements can be taken from the synthetic views. This particular synthetic image slice is 60° off the original scan axis.

Our experience in Bosnia and Germany demonstrated that the quality of the captured volume image was largely independent of the operator's level of training. Like conventional B-mode ultrasound, patient morphology and recent meals were the most important

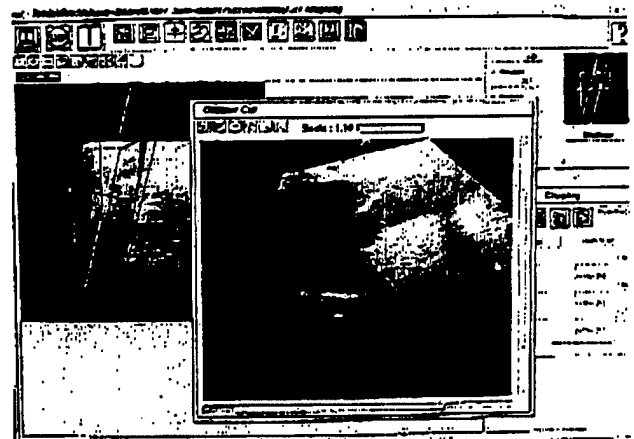


Fig 8 A 30-year-old female presented with symptoms of colic in the right upper quadrant, fat intolerance, flatulence and 'sand-coloured' stools. B-mode ultrasound and remote volumetric scan imaging of the right upper quadrant confirmed cholelithiasis. This image shows two of the major limitations of our telepresence technique. First, the three-dimensional re-slice is limited by the quality of the B-mode imaging system. Patients who are less 'sonogenic' in B-mode provide correspondingly poor three-dimensional re-slices. The second notable feature in this image is the preservation of shadow artefact streaming in the direction of the original angle of insonation, not straight down.

factors determining overall image quality. While our preliminary results have been promising, we feel this technique has limited value without the addition of such features as Doppler and realtime volume acquisition capabilities. We anticipate that the introduction of realtime volume imagers will be a bridge between work on three-dimensional ultrasonographic telepresence and more traditional teleultrasonography.

We plan to conduct a prospective, multicentre, multidisciplinary study to examine how telepresence technology compares with conventional ultrasonography in diagnostic efficiency and accuracy.

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APPENDIX G

**APPENDIX G: “Telemedicine and ultrasonography: making waves”,
Ultrasound Obstet Gynecol 1998;12:1-2.**

Opinion

Telemedicine and ultrasonography: making waves

'In a little more than a century, a united profession working in many lands has done more for the race than has ever been accomplished by any other body of men. So great have these gifts been that we have almost lost our appreciation of them. Vaccination, sanitation, anaesthesia, antiseptic surgery, the science of bacteriology, and the art of therapeutics have effected a revolution in our civilization to which can be compared only the extraordinary progress in the mechanical sciences. Over the latter, there is this supreme advantage, it is domestic – a bedroom revolution which sooner or later touches each one of us, if not in person, in those near and dear – a revolution which for the first time in the history of poor, suffering humanity brings us appreciably closer to that promised day when the former things should pass away, when there should be no more unnecessary death, when sorrow and crying should be no more, and there should not be any more pain.'

Sir William Bart Osler (1849-1919)

On the profession of medicine

Most medical practitioners today have heard of 'telemedicine', but few if any have a complete understanding of the impact of this emerging field on the future of their profession¹. Much of the ambiguity results from the fact that telemedicine is only a partial creation of physicians. Many of the developments in this field are adaptations of non-medical telecommunications technologies implemented in a medical environment². Telemedicine is, therefore, viewed with scepticism by those who see it as an external threat rather than an internal evolution.

Advances in telecommunications sciences are pushing telemedicine forward, but this should not lead us to the conclusion that this field is entirely technology driven. Medical decision-making has long been a complex process requiring a highly organized system of generalist and specialist practitioners deployed through multiple echelons of treatment facilities. The system works extraordinarily well in urban regions but performs much less efficiently in rural or isolated regions of the world³. In the time of Sir William Osler, this model provided the best possible medical system to the greatest number of people.

Sir William Osler and his contemporaries did not have ISDN and T1 lines, low earth orbiting satellites, and ultra-high speed fiber optic networks. He did not have a network PC on his desk. His mail was sealed in envelopes and carried to their recipients by humans. Dr Osler was, however, no technophobe. He embraced the advanced scientific technologies of his day. There is every indication that, if

he were alive today, he would be incorporating computers and advanced telecommunications into his research, his teaching, and his patient care.

Obstetric ultrasonography is a wonderful example of how the old 'echelon' paradigm needs to give way to a new 'web' paradigm⁴. At the 1995 meeting of the American College of Obstetricians and Gynecologists in San Francisco, I attended a lively debate between Dr Frederick Frigoletto, Chairman of Ob/Gyn at Harvard, and Dr Richard Berkowitz, Chairman of Ob/Gyn at New York University. They discussed the implications of the controversial Routine Antenatal Diagnostic Imaging with Ultrasound Study (RADIUS)⁵. While they disagreed on study design, cost analysis, and published study conclusions, they agreed on one point. Detection rates of major anomalies in RADIUS sites at less urban community hospitals were poor and dramatically different from rates reported by the major university hospitals in the RADIUS study and by European institutions in previously reported studies. The two agreed that inclusion of these results significantly skewed the findings of the study. This led Dr Berkowitz to comment that the only valid conclusion of RADIUS was that 'Fetal screening sonography examinations should only be performed in ultrasound centers of excellence'. Dr Frigoletto replied that, in small and densely populated countries, centers of excellence make sense. The United States and much of the rest of the world, however, are not situated this way.

This edition of the Journal contains an article from Dr Fergal Malone and his telemedicine research group at the New England Medical Center⁶. Their previously reported work on fetal ultrasonographic telemedicine, as well as work from Fisk and colleagues in the UK, points to a partial solution to the centers-of-excellence dilemma⁷⁻⁹. They propose extending the reach of ultrasound centers of excellence to smaller and remote facilities by leveraging the capabilities of commercially available teleconferencing systems. This most recent work by Malone and colleagues, as well as information from studies in Scandinavia, indicates that ultrasonographic telemedicine over teleconferencing systems (video telemedicine) may indeed be cost-effective or, at a minimum, cost neutral¹⁰.

Most professionals in our field would agree that having skilled sonographers performing examinations is at least as important as having skilled sonologists interpreting the images. Unfortunately, video telemedicine does not address the issue of sonographer proficiency. In the previously mentioned video telemedicine studies, skilled sonographers are used at the remote sites. But is it any

easier to find skilled *sonographers* who will go to less populated regions than it is to find *sonologists* to do the same?

We at the 3D Ultrasonographic Telepresence lab at Georgetown are performing basic and field research on how the expertise of the highly skilled sonographer can be transferred over telemedicine networks. Our system uses simple volumetric acquisition of ultrasonographic data followed by batch transfer, reconstruction, and virtual ultrasonography to 'move' a portion of the patient's body electronically to the center of excellence¹¹. There are, to be sure, many technical limitations to this method of examination. Others have addressed the issue by working in the opposite direction. They use a combination of video tele-sonography and tele-robotics mechanically to steer the ultrasound probe over the patient in the remote site. While these solutions may seem a bit exotic, working prototypes do exist. Our system has been used in places as remote as war-torn Bosnia and the base camp of Mount Everest (17 600 ft).

Telemedicine is being used in Ob/Gyn ultrasonography. Advances and refinements will come as the natural progress in telecommunications technologies evolves. Equipment of the future will probably have built-in teleconferencing/telementoring. Volumetric imaging will provide an alternative 'store-and-forward' means of obtaining consultations. Tele-robotics may eventually be used in our field, but will probably have to overcome significant patient and physician anxieties over the safety of robotic assistants. In my opinion, however, there is little doubt that the telemedicine revolution will decrease cost, improve quality of care, and make all of our lives more interesting.

Department of Obstetrics and Gynecology
Georgetown University Medical Center
Washington DC, USA

C. R. MACEDONIA

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