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NATIONAL
LABORATORY

LLNL-TR-746147

Enhanced Visualization Technologies with Medical and Manufacturing Application Final Report CRADA No. TC-1084-95

S. Burastero, D. D'Alfonse

February 9, 2018

This work performed under the auspices of the U.S. Department of Energy by Lawrence Livermore National Laboratory under Contract DE-AC52-07NA27344.

DISCLAIMER

Enhanced Visualization Technologies with Medical and Manufacturing Applications

Final Report
CRADA No. TC-1084-95

Date: June 30, 1999 Revision: 3

A. Parties

The project is a relationship between the Lawrence Livermore National Laboratory (LLNL) and Envision Medical Company (EMC).

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Envision Medical Corporation[1]
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B. Project Scope

In this CRADA effort, LLNL's core strengths in optics were leveraged to develop a design for prototype system that would be characterized by improved real-time endoscopic visualization. The visualization enhancements were targeted at image features which were critical elements of the surgical decision making process and were the surgeon's only visual and major sensory link during endoscopic surgical tool positioning.

Endoscopic "minimally-invasive" procedures are being performed more frequently in medicine. Many of the more routine laparoscopic and arthroscopic procedures have had their technical difficulties overcome. The demand for "minimally invasive" surgical procedures motivated new procedures to be attempted in smaller surgical fields. During these new procedures, new visualization challenges were present for which solutions were needed.

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[1] After the commencement of the CRADA, Envision Medical was purchased by Linvatec Corporation, a division of ConMed Corporation.

These challenges included:

1) A limitation in the geometric volume and configuration in which the visualization optics and surgical tools must fit. A ramification of this was the problems associated with physically smaller optical components.
2) Restrictions on the range of allowable orientations of the tools relative to the anatomic structures. This necessitated need for greater visual field of view. Associated with this were problems of optical visual distortion.
3) Within the more specialized tissue regions there was often a decrease in visual characteristics that could be used to differentiate tissue structures.
4) The need for flexible optical transmission methods (fiber optic systems). Ramifications of this were problems with image degradation due both to the optically discontinuous cross section of the fiber array and aspects of the physical coupling between the charged coupled device (CCD) sensor and fiber bundle.

The physical specifics described above resulted mostly to degrade image properties for images derived within this surgical context. Specific image characteristics such as spatial resolution, structure contrast, optical clarity and color fidelity were each negatively influenced, causing image degradation. This CRADA project pursued image processing and optical solutions aimed at improving these image properties.

Associated with the endoscopic procedure addressing carpal tunnel syndrome (CTS) of the wrist/hand complex were problems that were representative of many of the new endoscopic procedural endeavors in smaller surgical fields. The principal investigator on this project had a keen professional interest in problems in the medical area (cumulative trauma disorders or CTD's) for which this surgery addresses. The Endoscopic Carpal Tunnel Release (ECTR) procedure was used as the specific surgical example for describing the context of imaging problems which occurred during this new class of more miniaturized endoscopic surgeries.

CTS is one of the most costly and debilitating industrial injuries plaguing U.S. industry, accounting for roughly $10 - $15 billion in medical costs per year. Since the early 1980's, CTS has become common among keyboard workers, as well as employees in the food processing, construction, electronics, and garment industries. At LLNL, CTS cases have increased 20% each year. The standard cure for severe CTS has been the open surgical release (OSR). In the OSR procedure, a 4-5 inch skin incision is made and the flexor retinaculum, a tense fibrous band covering the carpal canal, is cut to allow decompression of the median nerve, and relief of symptoms. This has been reported to have a cure rate of approximately 90%. The patient usually returns to work in 6-8 weeks. OSR, however, is associated with significant post-operative pain.

ECTR surgery is a minimally invasive surgical technique which, has been clinically evaluated in the last few years and has been shown to significantly decrease the return to work time as well as post-operative pain. At least 10 employees at LLNL underwent ECTR during 1993.

However, significant technical problems and complications occur with ECTR, which lower its cure rates. The major problem is the surgeon's limited field of view when performing this technique. This can result in incomplete transection of the transverse carpal ligament, the ligament responsible for median nerve compression in CTS, and surgical failure. Poor visualization also results in inadvertent arterial, nerve, and tendon injuries, as described below. Unlike open procedures, these complications may not be recognized at the time of surgery and dealt with promptly.

The median nerve lies just deep to the radial side of the transverse carpal ligament (TCL). Its fibers are nearly perpendicular to the TCL fibers and it maintains its position in the canal by tethering nerve branches to the thumb muscles as well as synovial attachments to the TCL. The median nerve branches into the common digital nerves distal to the TCL at the level of the superficial arch. These nerves run at acute angles to the course of the median nerve and are tethered to it. This makes it easy to catch and section the digital nerves with the blade if the distal end of the cut is made too far into the palm. The nerves appear white in the screen and are the same color as the ligament.

Furthermore, the blade is distal to the lens, and while the surgeon may see only the very distal portion of the ligament, the blade may be in the area of the digital nerves.

The median nerve is tethered to the radial side of the carpal tunnel, and the procedure is directed toward the ulnar side of the carpal canal to avoid injury to the nerve. If the surgeon is not accurate in the entry point or in the orientation of the instrument, the median nerve can be caught by the blade and sectioned. With the current instruments, the nerve is the same color as the ligament and since it lies to the side of the canal, it is in the peripheral portion of the image the physician sees.

The ulnar nerve passes through Guyon's canal, which is superficial to the TCL and then plunges to the bases of the metacarpals just distal to the ligament. Inadvertent opening of the blade with the instrument directed ulnarly at the distal ulnar side of the carpal canal places this structure at risk of injury. Again, it is not possible to distinguish nerve from ligament with the current instruments.

Because of its position, the superficial arch is also at great risk for laceration because it runs parallel to the fibers of the transverse carpal ligament and is just distal to it. The branching of the median nerve into digital nerves occurs at the level of the superficial arch. There is no soft tissue interposed between the two structures and injury to the arch can easily accompany lacerations of a digital nerve. The arterial injury is not diagnosed since the surgery is done with exsanguination of the limb and use of a pneumatic tourniquet. The endoscope is no longer in the tunnel when the tourniquet is deflated, so bleeding is not observed. With this technique most lacerations would be complete, and bleeding would stop because of arterial spasm. Lesions of the superficial arch may impair the blood supply to areas in the hand and lead to weakness or pain with extended use.

Surgeons are very anxious to avoid injury to the arch or the digital nerves at the distal end of the TCL. For this reason, they tend to be too proximal when they initiate the cut. This can lead to incomplete section of the ligament and continued pressure from the ligament on the nerve. This error is the opposite of that, which produces digital nerve lacerations, but stems from the same cause—the surgeon's inability to clearly differentiate between the different structures in the hand.

Medical visualization systems are comprised of an endoscope, camera, light source, and adapters, integrated by equipment. 3-D video enables the endoscopic surgeon to have some depth perception, but this is limited at best. Images formed with endoscopes suffer from a spatial distortion due to the wide-angle nature of the endoscope's objective lens. The distortion causes areas in the image farther from the center of the field to appear proportionally smaller than they are. A need exists for correcting the distortion of the image. A polynomial correction formula can be developed for the endoscope lens and validated by comparing quantitative test areas before and after the distortion correction. An alternative would be to utilize optics which interface between the endoscopic and camera sensing elements.

Two interventions, which would improve current instruments, are accentuation of tissue visual characteristics and broad field of view with minimized distortion. Improvement of the optics so that structures such as the nerves and the vessels could be more easily distinguished from the TCL would be a great aid to the surgeon. The nerves are actually yellowish with vascular markings and have large amounts of lipids in their fibers, in comparison to the ligament, which is avascular and composed of type I collagen. The vessels have fat in the adventitia and if the arm is not completely exsanguinated, should have blood in their lumens. If these characteristics were accentuated, differentiation of nerve and vessel from ligament would help in the structure identification and orientation task required of the surgeon.

A broader field of view should allow the surgeon to visualize structures beside the instrument such as the median and digital nerves as well as structures in the area of the blade. This would help prevent unintentional laceration of vital structures in the hand.

This CRADA project leveraged existing LLNL technologies and clinical/industrial collaborations to improve visualization leading to performance improvements in the surgeons tool positioning and dexterity in the newer, more miniaturized, and more challenging endoscopic procedures. Specific to ECTR, this would ultimately improve cure rates for CTS and decrease postoperative complications. Also, this would lead to a lowering of the steep learning curve for surgeons learning ECTR, and result in decreased workers' compensation costs to industry.

Deliverable	Duration	Responsible Party
Delivery of current endoscopic system designs w/specifications to LLNL by Envision Medical Corporation	2 months	EMC
Assembly and delivery of problematic image examples	2 months	EMC
Thorough design review of existing endoscopic system	12 months	LLNL
Optical system improvements:		
Conclusions regarding determination of manufacturing options	18 months	LLNL/EMC
Design of improved endoscopic system	20 months	LLNL
Review of endoscopic system design relative to the functional and technical requirements of minimally invasive surgical practice	24 months	EMC

C. Technical Accomplishments

Digital signal processing techniques were evaluated by LLNL for improvements in image quality. High-resolution video and still images were made through the existing endoscope of medical procedures. These images were enhanced using a variety of image processing techniques including: contrast enhancements, improved edge definition, noise reduction techniques, field flattening techniques, and perhaps false color methods. These images were evaluated to determine their potential medical utility relating to minimally invasive surgical practice. Budget reductions necessitated a scaling back in deliverables. Because of a reduction in resources, this objective was later changed to focus on cost effective optical improvements, most notably, glare reduction. A proof-of-concept design was developed and piloted in the laboratory with surgical steel and moist tissues. A second design was shared with EMC, but resources did not permit its pilot trials.

D. Expected Economic Impact

Benefits to DOE/DP/LLNL

Cumulative Trauma Disorders (CTD's) have received increased attention by policy makers in recent years due to dramatic increases in their occurrence which has led to sky-rocketing health care and worker's compensation costs. CTD's continue to increase nationally, from less than 20% of occupational illnesses nationwide in 1981 to about

60% of occupational illnesses today. The number of cases reported annually in the U.S. has risen to over 150,000. CTD's cost the nation over $40 billion in total cost, including estimated loss of productivity during the rehabilitation period.

LLNL and other DP lab's worker's compensation statistics reflect a similar upswing in RSI. At LLNL, for example, hand injury cases such as carpal tunnel syndrome (CTS) have increased 20% each year. Successful ECTR would lead to a worker's compensation costs savings to DOE, DP, LLNL and American industry by decreasing the post-operative return to work time from 6-8 weeks to 2 weeks and significantly reducing post-operative pain. Improved visualization in ECTR will most likely increase the cure rate and lower its complication rate. DOE/DP/LLNL would additionally benefit by further developing its expertise in design of minimally invasive surgical tools.

Benefits to Participant

EMC expected to incorporate the technology into its endoscope systems at the completion of this CRADA. Successful implementation of this technology would result in improved visualization during surgical endoscopic procedures. The marked improvement in image quality for EMC's products was expected to make their endoscope systems the products of choice and significantly increase EMC's revenues. EMC's ability to compete against Japanese and German firms, who dominated the market, would be greatly enhanced with this technology.

Benefits to U.S. Economy

Improvements in minimally invasive surgeries (e.g., ECTR) will enhance U.S. economic competitiveness twofold: Reducing worker's compensation costs and decreasing recovery time off from work after surgery. Improvements in the technology used for endoscopic visualization can also economically benefit the U.S. company which is collaborating on this project and hence, the U.S. economy.

E. Partner Contribution

There were many image processing algorithms with proven edge and detail-enhancing capability that were considered. Processing the chrominance channels, as well as the intensity, could help recover and enhance the color information.

LLNL addressed the visualization goals in the following steps:

1) Design of dedicated hardware for the final low-cost implementation. LLNL determined the combination of algorithms that best addressed the specific application and operation condition.

   LLNL reviewed the basic optical characteristics of EMC's existing endoscopes, and determined what improvements in resolution, magnification, and uniformity of the endoscope field of view were desirable and possible. LLNL provided the optical design expertise for this review and the company provided the current design and expertise on design factors related to manufacturability and marketability of medical endoscope optical interface systems. This joint effort produced a list of potential improvements to the optics of the system. Two new optical designs incorporating these improvements were developed by LLNL. These designs could be implemented by an outside vendor selected jointly by EMC and LLNL or by EMC itself.

LLNL also constructed a spectroscopic microscope for measuring the spectrally resolved reflectivities of relevant tissues. The operation of the current endoscope was limited by the low contrast available from the anatomic tissue observed during surgical procedures using essentially white light illumination. Due to budget reductions, the spectroscopic microscope was not utilized to obtain the reflectivity of the different tissue types as a function of wavelength. The data from the spectroscopic microscopy measurements could be used to determine the optimum wavelengths of endoscope operation for maximum image contrast.

F. Documents/Reference List

a) Technical Publications

LLNL Publications: None

Participant Publications: None

b) Intellectual Property

i) Subject Inventions

Art. I(G): "Subject Invention" means any invention of The Regents or Participant conceived or first actually reduced to practice in the performance of work under this CRADA.

Art. XIV(A): The Parties agree to disclose to each other each and every Subject Invention, which may be patentable or otherwise protectable under the Patent Act.

<u>LLNL Subject Inventions:</u>

IL 10235, "Endoscopic Optical Isolation," Waleed S. Haddad, Robert L. Van Vorhis. Disclosure date 10/3/97.

IL-10236, "Image Improvement Using Spatial Light Modulation," Waleed S. Haddad, Robert L. Van Vorhis. Disclosure submitted 10/20/97. The Regents has elected not to retain title to this Subject Invention.

CRADA Article XV provides that each Party shall have first option to elect to retain title to any invention made by its employees. If a Party elects not to retain title to any invention of its employees, then the other party shall have the second option to elect to retain title to such invention under this CRADA. Participant has not indicated an interest in obtaining title to IL-10236.

Subject Inventions disclosed by Participant: None

Licensing Activity:

CRADA Appendix C provides that to the extent that The Regents obtains title or authority to license Intellectual Property first arising or produced under this CRADA and related Background Intellectual Property, The Regents shall negotiate in good faith with Envision Medical Corporation for a license to rights in such Intellectual Property for the life of the CRADA plus a period of not more than six months after the completion or termination of this CRADA.

Participant has indicated an interest in licensing IL-10235.

LLNL Background Intellectual Property: VISION Algorithm. Participant has not indicated an interest in licensing LLNL Background Intellectual Property.

ii) Copyrighted Computer Software

CRADA Article XIII requires that for all copyrighted computer software produced in the performance of this CRADA, the Party owning the copyright will provide the source code, an expanded abstract, and the object code and the minimum support documentation needed by a competent user to understand and use the software to DOE's Energy Science and Technology Software Center.

No copyrighted computer software was produced in the performance of work under this CRADA.

G. Acknowledgement

Participant's signature of the final report indicates the following:

1) The Participant has reviewed the final report and concurs with the statements made therein.
2) The Participant agrees that any modifications or changes from the initial proposal were discussed and agreed to during the term of the project.
3) The Participant certifies that:
   a) all reports either completed or in process are listed;
   b) all subject inventions attributable to the project have been disclosed or are included on a list attached to this report; and
   c) appropriate measures have been taken to protect intellectual property attributable to this project.
4) The Participant certifies that if tangible personal property was exchanged during the agreement, all has either been returned to the initial custodian or transferred permanently.
5) The Participant certifies that proprietary information has been returned or destroyed by LLNL.

4/11/00

David D'Alfonso
Envision Medical Corporation

Date

6/23/00

Steve Burastero
Lawrence Livermore National Laboratory

Date

Attachment I – Final Abstract
Attachment II – Project Accomplishments Summary
Attachment III – Final Quarterly Report

Enhanced Visualization Technologies with Medical and Manufacturing Applications

Final Abstract
Attachment I
CRADA No. TC-1084-95

Date: July 6, 1999 | Revision: 2

In this CRADA effort, LLNL's core strengths in optics were leveraged to develop a second generation prototype system that would be characterized by improved real-time endoscopic visualization. The visualization enhancements were targeted at image features which were critical elements of the surgical decision making process and were the surgeon's only visual and major sensory link during endoscopic surgical tool positioning.

Endoscopic "minimally-invasive" procedures are being performed more frequently in medicine. Many of the more routine laparoscopic and arthroscopic procedures have had their technical difficulties overcome. The demand for "minimally invasive" surgical procedures motivated new procedures to be attempted in smaller surgical fields. During these new procedures, new visualization challenges were present for which solutions were needed.

The objective was to develop a system that used optics to minimize glare while preserving color integrity.

Enhanced Visualization Technologies with Medical and Manufacturing Applications

Project Accomplishments Summary (Attachment II)
CRADA No. TC-1084-95

Date: July 7, 1999 Revision: 1

A. Parties

The project is a relationship between the Lawrence Livermore National Laboratory (LLNL) and Envision Medical Corporation (EMC).

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David D'Alfonso
(805) 967-6000 ext. 111

B. Background

In this CRADA effort, LLNL's core strengths in optics were leveraged to develop a prototype system that would surgeon's visualization. During endoscopic surgery, the enhancements were targeted at glare reduction, which were critical elements and were the surgeon's only visual and major sensory link during endoscopic surgical tool positioning.

Endoscopic "minimally-invasive" procedures are being performed more frequently in medicine. Many of the more routine laparoscopic and arthroscopic procedures have had their technical difficulties overcome. The demand for "minimally invasive" surgical procedures motivated new procedures to be attempted in smaller surgical fields. During these new procedures, new challenges were present for which solutions were needed.

[2] After the commencement of the CRADA, Envision Medical was purchased by Linvatec Corporation, a division of ConMed Corporation.

C. Description

Two technical objectives were identified which addressed our overall goal of improving the visualization during Endoscopic Surgical procedures.

a) Improvements in the Optical System

During ECTR, the surgeon must differentiate between structures by endoscopic anatomy and color. During Carpal Tunnel Release, these structures are the carpal ligament, median nerve, arteries, and fat. Optical techniques which result in reduction of glare due to specular reflection from anatomic structures such as these will allow the surgeon to have greater success and require less mental effort during identification of anatomic landmarks through the endoscopic visualization system.

b) Computer Image Enhancements

After a thorough review of the endoscopic system,, and consideration of budget reductions, it was decided to focus the project on optical improvement and reduction in glare during surgery.

D. Expected Economic Impact

Cumulative Trauma Disorders (CTD's) have received increased attention by policy makers in recent years due to dramatic increases in their occurrence which has led to sky-rocketing health care and worker's compensation costs. CTD's continue to increase nationally, from less than 20% of occupational illnesses nationwide in 1981 to about 60% of occupational illnesses today. The number of cases reported annually in the U.S. has risen to over 150,000. CTD's cost the nation over $40 billion in total cost, including estimated loss of productivity during the rehabilitation period.

Benefits to Participant

EMC expected to incorporate the technology into its endoscope systems at the completion of this CRADA. Successful implementation of this technology would result in improved visualization during surgical endoscopic procedures. The marked improvement in image quality for EMC's products was expected to make their endoscope systems the products of choice and significantly increase EMC's revenues. EMC's ability to compete against foreign firms would be greatly enhanced with this technology.

Benefits to U.S. Economy

Improvements in minimally invasive surgeries (e.g., ECTR) will enhance U.S. economic competitiveness twofold: Reducing worker's compensation costs and decreasing time off from work after surgery. Improvements in the technology used for endoscopic visualization can also economically benefit the U.S. company which is collaborating on this project and hence, the U.S. economy.

E. Benefits to DOE

All cost savings and decreased disability resulting from minimally invasive surgical procedures applied to DOE employees as well as to the American population. Specific to

ECTR, LLNL worker's compensation statistics reflect an upswing in carpal tunnel syndrome (CTS) 20% each year. Improved ECTR would lead to a reduction in worker's compensation costs to DOE, DP, LLNL and American industry by decreasing the post-operative return to work time from 6-8 weeks to 2 weeks and significantly reducing post-operative pain.

This CRADA delivered two designs for a medical prototype with visualization improvements aimed at reduction of glare during surgery.

The Laboratory (LLNL) used the developed technologies, the prototype system, and the advancement of expertise as part of the suite of new manufacturing technologies necessary for the Factory of the Future/Advanced Design and Production Technologies (FoF/ADAPT) application. The industrial partner used the developed technologies for medical endoscopic surgery applications. The technology is useful within the National Ignition Facility (NIF) for metrologic functions and nondestructive evaluation. Personnel on this project have experience developing similar systems for laboratory test programs and for robot micro assembly of photonic systems for computer and communication applications; the latter being significant to the Advanced Scientific Computing Initiative (ASCI).

This project provided a strong contribution to the "Factory of the Future"(FoF) initiative. Automated material processing, monitoring and characterization will require high resolution, high contrast real-time imaging with good color fidelity, and all packaged within in a compact and economical system. The medical prototype delivered by this project has this imaging capability. The technology is directly applicable in the contexts of agile/flexible manufacturing, designer materials and high precision machining since it is one of the new suite of advanced techniques for assessing performance of laboratory-based assemblies and subassemblies. In the Advanced Design and Production Technologies (ADAPT) context, miniaturized imaging is used during real-time fabrication defect inspection—this critical to support on-machine acceptance and reliability assessment of components. For safety and reliability purposes, in situ miniaturized real-time imaging is likely to be part of the physical link to the interior of sensitive products. An imaging role continues throughout product life cycle during in situ and periodic non-destructive monitoring.

Quality remote real-time visualization/imaging technology has been proven essential during processing in hazardous environments such as waste management/minimization, hazardous materials processing and components manufacturing, handling-sensitive material synthesis, processing and shaping. Additional applications include unique materials processing and manufacturing and during laser processing. Experience within the technical team of this CRADA already exists for robotic waste sorting in hostile environments such as during hazardous materials processing.

This project applies to the National Ignition Facility (NIF) during both the manufacturing and day-to-day operation phases in the areas of process inspection, monitoring and feedback/control. Real-time visualization/imaging contributes to metrological functions including NDT testing and inspection of in situ components, alignment of pinholes within the laser chain, and verification of laser amplifier quality.

The application focus by our industrial partner is the major market of endoscopic surgical tools, which includes treating the cumulative trauma injury known as carpal tunnel syndrome (CTS). Unfortunately, CTS relates to all DP activities and is a common disabling and costly injury at the DP labs. CTS is well known to affect workers in microelectronics assembly, buffing, grinding, conveyor belt assembly, packing and other hand intensive jobs—in addition to routine office keyboard work. This CRADA resulted in improvements in the surgical process and enabled a sooner return-to-work time and higher productivity for these ailing employees.

In summary, endoscopic visualization improvements are closely related to DP core missions in FoF/ADAPT and have relevance to NIF, ASCI and other areas. Furthermore, the project addresses carpal tunnel syndrome, a disabling injury in high technology manufacturing and office sectors including the DOE weapons complex.

F. Industry Area

Medical care, laser, robotics, and medical equipment

G. Project Status

The project was completed in that two enhanced visualization designs were presented to the industrial partner and resources were requested.

Intellectual Property

i) Subject Inventions

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Subject Inventions disclosed by Participant: None

Licensing Activity:

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H. LLNL Point of Contact for Project Information

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Livermore, CA 94550
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Fax: (925) 422-2234

I. Company Size and Point(s) of Contact

Linvatec Corporation has annual sales of $157 million, and the company employs 1,000 people.

The primary contact is:
David D'Alfonso
Vice President
Envision Medical Corporation
749 Ward Drive
Santa Barbara, CA 93111
Phone: (805) 967-6000 ext. 111
Fax: (805) 967-2119

J. Project Examples

There is an interactive endoscopic project demo which can be used in exhibit format that illustrates glare reduction.

K. Release of Information

I certify that all information contained in this report is accurate and releasable to the best of my knowledge.

NED

Karena McKinley 6/30/00

Karena McKinley, Director
Industrial Partnerships and Commercialization

Date

RELEASE OF INFORMATION

I have reviewed the attached Project Accomplishment Summary prepared by Lawrence Livermore National Laboratory and agree that the information about our CRADA may be released for external distribution.

4/11/00

David D'Alfonso
Envision Medical Corporation

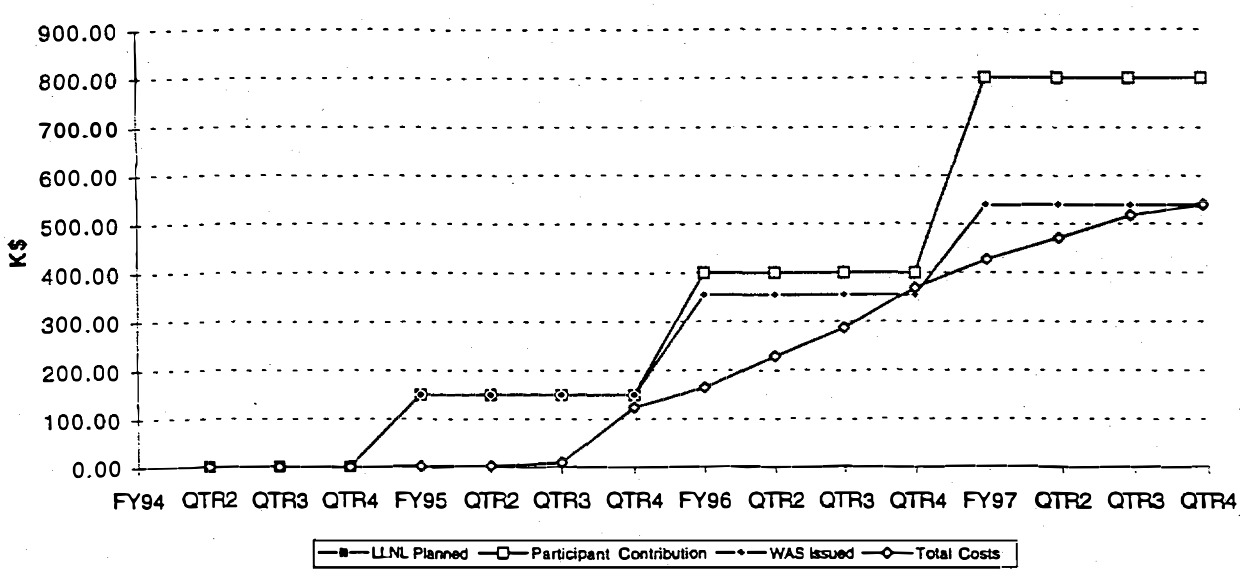
Date

Lawrence Livermore National Laboratory

Title:	Enhanced Visualization Technologies with Medical and Manufacturing Applications	Reporting Period:	07/01/95 - 09/30/97
		Date CRADA Executed:	4/21/95
Participant:	Envision Medical Corporation	DOE Approval Date:	4/21/95
DOE TTI No.:	95-LLNL-072-HC	Scheduled Ending Date:	4/24/98
CRADA No.:	TC-1084-95	Completion Date:	
Account Numbers:	4755-10, 7602-01	B & R Code (S):	DP0301
Accounts Closed:	N/A		35DP03

Approved Funding Profile ($K)

	FY94	FY95	FY96	FY97	FY98	Total
LLNL Planned	0	150	250	400	0	800
Participant In-Kind	0	150	250	400	0	800
Paticipant Funds-In	0	0	0	0	0	0
WAS Operating	0	100	176	186	0	462
WAS Capital	0	50	29	-1	0	78
Total Costs	0	124	246	170	0	539



DP0301	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	FYTD
FY94	0	0	0	0	0	0	0	0	0	0	0	0	0
FY95	0	0	0	0	0	0	0	1	6	23	39	18	86
FY96	15	12	14	14	16	17	12	14	18	23	16	39	210
FY97	16	21	16	14	13	18	17	14	16	14	16	-8	166
FY98	0	0	0	0	0	0	0	0	0	0	0	0	0

462

35DP03	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	FYTD
FY94	0	0	0	0	0	0	0	0	0	0	0	0	0
FY95	0	0	0	3	0	0	0	0	0	3	0	32	39
FY96	0	0	0	0	0	17	0	0	14	0	-6	11	35
FY97	4	0	0	0	0	0	0	0	0	0	0	0	4
FY98	0	0	0	0	0	0	0	0	0	0	0	0	0

78

STAFF w/phone:

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Participant: David D'Alfonso (805) 967-6000
Resource Manager: Chris Skillern (510) 422-8812
DOE OAK: Jerry Scheinberg (510) 637-1653
DOE HQ: J. Uecke (202) 586-5431

Lawrence Livermore National Laboratory

Reporting Period: 07/01/95 - 09/30/96
Participant: Envision Medical Corporation
DOE TTI No.: 95-LLNL-072-HC

Milestones and Deliverables:

List the complete set of milestones for all phases of the CRADA. Continue on a separate page if necessary.
Report any changes from the original CRADA or previous quarterly report on the CRADA Change Form.

Completion Date:
Scheduled   Actual

See attached report

Verification of participants' in-kind contribution was made in accordance with LLNL policy. Explain basis of verification:

Please initial: YES X NO ____

List any subject inventions by either party (include IL# for LLNL inventions), additional background intellectual property, patents applied for, software copyrights, publications, awards, licenses granted or reportable economic impacts

See attached report

Accomplishments

Describe Technical/Non-Technical lessons learned (address and be specific about milestones, participant contributions)
Summarize causes/justification of deviations from original scope of work. Continue on a separate page if necessary.

Please see attached sheet.

Reviewed by CRADA project Program Manager: ____________ Date: ____

Reviewed by Karena McKinley, Director, LLNL/IP&C: Karena McKinley Date: 6/20/97

Direct questions regarding this Report to IP&C Resource Manager, Carol Asher, at (510) 422-7618