

UNCLASSIFIED

FY 2002 / 2003 RDT&E,N BUDGET ITEM JUSTIFICATION SHEET

DATE: February 2002

BUDGET ACTIVITY: 5 PROGRAM ELEMENT: 0604771N
 PROGRAM ELEMENT TITLE: Medical Development
 (Engineering)

PROJECT NUMBER:
 PROJECT TITLE:

(U) COST: (Dollars in Thousands)

PROJECT NUMBER & TITLE	FY 2001 ESTIMATE	FY 2002 ESTIMATE	FY 2003 ESTIMATE	FY 2004 ESTIMATE	FY 2005 ESTIMATE	FY 2006 ESTIMATE	FY 2007 ESTIMATE	TO COMPLETE	TOTAL PROGRAM
M0933 Medical / Dental Equipment Development									
	26,189	9,372	7,154	7,270	7,461	7,609	7,760		
M2650 Voice Instructional Devices (VID)									
	0	5,947	0	0	0	0	0		
M2896 Military Dental Research									
	0	2,775	0	0	0	0	0		
M2897 High Resolution Digital Mammography									
	0	1,487	0	0	0	0	0		
M2795 Coastal Cancer Control (MUSC)									
	0	3,469	0	0	0	0	0		
Total	26,189	23,050	7,154	7,270	7,461	7,609	7,760		

A. (U) MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: The purpose of this item is to develop biomedical equipment and related techniques to reduce morbidity, to enhance the logistic feasibility of modern medical care for combat casualties, to sustain casualties for evacuation to fixed medical facilities for definitive care, and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a documented, authenticated military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms / industry participation in the projects.

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M0933 Medical / Dental Equipment Development	26,189	9,372	7,154	7,270	7,461	7,609	7,760		

A. (U) MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: The purpose of this item is to develop biomedical equipment and related techniques to reduce morbidity, to enhance the logistic feasibility of modern medical care for combat casualties, to sustain casualties for evacuation to fixed medical facilities for definitive care, and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a documented, authenticated military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms / industry participation in the projects.

(U) PROGRAM ACCOMPLISHMENT AND PLANS:

1. (U) FY 2001 ACCOMPLISHMENTS:

- (U) (\$1,565) DNA VACCINE TECHNOLOGY: Completed FDA clinical trial of 5 plasmid DNA vaccine in humans; completed manufacture of new 9 plasmid (not 15 plasmid) vaccine; initiated studies of DNA vaccines in neonatal animals to prepare for efficacy studies in humans.
- (U) (\$152) FLIGHT OPERATIONS NOISE MITIGATION TEST-BED: Completed tests with noise mitigation materials on aircraft carriers during at-sea flight operations. Final report due in December 2001.
- (U) (\$1,857) TACTILE SITUATIONAL AWARENESS SYSTEM (TSAS): Completed evaluation of system on V-22 simulator; conducted successful flight demonstration using USAF Special Operations aircraft; initiated work on pitch/roll algorithms; produced initial helicopter system for test and procurement; purchased additional suits and constructed a laboratory-based system and one additional flight system; initiated unmanned aerial vehicle demonstrations and evaluations and continued fixed wing demonstrations and evaluations of flight system.

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- (U) (\$230) VIRTUAL FIT CHECK SYSTEM: Completed interface between the digital anthropometric video-imaging device and the automated anthropometric evaluation program at Naval Air Warfare Center to form the Virtual Fit Check System; conducted recruitment of candidates for the study and began collection of data. Minor technical difficulties have delayed completion of this effort until FY 2002.
- (U) (\$165) CERTIFICATION OF MEDICAL ANCILLARY EQUIPMENT FOR USE IN HYPERBARIC CHAMBERS: Initiated evaluation of seven ventilators, three intravenous infusion pumps, and one cardiac monitor for use in Navy hyperbaric chambers. Of these, two ventilators, one IV infusion pump and the cardiac monitor were determined to be safe for hyperbaric use; continuing safety evaluation of other equipment; equipment determined to be safe is being assessed for accuracy during hyperbaric exposure.
- (U) (\$278) EVALUATION OF FIELD-BASED PROCEDURES FOR SCREENING DIVERS' AIR: All equipment for testing has been received; initiated and completed laboratory evaluation to ensure that all items meet the required performance specifications prior to initiation of the field test; two NAVSEA test sites identified where field tests will be performed; actual field testing will begin in the third quarter of FY 2001.
- (U) (\$400) RESCUE OF MILITARY CASUALTIES FOLLOWING LETHAL BONE MARROW INJURY: Completed first phase of FDA review to use specific cell line in a Phase I study of patients undergoing radiation therapy for breast cancer; initiated and completed additional safety and procedural requirements for FDA second phase review; initiated FDA- required pre-clinical safety studies in large animals; initiated growth of pre-clinical stem cell expansion cultures. Discontinued due to failure to obtain approval by FDA to perform clinical trials.
- (U) (\$2,979) BONE MARROW TRANSPLANTATION TECHNOLOGY: Initiate Phase I and Phase II Clinical Trials of a proprietary compound that is used to inhibit the replication of T cells in donated bone marrow, while preserving other immunologic functions. Previously supported by an FY00 add in PE 0603706N.
- (U) (\$3,972) DENTAL RESEARCH: Initiate studies to address dental readiness and preparedness issues prior to deployment as well as injuries and oral diseases during combat redeployment operations. Previously supported by an FY00 add in PE 0603706N.
- (U) (\$1,489) MOBILE INTEGRATED DIAGNOSTIC AND DATA ANALYSIS SYSTEM: Initiate studies to develop a light-weight, portable system of linked sensors to monitor tympanic membrane temperature, electrocardiogram, and pulse and respiratory rates in victims of trauma.

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- (U) (\$1,986) HIGH RESOLUTION DIGITAL MAMMOGRAPHY: Initiate studies to develop second generation enhanced resolution digital mammography. Previously supported by an FY00 add in the Defense Health Program (P8).
- (U) (5, 958) VOICE INTERACTIVE DEVICE: Continue studies to modify, demonstrate and validate the Naval voice interactive device as a tool for medical personnel aboard ships or in the field to facilitate the collection, processing, storing, and forwarding of critical medical data for treating combat casualties.
- (U) (\$993) SMART AORTIC ARCH CATHETER: Initiate studies to develop a sensor-equipped catheter for emergency assisted placement in the aortic arch via a parasternal approach. The catheter, once properly placed, will deliver cold solutions to the brain, heart and spinal cord for protection of those tissues during periods of low or no blood flow.
- (U) (4,965) COASTAL CANCER CONTROL: Continue studies to extend the Coastal Cancer Control activities centered on primary and secondary prevention and focusing on underserved populations as well as active duty military personnel and their beneficiaries. The program will include remote diagnosis, outreach telemedicine, and epidemiology and risk factor identification as related to cancer control.

Studies supported this year include incidence and prevalence of cancer in South Carolina and in the DoD population, occupational studies of cancer, risk factor identification, patterns of use and delivery of health care, epidemiologic and statistical analyses, and geographic information systems.

2. (U) FY 2002 PLAN:

- (U) (\$1,650) DNA VACCINE TECHNOLOGY: Complete studies of 9 plasmid (not 15 plasmid) vaccine in healthy adult subjects; initiate clinical trials of new formulation of DNA vaccines designed to improve antibody responses; complete pre-clinical trial in neonatal animals.
- (U) (\$1,700) TACTILE SITUATIONAL AWARENESS SYSTEM (TSAS): Complete development of additional lab and flight systems; complete unmanned aerial vehicle and fixed demonstrations and evaluations; complete rotary and fixed wing suits and pitch/roll algorithms; complete operational testing of suits; write final report and deliver product to NAVAIR.
- (U) (\$85) VIRTUAL FIT CHECK SYSTEM: Complete data collection and analysis, and write final report (completion extended from FY 2001).
- (U) (\$100) CERTIFICATION OF MEDICAL ANCILLARY EQUIPMENT FOR USE IN HYPERBARIC CHAMBERS: Complete accuracy testing of selected equipment and develop a list of items for submission to the Supervisor of Diving for inclusion on the authorized Navy list for hyperbaric use; write final report.

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- (U) (\$243) EVALUATION OF FIELD-BASED PROCEDURES FOR SCREENING DIVERS' AIR: Complete field testing of gas analysis equipment; write final report.
- (U) (\$24) SEA TRIALS OF NEW SUBMARINE WATCHSTANDING SCHEDULE: Initiate, in third quarter FY 2002, a study to evaluate the effectiveness of a new watchstanding schedule on submariner performance.
- (U) (\$179) UNDERWATER AND DIVE STATION WORK-SITE NOISE SURVEYS: Initiate study to determine the total noise exposure of Navy diving operations (surface and underwater combined) and establish recommendations for length of exposure that will not cause long-term hearing loss.
- (U) (\$97) FEASIBILITY OF USING HAND-HELD PERSONAL DIGITAL ASSISTANTS IN HYPERBARIC ENVIRONMENTS: Initiate and complete one-year study to evaluate the use of personal digital assistants (PDAs) to function in hyperbaric environments as a device for running the established Submarine Escape and Rescue Program (SEAREX).
- (U) (\$327) MERCURY ABATEMENT IN DENTAL WASTEWATER: Initiate test and evaluation of several commercial mercury abatement systems for use in Navy Dental Treatment Facilities. Systems will be recommended to Navy Dentistry that have the greatest potential for long term use in light of increasingly stringent standards for mercury in wastewater.
- (U) (\$400) TACTICAL MEDICAL COORDINATING SYSTEM: Initiate field testing of a radio frequency device to track the location of casualties through the medical evacuation system. Effort will be coordinated with other IM/IT initiatives and structured to be compatible with TMIP.
- (U) (\$250) SOF MOBILE PERFORMANCE EVALUATION TEST BATTERY: Initiate field testing of a refined research tool used for determining physical and cognitive performance decrements in special operations forces that result from fatigue or environmental exposure.
- (U) (\$400) ADVANCED FROZEN BLOOD PROCESSOR: Initiate clinical testing of an advanced frozen red blood cell processor that will prolong the shelf life of red cells after they have been thawed from 24 hours to 2 weeks.
- (U) (\$2,500) NAVAL MEDICAL RESEARCH CENTER RADIATION EXPOSURE TREATMENT: Initiate investigations into optimizing the efficacy and safety of rescuing adult hematopoietic stem cells from irradiated bone marrow.
- (U) (\$1,000) NAVAL BLOOD RESEARCH LABORATORY: Initiate studies to obtain FDA approval for use of frozen platelets.
- (U) (\$500) SONARMAN EARCOM TECHNOLOGY: Initiate studies to develop a combined hearing protection and voice communications terminal for use in high noise-level environments.

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3. (U)FY 2003 PLAN:

- (U) (\$150) SEA TRIALS OF NEW SUBMARINE WATCHSTANDING SCHEDULE: Complete study to evaluate the effectiveness of a new watchstanding schedule on submariner performance.
- (U) (\$200) UNDERWATER AND DIVE STATION WORK-SITE NOISE SURVEYS: Complete study to determine the total noise exposure of Navy diving operations (surface and underwater combined) and establish recommendations for length of exposure that will not cause long-term hearing loss.
- (U) (\$300) MERCURY ABATEMENT IN DENTAL WASTEWATER: Complete test and evaluation of several commercial mercury abatement systems for use in Navy Dental Treatment Facilities. Recommend system to Navy Dentistry for installation in Dental Treatment Facilities and Clinics.
- (U) (\$380) TACTICAL MEDICAL COORDINATING SYSTEM: Complete field testing of a radio frequency device to track the location of casualties through the medical evacuation system. Effort will be coordinated with other IM/IT initiatives and structured to be compatible with TMIP.
- (U) (\$225) SOF MOBILE PERFORMANCE EVALUATION TEST BATTERY: Complete field testing of a refined research tool used for determining physical and cognitive performance decrements in special operations forces that result from fatigue or environmental exposure.
- (U) (\$425) ADVANCED FROZEN BLOOD PROCESSOR: Complete clinical testing of an advanced frozen red blood cell processor that will prolong the shelf life of red cells after they have been thawed from 24 hours to 2 weeks.
- (U) (\$5,515) TRANSITION PROJECTS FROM THE WARFIGHTER PROTECTION FUTURE NAVAL CAPABILITY: Provide test and evaluation of a variety of products (not yet determined) that arise from the Warfighter Protection Future Naval Capability.

B. (U)PROGRAM CHANGE SUMMARY:

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	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>
(U) President's Budget:	5,273	5,455	0
(U) Adjustments from FY 2000 PRESBUDG:	20,916	3,917	0
(U) FY 2002 / 2003 President's Submission	26,189	9,372	7,154

(U) CHANGE SUMMARY EXPLANATION:

(U) Funding:

(U) FY 2001: Decrease of (-194) for Section 8086: .7% Pro-Rate Reduction

Increase of (3,000) due to FY 2001 Congressional Add – Bone Marrow Transplant Technology

Increase of (4,000) due to FY 2001 Congressional Add –Dental Research

Increase of (2,000) due to FY 2001 Congressional Add –High Resolution Digital Mammography

Increase of (1,500) due to FY 2001 Congressional Add –Mobile Intergrated Diagnostic

Increase of (6,000) due to FY 2001 Congressional Add –Voice Interactive Device

Increase of (1,000) due to FY 2001 Congressional Add –Smart Aortic Arch Catheter

Increase of (5,000) due to FY 2001 Congressional Add –Coastal Cancer Control

Decrease of (-60) for Government-Wide Rescission

Decrease of (-530) for SBIR

Decrease of (-800) for 01 Actuals

(U) FY 2002: Decrease of (-83) for Section 8123: Management Reform

Increase of (500) due to FY 2002 Congressional Add – Sonarman Earcom Technology

Increase of (1,000) due to FY 2002 Congressional Add – Naval Blood Research Laboratory

Increase of (2,500) due to FY 2002 Congressional Add – Naval Medical Research Center Radiation Exposure Treatment

(U) Schedule: Not applicable.

(U) Technical: Not applicable.

C. (U) OTHER PROGRAM FUNDING SUMMARY: Not applicable.

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PROGRAM ELEMENT TITLE: Medical Development
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PROJECT NUMBER:
PROJECT TITLE:

(U) RELATED RDT&E:

(U) Program Element 0603706N, Medical Development.

D. (U) SCHEDULE PROFILE: Not applicable.

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(U) COST: (Dollars in Thousands)

PROJECT NUMBER & TITLE	FY 2001 ESTIMATE	FY 2002 ESTIMATE	FY 2003 ESTIMATE	FY 2004 ESTIMATE	FY 2005 ESTIMATE	FY 2006 ESTIMATE	FY 2007 ESTIMATE	TO COMPLETE	TOTAL PROGRAM
M2650 Voice Instructional Devices (VID)	0	5,947	0	0	0	0	0		

Note: FY 2001 Voice Instructional Devices funds (\$6,000) were received in this Program Element under project M0933.

A. (U) MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: The purpose of this item is to develop biomedical equipment and related techniques to reduce morbidity, to enhance the logistic feasibility of modern medical care for combat casualties, to sustain casualties for evacuation to fixed medical facilities for definitive care, and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a documented, authenticated military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms / industry participation in the projects.

(U) PROGRAM ACCOMPLISHMENT AND PLANS:

1. (U) FY 2002 PLAN:

- (U) (\$5,896) VOICE INSTRUCTIONAL DEVICES (VID): Continue development of preventive medicine and clinical consult systems and expand product lines to include integrating voice activation capability into a portable diagnostics system and at least one other medical information system.

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B. (U) PROGRAM CHANGE SUMMARY:

	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>
(U) President's Budget:	0	0	0
(U) Adjustments from FY 2000 PRESBUDG:	0	5,947	0
(U) FY 2002 / 2003 President's Submission	0	5,947	0

(U) CHANGE SUMMARY EXPLANATION:

(U) Funding:

(U) FY 2002 : Increase of (6,000) due to FY 2002 Congressional Add – VID; decrease of (-53) for Section 8123: Management Reform

(U) Schedule: Not applicable.

(U) Technical: Not applicable.

C. (U) OTHER PROGRAM FUNDING SUMMARY: Not applicable.

(U) RELATED RDT&E:

(U) Program Element 0603706N, Medical Development.

D. (U) SCHEDULE PROFILE: Not applicable.

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PROJECT NUMBER & TITLE	FY 2001 ESTIMATE	FY 2002 ESTIMATE	FY 2003 ESTIMATE	FY 2004 ESTIMATE	FY 2005 ESTIMATE	FY 2006 ESTIMATE	FY 2007 ESTIMATE	TO COMPLETE	TOTAL PROGRAM
M2896 Military Dental Research	0	2,775	0	0	0	0	0		

Note: FY 2001 Military Dental Research funds (\$4,000) were received in this Program Element under project M0933.

A. (U) MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: The purpose of this item is to develop biomedical equipment and related techniques to reduce morbidity, to enhance the logistic feasibility of modern medical care for combat casualties, to sustain casualties for evacuation to fixed medical facilities for definitive care, and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a documented, authenticated military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms / industry participation in the projects.

(U) PROGRAM ACCOMPLISHMENT AND PLANS:

1. (U) FY 2002 PLAN:

- (U) (\$2,775) Continue studies to address dental readiness and preparedness issues prior to deployment, as well as further development of salivary tests to identify exposure to infectious diseases and bioterrorism agents.

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B. (U) PROGRAM CHANGE SUMMARY:

	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>
(U) President's Budget:	0	0	0
(U) Adjustments from FY 2000 PRESBUDG:	0	2,775	0
(U) FY 2002 / 2003 President's Submission	0	2,775	0

(U) CHANGE SUMMARY EXPLANATION:

(U) Funding:

(U) FY 2002: increase of (2,800) due to FY02 Congressional Add – Military Dental Research; decrease of (-25) due to Section 8123: Management Reform

(U) Schedule: Not applicable.

(U) Technical: Not applicable.

C. (U) OTHER PROGRAM FUNDING SUMMARY: Not applicable.

(U) RELATED RDT&E:

(U) Program Element 0603706N, Medical Development.

D. (U) SCHEDULE PROFILE: Not applicable.

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(U) COST: (Dollars in Thousands)

PROJECT NUMBER & TITLE	FY 2001 ESTIMATE	FY 2002 ESTIMATE	FY 2003 ESTIMATE	FY 2004 ESTIMATE	FY 2005 ESTIMATE	FY 2006 ESTIMATE	FY 2007 ESTIMATE	TO COMPLETE	TOTAL PROGRAM
M2897 High Resolution Digital Mammography	0	1,487	0	0	0	0			

Note: FY 2001 High Resolution Digital Mammography Funds (\$2,000) were received in this Program Element under project M0933.

A. (U) MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: The purpose of this item is to develop biomedical equipment and related techniques to reduce morbidity, to enhance the logistic feasibility of modern medical care for combat casualties, to sustain casualties for evacuation to fixed medical facilities for definitive care, and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a documented, authenticated military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms / industry participation in the projects.

(U) PROGRAM ACCOMPLISHMENT AND PLANS:

1. (U) FY 2002 PLAN:

- (U) (1,487) Continue studies to develop second generation enhanced resolution digital mammography.

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B. (U) PROGRAM CHANGE SUMMARY:

	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>
(U) President's Budget:	0	0	0
(U) Adjustments from FY 2000 PRESBUDG:	0	1,487	0
(U) FY 2002 / 2003 President's Submission	0	1,487	0

(U) CHANGE SUMMARY EXPLANATION:

(U) Funding:

(U) FY 2002: increase of (1,500) due to FY02 Congressional Add – High Resolution Digital Mammography, decrease of (-13) due to Section 8123: Management Reform

(U) Schedule: Not applicable.

(U) Technical: Not applicable.

C. (U) OTHER PROGRAM FUNDING SUMMARY: Not applicable.

(U) RELATED RDT&E:

(U) Program Element 0603706N, Medical Development.

D. (U) SCHEDULE PROFILE: Not applicable.

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M2795 Coastal Cancer Control (MUSC)	0	3,469	0	0	0	0	0		

Note: FY 2001 Coastal Cancer Control funds (\$5,000) were received in this Program Element under project M0933.

A. (U) MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: The purpose of this item is to develop biomedical equipment and related techniques to reduce morbidity, to enhance the logistic feasibility of modern medical care for combat casualties, to sustain casualties for evacuation to fixed medical facilities for definitive care, and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a documented, authenticated military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms / industry participation in the projects.

(U) PROGRAM ACCOMPLISHMENT AND PLANS:

1. (U) FY 2002 PLAN:

- (U) (\$3,469) COASTAL CANCER CONTROL (MUSC): Continue research efforts that will focus on supporting applied cancer research projects that focus on primary and secondary prevention in underserved areas.

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	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>
(U) President's Budget:	0	0	0
(U) Adjustments from FY 2000 PRESBUDG:	0	3,469	0
(U) FY 2002 / 2003 President's Submission	0	3,469	0

(U) CHANGE SUMMARY EXPLANATION:

(U) Funding:

(U) FY 2002: increase of (3,500) due to FY02 Congressional Add – Coastal Cancer Control (MUSC); decrease of (-31) due to Section 8123: Management Reform

(U) Schedule: Not applicable.

(U) Technical: Not applicable.

C. (U) OTHER PROGRAM FUNDING SUMMARY: Not applicable.

(U) RELATED RDT&E:

(U) Program Element 0603706N, Medical Development.

D. (U) SCHEDULE PROFILE: Not applicable.