ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2004

BUDGET ACTIVITY	PE NUMBER AND TITLE
4 - Advanced Component Development and Prototypes	**0603807A - Medical Systems - Adv Dev**

COST (In Thousands)		FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost		13280	13392	10258	10458	11929	13193	12666	Continuing	Continuing
808	DOD DRUG & VACC AD	4884	5484	5421	5566	5510	6401	6151	Continuing	Continuing
811	MIL HIV VAC&DRUG DEV	0	135	0	146	147	146	146	Continuing	Continuing
836	COMBAT MEDICAL MATL AD	3820	4180	4095	3804	3781	4803	4602	Continuing	Continuing
837	SOLDIER SYS PROT-AD	849	1120	742	942	2491	1843	1767	Continuing	Continuing
A01	COMBAT SUPPORT HOSPITAL - MOBILE SURGICAL UNIT	2388	0	0	0	0	0	0	0	2387
MD4	FUTURE MEDICAL SHELTER	1339	0	0	0	0	0	0	0	4696
MD7	AUTOMATED LABORATORIES FOR BIODEFENSE (CA)	0	2473	0	0	0	0	0	0	2473

A. Mission Description and Budget Item Justification: This program element (PE) funds advanced development of medical materiel within the early-on system integration in the System Development and Demonstration portion of the acquisition life cycle. The PE supports the transition of Science and Technology initiatives, prototypes, or candidate technologies into the first scale-up, integrated models for initial test and evaluation both technically and operationally when applicable. These programs have been aligned to meet Future Force (F2) requirements stressed within the concept documents and organizational structures. The PE provides funding for early Phase 1 and 2 U.S. Food and Drug Administration (FDA) regulated human clinical trials. The major enablers that will be supported by this PE are as follows:

Infectious disease vaccines and preventive drugs that will reduce the risk of service members contracting these debilitating or fatal diseases, especially within a battlefield of growing potentials as urban warfare risks increase. Disease and non-battle injuries are the largest contributors to the medical footprint. Significant reductions in echelon 3 facilities can be achieved by reducing the number of ill soldiers. Equally important, the reduction of patient evacuation within F2 units will act as a force multiplier because timely replacement of these uniquely skilled soldiers will be nearly impossible.

Combat Casualty Care devices and biologics have two major focuses: enhance forward care at the first responder level and reduce footprint of medical organizations for greater mobility and easier sustainment. The F2 concept will place soldiers into a more austere environment with lengthened evacuation times (both arrival and transit). This requires greater capability in the hands of medics and first responders to save lives and extend stabilization. Reduction in weight, cube, and sustainment will allow medical units to increase mobility and maintain contact with their supported maneuver units.

Soldier Performance Enhancers in the form of drugs or diagnostics that will allow commanders to increase soldiers' cognitive awareness and stamina. This has direct relationship to increased soldier capabilities and a potential to reduce casualties.

Military HIV Vaccine and Drug Development – funds militarily relevant HIV medical countermeasures including advanced component development of sufficient candidate vaccines and drugs to permit large-scale field testing and education/training materials.

This program is managed by the U.S. Army Medical Research and Materiel Command.

This program supports the Future Force transition path of the Army Transformation Campaign Plan (TCP).

There are no Defense Emergency Response Funds provided to this program or project.

B. Program Change Summary	FY 2003	FY 2004	FY 2005
Previous President's Budget (FY 2004)	13340	11042	10012
Current Budget (FY 2005 PB)	13280	13392	10258
Total Adjustments	-60	2350	246
Congressional program reductions		-127	
Congressional rescissions			
Congressional increases		2500	
Reprogrammings	-60	-23	
SBIR/STTR Transfer			
Adjustments to Budget Years			246

Change Summary Explanation: Funding - FY 2004: Congressional add for Automated Laboratories for Biodefense (+2,500).

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2004

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
4 - Advanced Component Development and Prototypes	**0603807A - Medical Systems - Adv Dev**	**808**

COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
808 DOD DRUG & VACC AD	4884	5484	5421	5566	5510	6401	6151	Continuing	Continuing

A. Mission Description and Budget Item Justification: This project funds technical development of candidate medical countermeasures for infectious diseases that occur within militarily relevant areas of the world. Current products fall within three major areas: vaccines, drugs, and diagnostic kits. The funds support Phase 1 and 2 human clinical trials for safety, immunogenicity, and small-scale efficacy testing. This work, which is performed in military laboratories or civilian pharmaceutical firms, is directed toward the prevention of disease, early diagnosis if contracted, and speed recovery once diagnosed. These trials are required to meet U.S. Food and Drug Administration (FDA) regulatory approval guidance, a mandatory obligation for all military products placed into the hands of medical providers or service members. Priority is based upon four major factors: the extent of the disease within the Combatant Commands theater of operations, the clinical severity of the disease, the technical maturity of the proposed solution, and the affordability of the solution (development and production). The reduction in risk to contract infectious diseases within the force supports the Army Transformation Campaign Plan (TCP) and directly enables the Future Force concept through reduction of evacuations of uniquely qualified soldiers and decrease in medical footprint to sustain these evacuees.

There are no Defense Emergency Response Funds provided to this program or project.

Accomplishments/Planned Program	FY 2003	FY 2004	FY 2005
Reviews, evaluations, and trials of malarial/anti-malarial vaccines, drugs, and diagnostics: In FY03, initiated planning and contract modification to conduct true negative trials and initiated a fingerstick (OCONUS) trial of the Malaria Rapid Diagnostic Device (MRDD); initiated preparations for a Phase 1/2 safety and efficacy trial with RTS,S/improved adjuvant (P. falciparum) malaria vaccine in U.S. volunteers. In FY04, conduct true negative (CONUS) and complete fingerstick (OCONUS) trials with the MRDD; initiate a Phase 1/2 safety and efficacy trial with RTS,S/improved adjuvant (P. falciparum) malaria vaccine in U.S. volunteers. In FY05, conduct a MS C IPR to transition the MRDD to full-rate production and deployment; conduct a Critical Design Review to determine if the RTS,S/improved adjuvant (P. falciparum) malaria vaccine should continue to advanced Phase 2/3 testing OCONUS.	1529	2004	5031
Clinical trials, safety evaluations, and reviews of diarrheal vaccines. In FY03, planned and initiated protocol review for a Phase 2 safety and immunogenicity study of a Shigella flexneri vaccine OCONUS.	521	0	0
Trials, evaluations, and reviews for grouped infectious disease vaccines and drugs (Hepatitis E and Leishmania). In FY03, continued a multiyear Phase 2 field trial in Nepal to evaluate the effectiveness of Hepatitis E vaccine; completed pre-clinical studies for submission of a new Investigational New Drug (IND) for good manufacturing practices (GMP) for L. tropica skin test kits and initiated drafting of a Phase 1 safety trial protocol with industry partner's Leishmania skin test kits; initiated a Phase 2 clinical trial of paromomycin/gentamicin topical antileishmanial cream in France and Tunisia to treat Old World leishmaniasis. In FY04, complete evaluation of the results of the multiyear Phase 2 trial of the Hepatitis E vaccine conducted in Nepal; conduct an In Process Review on the Hepatitis E vaccine to determine future development plans; complete the Phase 2 field trial of the paromomycin/gentamicin topical antileishmanial cream; transition the paromomycin/gentamicin topical antileishmanial cream to a co-development partner; complete Phase 1 safety trial with Leishmania skin test kits.	1748	508	0
In FY03, initiated a Phase 1b dengue tetravalent vaccine pediatric trial and began a 5-year follow-up; continued production and testing of master dengue vaccine seeds; initiated a protocol for a Phase 2 study in Panama. In FY04, conduct a Phase 2 study in second OCONUS dengue endemic area; complete production and testing of master vaccine seeds. In FY05, conduct a Critical Design Review and transition to Phase 3 field-testing.	881	2871	390
Developmental test and evaluation, and reviews of insect vector control products: In FY03, conducted a Special IPR to terminate the development of the lethal trap for dengue vectors program; initiated contracting for a preplanned product improvement to develop new dispensers for camouflage face paint with insect repellent and reduced infrared signature.	205	0	0

Accomplishments/Planned Program (continued)	FY 2003	FY 2004	FY 2005
Small Business Innovative Research/Small Business Technology Transfer Programs	0	101	0
Totals	4884	5484	5421

B. Other Program Funding Summary: Not applicable for this item.

C. Acquisition Strategy: Test and evaluate in-house and commercially developed products in extensive government-managed clinical trials to gather data required for FDA licensure and Environmental Protection Agency registration.

ARMY RDT&E COST ANALYSIS(R3)

February 2004

BUDGET ACTIVITY
4 - Advanced Component Development and Prototypes

PE NUMBER AND TITLE
0603807A - Medical Systems - Adv Dev

PROJECT
808

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			2943	439		475		448		Continue	4305	Continue
Subtotal:			2943	439		475		448		Continue	4305	Continue

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			394	147		158		149		Continue	848	Continue
Subtotal:			394	147		158		149		Continue	848	Continue

ARMY RDT&E COST ANALYSIS(R3)

February 2004

BUDGET ACTIVITY
4 - Advanced Component Development and Prototypes

PE NUMBER AND TITLE
0603807A - Medical Systems - Adv Dev

PROJECT
808

III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			9855	3517		4007		4025		Continue	21404	Continue
Subtotal:			9855	3517		4007		4025		Continue	21404	Continue

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			2095	781		844		799		Continue	4519	0
Subtotal:			2095	781		844		799		Continue	4519	0

Project Total Cost:			15287	4884		5484		5421		Continue	31076	Continue

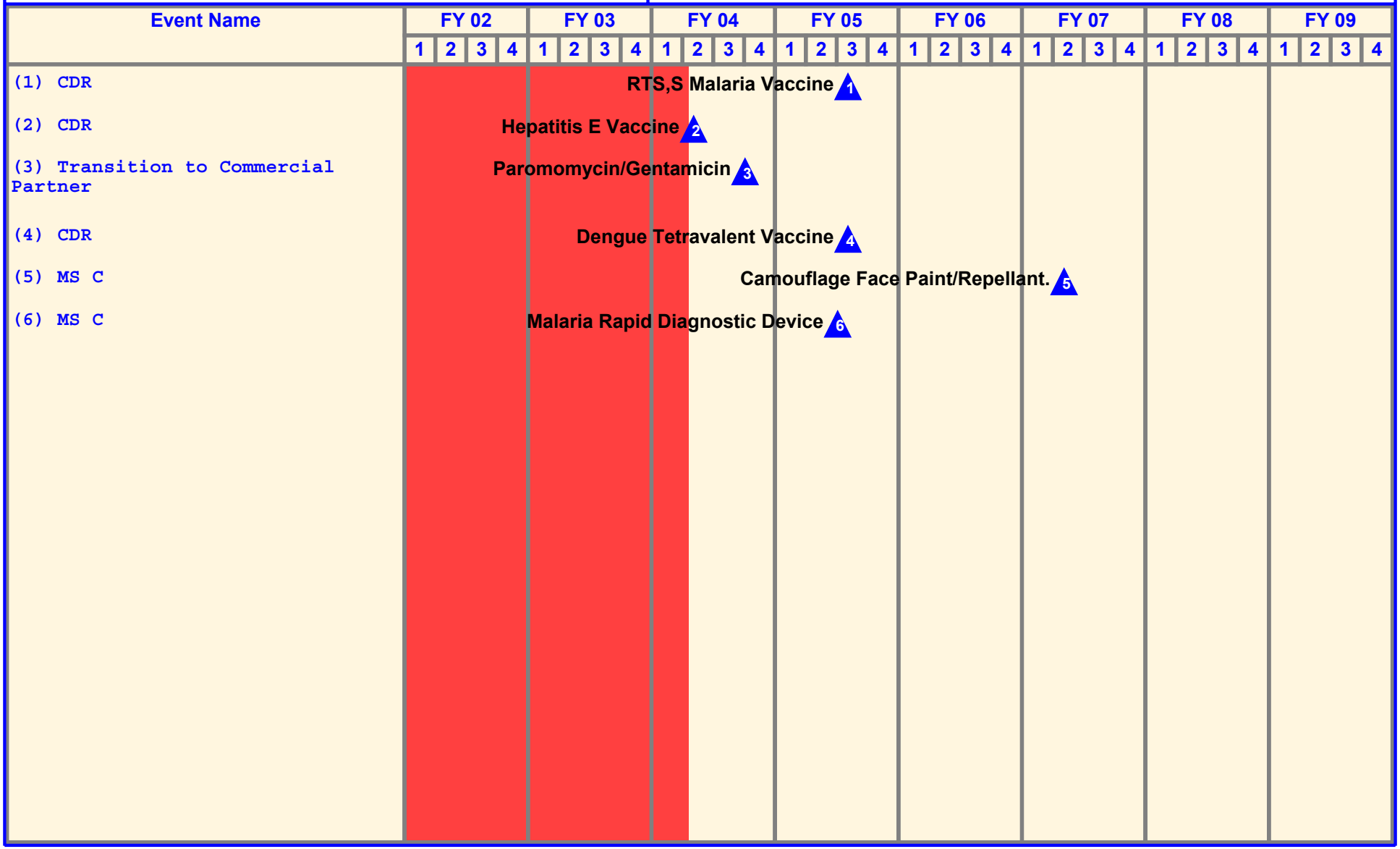
Schedule Profile (R4 Exhibit)

February 2004

BUDGET ACTIVITY
4 - Advanced Component Development and Prototypes

PE NUMBER AND TITLE
0603807A - Medical Systems - Adv Dev

PROJECT
808



Schedule Detail (R4a Exhibit)

February 2004

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
4 - Advanced Component Development and Prototypes	**0603807A - Medical Systems - Adv Dev**	**808**

Schedule Detail	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Paromomycin/Gentamicin		3-4Q					
Hepatitis E vaccine		3-4Q					
RTS,S/improved adjuvant (P. falciparum) malaria vaccine			1Q				
Malaria Rapid Diagnostic Device (Milestone C)			3Q				
Camouflage face paint (MS C) (Repellent: Thermal)					2Q		
Dengue tetravalent vaccine (Critical Design Review)			3Q				

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2004

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
4 - Advanced Component Development and Prototypes	**0603807A - Medical Systems - Adv Dev**	**836**

COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
836 COMBAT MEDICAL MATL AD	3820	4180	4095	3804	3781	4803	4602	Continuing	Continuing

A. Mission Description and Budget Item Justification: This project funds technical development of candidate medical products for the advancement of combat casualty care; especially far forward on the battlefield with first responders, combat life savers, and field medics. This funds Phase 1 and 2 human clinical trials for safety and efficacy of devices or biologics unique to military operational requirements. These products will decrease mortality rates thereby increasing soldier morale and willingness to place themselves in danger. Additionally, several products will reduce medical organizational sustainment footprint through smaller weight and cube or equipment independence from supporting materiels. Priority is given to those products that provide the greatest clinical benefit balanced with the technical and financial risks. These products support both the Army Transformation Campaign Plan (TCP) and Future Force doctrine/organizational structure.

There are no Defense Emergency Response Funds provided to this program or project.

Accomplishments/Planned Program	FY 2003	FY 2004	FY 2005
Hemostatic Dressing (HD): FY03: Completed Battlefield Investigational New Drug Protocol, received U.S. Food and Drug Administration (FDA) approval, and implemented protocol in Operation Iraqi Freedom. Delayed Phase 1/2 clinical trials due to American Red Cross financial problems. FY04: Directly compare HD to a competitor, the Chitosan Bandage, in a series of animal studies. Attain Milestone B (MS B) FY05: Continuation of this program is dependent on the outcome of the comparative studies.	1565	1064	2900
Demonstrate, evaluate, and continue to develop medical evacuation systems. Special Medical Emergency Evacuation Device (SMEED): FY03: Conducted computer-simulation and determined further testing is required. Completed the U.S. Air Force Air Worthiness Release (AWR) certification. Completed patent licensure to commercial vendor. Awaiting results of simulation prior to AWR testing and certification by the Army. FY04: Complete AWR and Crash Worthiness Testing, attain Milestone C (MS C), and field basic systems.	200	50	0

Accomplishments/Planned Program (continued)	FY 2003	FY 2004	FY 2005
Conduct/Perform development, testing and Milestone IPRs for field medical treatment and treatment aid devices: (1) Ceramic Oxygen Generator System (COGS): FY03: Completed fabrication of ceramic oxygen cell structures. Built and demonstrated a 3-liter per minute prototype generator. Began developing heat exchangers, enclosure, controls, and start up heater. FY04: Attain MS B. Begin development of full-scale engineering development model. FY05: Continue development of full-scale model, and refine manufacturing process to use existing device manufacturing techniques found in the electronics industry. (2) Ventilatory Assist Device (VAD): FY03: Completed user evaluation. Prepared final test report. FY04: Develop an FDA approved anesthetic agent scrubber that will not require exterior venting, and conduct clinical use and evaluation of the completed anesthesia system at 10 Army Medical Treatment Facilities. Attain Milestone B (MS B). (3) Pressure Swing Adsorption Oxygen Generator (PSAOC): FY03: Terminated PSAOG project due to change in operational requirements. (4) One-Handed Tourniquet (OHT): FY03: Developed portable training package. Conducted user evaluation of 5,000 units with SOCOM and received no adverse reports. Started human use technical testing and human factors evaluation. FY04: Develop a product specification and Technical Data Package. Attain Milestone C. (5) Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG): FY03: Built initial advanced development prototype. FY04: Design advanced prototype to use smaller, lighter and more efficient air compressor. Test reliability of new compressor. Attain Milestone B. 6) Non-Contact Respiration Monitor (NCRM): FY03: Developed first prototype, and demonstrated technical feasibility. FY04: Refine respiration sensor, miniaturize electronics, and reduce prototype weight and volume. FY05: Conduct user evaluation and attain Milestone B.	2055	2992	1195
Small Business Innovative Research/Small Business Technology Transfer Programs	0	74	0
Totals	3820	4180	4095

B. Other Program Funding Summary: Not applicable for this item.

C. Acquisition Strategy: Evaluate commercially developed materiel in government-managed tests for hardening or other modification.

ARMY RDT&E COST ANALYSIS(R3)

February 2004

BUDGET ACTIVITY
4 - Advanced Component Development and Prototypes

PE NUMBER AND TITLE
0603807A - Medical Systems - Adv Dev

PROJECT
836

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Hemostatic Dressing		American National Red Cross, Charlotte, N.C.	3768	1565		1000	4Q	3214		Continue	9547	0
b . No other contract exceeds $1M			11824	0		0		0		0	11824	0
Subtotal:			15592	1565		1000		3214		Continue	21371	0

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:			0	0		0		0		0	0	0

Remarks: No product/contract costs greater than $1M individually.

ARMY RDT&E COST ANALYSIS(R3)

February 2004

BUDGET ACTIVITY
4 - Advanced Component Development and Prototypes

PE NUMBER AND TITLE
0603807A - Medical Systems - Adv Dev

PROJECT
836

III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:			0	0		0		0		0	0	0

Remarks: No product/contract costs greater than $1M individually.

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $M individually.			4436	2255		3180		881		0	10752	0
Subtotal:			4436	2255		3180		881		0	10752	0
Project Total Cost:			20028	3820		4180		4095		Continue	32123	0

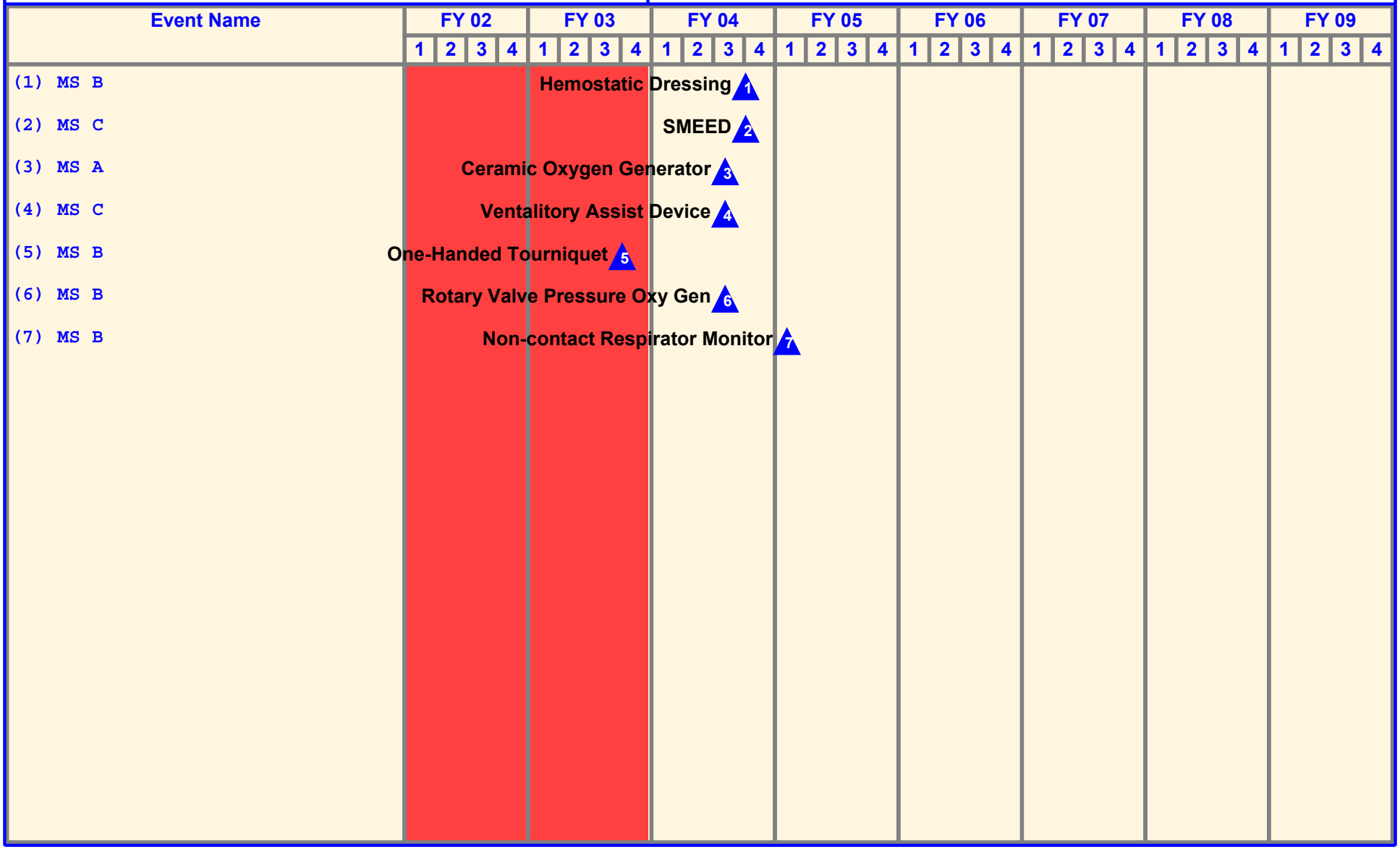
Schedule Profile (R4 Exhibit)

February 2004

BUDGET ACTIVITY
4 - Advanced Component Development and Prototypes

PE NUMBER AND TITLE
0603807A - Medical Systems - Adv Dev

PROJECT
836



Schedule Detail (R4a Exhibit)

February 2004

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
4 - Advanced Component Development and Prototypes	**0603807A - Medical Systems - Adv Dev**	**836**

Schedule Detail	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Hemostatic Dressing (MS B)		4Q					
SMEED (MS C)		4Q					
Ceramic Oxygen Generator Systems(MS B)		3Q					
Ventilatory Assist Device (MS C)		3Q					
One-Handed Tourniquet (MS B)	4Q						
Rotary Valve Pressure Swing Oxygen Generator (MS B)		3Q					
Non-Contact Respiration Monitor (MSB)			1Q				