

October 26, 1997

3721 '97 OCT 28 P1:35

Docket Number 95S-0158
Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm. 1-23
Rockville, MD 20857

RE: **IDE Number G960214**
CardioLogic VEST-CPR® System
Information Concerning Public Disclosures - Hamot Medical Center of Erie, Pennsylvania

Dear Sir/Madam:

In accordance with 21 CFR §312.54(a), we are enclosing copies of the public disclosure plan and information that has been publicly disclosed by the Hamot Medical Center Institutional Review Committee (IRC), concerning research involving an exception to informed consent, as required by 21 CFR §50.24(a)(7)(ii) and 21 CFR §50.24(a)(7)(iii).

If there are any questions concerning this information, please contact me at 410/691-5200, ext.45.

Sincerely,



Timothy R. Placek
Director of Regulatory Affairs
and Quality Assurance
Official Correspondent

Attachments: 1. Plan of Public Disclosure and Attachments
 2. Public Response Summary Memo

955-0158

SUP13

CARDIOLOGIC SYSTEMS, INC.

**IDE Number G960214
Public Disclosure Information
October 26, 1997**

VOLUME 1

**SPONSORED BY:
CARDIOLOGIC SYSTEM, INC.
7455-T NEW RIDGE ROAD
HANOVER, MARYLAND, USA 21076-3143**



**PLAN OF PUBLIC DISCLOSURE
HAMOT MEDICAL CENTER
ERIE, PA**

The VEST-CPR trial consists of testing a new device in patients who experience cardiac arrest. Because of the emergent nature of this condition and the difficulty with identifying patients before the event, an exception from informed consent requirement is requested.

To fulfill FDA requirements regarding this exception (21 CFR 50.24), the following plan will be implemented:

- consultation with the community at a public meeting to be held in the Hamot Medical Center Auditorium on October 21, 1997. The purpose, procedures, risks, and benefits of this study will be described. A discussion of FDA guidelines regarding exception from informed consent requirements will be provided. A question and answer session will be held. (Agenda/Questionnaire/Brochure - Attachment 1);
- one advertisement each will be placed in the Erie Daily Times and Erie Morning News (combined circulation- 90,000) and one will be placed in the Sunday Times News (circulation- 99,000) (Advertisement - Attachment 2);
- an article describing the study in more detail will be written after an interview with the Principal Investigator. This will be placed in the Pulse magazine of the Erie Daily Times (circulation 90,000) (Press Release - Attachment 3);
- broadcast (WJET - 50,000; WSEE - 24,000; WICU - 15,000 viewers) and radio (Hamot House Calls - 7,000 listeners) media will be contacted to schedule interviews with Leo Bennett, MD and/or Brad Cooper, PharmD;
- physicians will be informed regarding the study utilizing an article placed in the Hamot Physician (Attachment 4) and by inservicing at department meetings and Grand Rounds;
- posters will be placed in MCICU and Stepdown units (Attachment 5);
- public comments will be summarized and submitted to the IRC Chairperson before active patient enrollment begins; and
- further public notification regarding study progress will be accomplished through notices in the local newspaper as described above.

Geoffrey R. Burbridge MD 10/20/97
Geoffrey Burbridge, MD Date
IRC Chairman



Attachment 1

AGENDA
VEST-CPR® Public Forum
1997

00 pm **Welcome/Introductions**

05 pm **FDA Guidelines and IRB**

20 pm **Protocol Review / Risks and Benefits**

40 pm **Review/Demo Standard CPR**

50 pm **Review/Demo VEST-CPR®**

00 pm **Questions**

QUESTIONS

Please answer a few questions by circling the appropriate answer.

Age? < 40 < 50 50-65 > 65

Sex? Male Female

Race? Caucasian African American Asian Hispanic

Other: _____

Occupation? _____

Do you work in healthcare? Yes No

Are you certified to give CPR? Yes No

Have you ever given CPR? Yes No

Do you know anyone who has received CPR? Yes No

Do you approve of this study? Yes No

Comments:

CARDIOLOGIC SYSTEMS, INC.

IS SEEKING YOUR ASSISTANCE IN
CONDUCTING A CLINICAL TRIAL OF
SIGNIFICANT MEDICAL IMPORTANCE.
WITH YOUR PARTICIPATION, WE CAN
CONTINUE TO SUCCESSFULLY TEST
AND DEVELOP THE INNOVATIVE

VEST-CPR® SYSTEM.

HOPEFULLY, OUR
COMBINED EFFORTS
WILL RESULT IN THE
ADVANCEMENT OF CPR
TECHNOLOGY AND



THE IMPROVEMENT OF HEALTH
CARE DELIVERY FOR CARDIAC
ARREST PATIENTS.

For more information pertaining to the study
protocol or reprints of published studies contact:

OR



CardioLogic Systems, Inc.
Dept. of Clinical Affairs
7455-T New Ridge Road
Hanover, MD 21076-3143
(410) 691-5200 • (800) 321-4277

CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use.
VEST-CPR® is a registered trademark of CardioLogic Systems, Inc. U.S. patent No. 4928674,
other patents pending.

VEST-CPR®



CLINICAL STUDY

THE CLINICAL

TRIAL OF THE

INNOVATIVE

VEST-CPR SYSTEM



TO ADVANCE CPR TECHNOLOGY . . .

The Institutional Review Board of this hospital has chosen to take part in a CPR clinical study. Several hospitals across the nation will be participating in this multi-center randomized-controlled clinical trial. The trial will evaluate the resuscitation of patients treated with manual CPR vs. VEST-CPR®, a new technology developed at The Johns Hopkins University (JHU).

PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE . . .

On September 9, 1993, the following results of preliminary studies conducted at The Johns Hopkins Hospital were published in The New England Journal of Medicine.

- VEST-CPR® increased coronary perfusion pressure from 15+/-8 mm Hg to 23+/-11 mm Hg (P=0.003)
- VEST-CPR® increased peak aortic pressure from 78+/-26 mm Hg to 138+/-28 mm Hg (P=0.001)
- VEST-CPR® produced 47% return of spontaneous circulation compared with 18% for manual CPR.

THE REASON TO IMPROVE CPR . . .

Each year more than 300,000 people die of cardiac arrest. The success rate for manual CPR averages only 15% for both in and out of hospital cardiac arrest patients. For each 1% improvement in CPR, 3,000 lives could be saved.

Since 1960, manual CPR has been taught as a means of providing oxygenated blood to the heart and brain. But even the best manual CPR usually results in death. Although potential risks of VEST-CPR® may not entirely be known, preliminary studies indicate that they are no higher than those experienced with manual CPR.

OBJECTIVES OF THE VEST-CPR® CLINICAL TRIAL

Standard Advanced Cardiac Life Support (ACLS) procedures will be administered to cardiac arrest patients. The only difference will be the way CPR chest compressions are performed. Patients who qualify for the study will be randomized to receive either manual or VEST-CPR®. The study will measure return of spontaneous circulation (ROSC), long term survival, and neurological function.

The conditions of the study are closely supervised by the hospital Institutional Review Board under a recent ruling by the FDA which allows that under strict circumstances, patients in life threatening situations (and for whom there is no one available to give their consent) may be given experimental treatment if there is no acceptable alternative with a good chance of success. Patients or their families will be notified at the earliest opportunity of their inclusion in the research study.

VEST-CPR®

The VEST-CPR® system is the result of more than a decade of research at JHU where manual CPR was invented. CardioLogic Systems, Inc. (CSI), in agreement with JHU, has developed this patented technology. CSI is sponsoring this trial after applying for and receiving an Investigational Device Exemption from the Food and Drug Administration.

The VEST-CPR® System consists of a vest that looks like a large blood pressure cuff and wraps around the patient's chest. It is connected to a computerized pneumatic



system that directs compressed air into and out of the vest to compress the chest circumferentially. Defibrillation shocks can be administered without stopping compressions with the use of disposable electrodes under the vest. On every fifth sequential cycle the computer extends the deflation time for ventilation.



Hamot Medical Center
201 State Street
Erie, PA 16550
(814) 877-6000
<http://www.hamot.org>

The Public Forum meeting which was announced in Erie, PA's Sunday Times News (10/19/97), Morning News (10/20/97), and Erie Daily Times (10/20/97) was held in the auditorium of Hamot Medical Center at 7:00 PM on October 21, 1997.

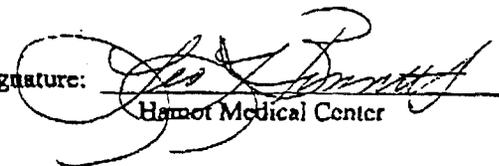
Individuals present for this meeting included Dr. Leo Bennett, Principle Investigator, Dr. Brad Cooper, Co-Investigator, and Regina Driver, Senior Clinical Research Associate of the sponsor company, CardiolLogic Systems, Inc. Three members of the Erie community were also present.

Dr. Cooper gave a brief presentation on the VEST-CPR clinical study, as well as a demonstration of standard CPR. Ms. Driver gave a brief presentation on waiver of informed consent, along with a demonstration of VEST-CPR.

Questions that were asked by the community members present are as follows:

1. Can this vest be used on frail little ladies who have osteoporosis?
2. How long does this vest have to stay on?
3. Can you adjust the pressure?
4. What kind of side effects can this vest produce?
5. If this is an emergency vest, why aren't you using it in the Emergency Room?

Signature:



Hamot Medical Center



Attachment 2

An Important Message to the Community

Hamot Medical Center to Help Test VEST-CPR® System

Every year, about 400,000 people in the United States have a cardiac arrest (the heart stops beating). If the heart is not restarted in minutes, brain damage and/or death will occur.

When a patient's heart stops beating in the hospital, an electric shock is given to restart the heart. If this does not work, manual CPR is used. CPR involves rhythmically pushing down on the person's chest with the hands. CPR is only successful 15% of the time.

Recently, a device was developed called VEST-CPR® that can be used when patients suffer cardiac arrest. The VEST-CPR® device, which is experimental, consists of a vest that goes around the person's chest just like a blood pressure cuff goes around the arm. The vest connects to a computer-controlled air pump that inflates the vest so it rhythmically squeezes the person's chest. The VEST-CPR® system may prove superior to manual compressions because the amount of pressure exerted on the patient is the same each time.

Hamot Medical Center is participating in a study of the VEST-CPR® device. The purpose of the study is to compare the safety and effectiveness of manual CPR (using the hands) to the VEST-CPR® system. All patients will receive standard care to restore a normal heart beat. In addition, some patients will have chest compressions performed by the VEST-CPR device. Preliminary scientific evidence indicates that VEST-CPR® may increase the survival rate of cardiac arrest patients over manual CPR. Other expected benefits are improved neurological function and reduced internal injuries. Although some risks may not be currently known, studies indicate that they are no higher than those experienced with manual CPR.

In most research, patients are told the facts about a study and then asked if they want to participate. This process is called informed consent. In the case of an unexpected and life-threatening condition such as cardiac arrest, the patient is unable to give consent and the patient's legal guardian or family can not usually be reached in time to do so. In circumstances such as these, the Food and Drug Administration (FDA) now allows research to be performed without the patient or families' consent if very specific procedures are followed. One requirement is notification of the public. The results of this study will be used by the FDA to decide whether this device should be approved for sale in the United States.

A public meeting will be held in the Hamot Medical Center Auditorium at 7:00 pm on October 21, 1997 for all parties interested in learning more about the study. This forum is to inform the public of the study. Public comments regarding this investigation are also welcomed. Please direct your questions and comments to:

Brad Cooper, PharmD
Hamot Medical Center
201 State St.
Erie, PA 16550
(814) 877-2257

Monday, October 20, 1997

Erie Daily Times

Hamor Medical Center to Help Test VEST-CPR® System

Every year, about 400,000 people in the United States have a cardiac arrest (the heart stops beating). If the heart is not restarted in minutes, brain damage and/or death will occur.

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PA Morning News

44 PAGES | VOL. 41, NO. 201

15 | © 1997, TIMES PUBLISHING CO., 265 W. 12TH, ERIE, PA 16534 | (814) 870-1600 | E-MAIL: TO AMNEWS@TIMESNEWS.COM

track bill that excludes protection for workers, the environment and consumers, I think they will pay a price at the polls," said Trumka, also on "Face the Nation."

Quality differently

in the poll said they had an experience at their job in the past two years that they felt was sexual harassment. That rose to about two in five among women under age 35.

Among men and women alike, one in five admitted having made a comment about a co-worker of the opposite sex that "crossed the line of appropriate behavior" within the past five years.

NBC released the poll to kick off a series of reports called "The Sex War: The Tension Between Men and Women," appearing throughout this week on various news programs on the network and its cable network MSNBC.

bills needed to finance the government. Two others are at the White House awaiting his signature, and two more are awaiting final passage in Congress.

Four others are enmeshed in controversy, including legislation covering the departments of Health and Human Services, Education, Labor, State, Justice and Commerce; foreign aid; and the District of Columbia.

Relatively little controversy has arisen this year about funding levels because of last spring's balanced-budget deal between the White House and Congress.

Instead, the remaining disputes involve such issues as abortion, the 1990 census, a Republican proposal for school vouchers for certain lower-income children in Washington, D.C., and Clinton's call for national educational testing standards.

Veto confrontations are possible on some or all of the disputed bills, but the stopgap bill is expected to move smoothly to passage.

Hamot Medical Center to Help Test VEST-CPR® System

Every year, about 400,000 people in the United States have a cardiac arrest (the heart stops beating). If the heart is not restarted in minutes, brain damage and/or death will occur.

When a patient's heart stops beating in the hospital, an electric shock is given to restart the heart. If this does not work, manual CPR is used. CPR involves rhythmically pushing down on the person's chest with the hands. CPR is only successful 15 percent of the time.

Recently, a device was developed called VEST-CPR that can be used when patients suffer cardiac arrest. The VEST-CPR device, which is experimental, consists of a vest that goes around the person's chest just like a blood pressure cuff goes around the arm. The vest connects to a computer-controlled air pump that inflates the vest so it rhythmically squeezes the person's chest. The VEST-CPR system may prove superior to manual compressions because the amount of pressure exerted on the patient is the same each time.

Hamot Medical Center is participating in a study of the VEST-CPR device. The purpose of the study is to compare the safety and effectiveness of manual CPR (using the hands) to the VEST-CPR system. All patients will receive standard care to restore a normal heart beat. In addition, some patients will have chest compressions performed by the VEST-CPR device. Preliminary scientific evidence indicates that VEST-CPR may increase the survival rate of cardiac arrest patients over manual CPR. Other expected benefits are improved neurological function and reduced internal injuries. Although some risks may not be currently known, studies indicate that they are no higher than those experienced with manual CPR.

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I REGION

Hamot Medical Center to Help Test VEST-CPR® System

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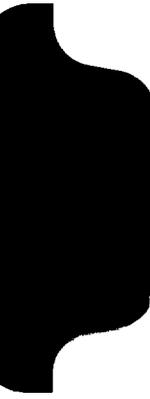
In most research, patients are told the facts about a study and then asked if they want to participate. This process is called informed consent. In the case of an unexpected and life-threatening condition such as cardiac arrest, the patient is unable to give consent and the patient's legal guardian or family can not usually be reached in time to do so. In circumstances such as these, the Food and Drug Administration (FDA) now allows research to be performed without the parent or families' consent if very specific procedures are followed. One requirement is notification of the public. The results of this study will be used by the FDA to decide whether this device should be approved for sale in the United States.

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2859

 Hamot

*Leading the way
in health care*



Attachment 3

Press Release

HAMOT MEDICAL CENTER TO HELP TEST VEST-CPR® SYSTEM

October 13, 1997

Hamot Medical Center of Erie, Pennsylvania will be one of fourteen centers in the United States conducting a study of a new, potentially life-saving treatment for patients suffering cardiac arrest. The study has been approved by the Institutional Review Committee (IRC) of Hamot Medical Center. The IRC is a committee composed of community members, clergy, scientists, physicians, and others that protects the safety of patients enrolled in research by reviewing studies to see that they are well designed and by determining that risks are reasonable in relation to potential benefits. Randomly selected patients suffering cardiac arrest in some areas of the hospital will be treated with a new way of performing Cardio Pulmonary Resuscitation (CPR). The conditions of the study are carefully described in an FDA-approved Investigational Device Exemption.

The new treatment, called VEST-CPR®, relies on a device invented at The Johns Hopkins University Hospital in Baltimore and further developed by CardioLogic Systems, Inc., located in Hanover, Maryland. This device performs the CPR chest compressions using a "vest" that resembles an oversized blood pressure cuff, around the chest. Scientific evidence indicates that VEST-CPR® may increase the survival rate of cardiac arrest patients when compared to manual CPR because the amount of pressure exerted on the patient is standard. Other expected benefits are improved neurological outcomes and reduced internal injuries. Although potential risks are not entirely known, preliminary studies indicate that they are no higher than those experienced with manual CPR.

Patients who decide not to participate, or are not eligible to enroll in the study, will be treated with conventional CPR. Some patients may not be able to give their consent for participation in the study, due to the nature of their condition and their critical need for immediate treatment. An exception from consent, authorized by the U.S. Food and Drug Administration (21 CFR 50.24) will be used when it is not feasible to obtain informed consent from the patient, a family member, or a legally authorized representative. Patients or their families will be notified at the earliest opportunity of their inclusion in the research study. A patient may withdraw or be withdrawn from the study at any time without influencing his or her medical care.

A public meeting will be held in the auditorium at Hamot Medical Center, 201 State Street, Erie, Pennsylvania, at 7:00 PM on October 21, 1997, for all interested parties who would like to learn more about the study, and to offer feedback to representatives of Hamot Medical Center.

For more information on this study, please contact Brad Cooper, PharmD, at: (814) 877-2257.



Hamot

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<http://www.hamot.org>

As per our public disclosure plan, I have contacted the three major television stations in our area to set up interviews for the VEST-CPR® study. The assignment editors for WSEE, WICU and WJET are aware that we are currently undergoing training and expect to start the study soon. The assignment editor from WICU specifically stated that they are interested in conducting an interview, and I should hear from her in the near future. Follow-up calls for the other two stations are scheduled for later this week.

Thank you,

Tammy Trinidad
Manager, Media Relations
814/877-7033



Attachment 4

HAMOT PHYSICIAN RELEASE

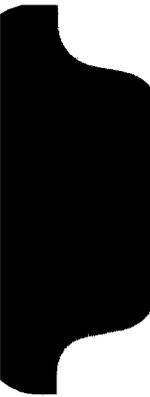
Hamot Medical Center will be one of fourteen centers in the United States conducting a study of a new resuscitation device for patients experiencing cardiac arrest. This study will be under the direction of Leo Bennett, MD.

VEST-CPR is a device that was invented at The Johns Hopkins University Hospital and developed by Cardiologic Systems, Inc., Hanover, Maryland. The device performs CPR chest compressions using a vest that resembles an oversized blood pressure cuff. Previous studies indicate that VEST-CPR may increase the survival rate post-cardiac arrest compared with manual CPR.

The VEST-CPR device will be located in MCICU and Stepdown. When a patient experiences cardiac arrest that has not responded to standard resuscitative efforts, the patient will be randomized to receive either manual CPR or the VEST-CPR system. Patients must be at least 18 years old. Exclusion criteria include pregnancy, end stage disease, participating in another study, neurological impairment, major thoracic or abdominal surgery/trauma within six weeks, hemorrhagic or hypothermic cardiac arrest, severe bony abnormality, massive pulmonary embolism, severe bullous emphysema or subcutaneous emphysema. If a patient has DNR orders or is unlikely to survive hospitalization, they will also be excluded.

Based on a final rule recently published by the Food and Drug Administration, the Hamot Medical Center Institutional Review Committee has granted an exception from informed consent requirements. The FDA allows a waiver of informed consent for emergency research under very special circumstances.

If you have any questions about this study, please contact Dr. Bennett or Brad Cooper, PharmD.



Attachment 5

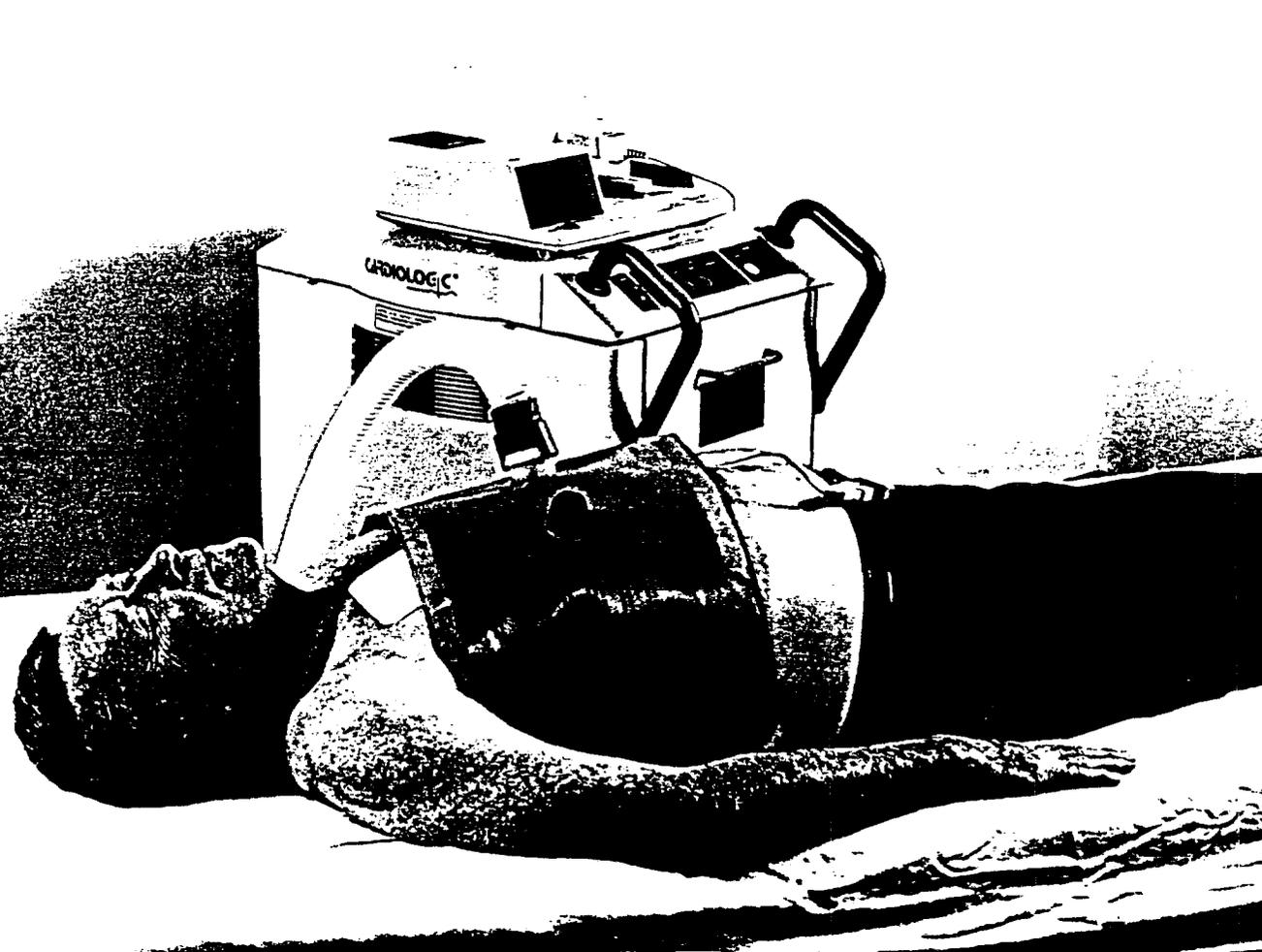
DRAFT POSTER

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If you would like more information about this study, please ask one of the nurses on this unit or call Brad Cooper, PharmD at (814) 877-2257.







Hamot Medical Center
201 State Street
Erie, PA 16550
(814) 877-6000
<http://www.hamot.org>

October 27, 1997

Geoffrey R. Burbridge, M.D.
Chairman, IRB
Medicor Associates, Inc.
104 East Second Street
Erie, Pennsylvania 16507

Dr. Burbridge:

Since the initial public notice on October 19, 1997, there have been no negative comments received by myself concerning the Vest-CPR trial. I will let you know if I do receive any negative comments with any of our further public notices (radio or television interviews).

Sincerely,

Brad E. Cooper, Pharm.D.