

SUMMARY OF PUBLIC DISCLOSURE

Community Consultation

The Community Consultation meeting for this IDE occurred on May 8, 2002 at the Italian Community Center in Milwaukee, WI. The presentation script for that meeting has been previously submitted and approved by the FDA. The meeting was videotaped and that videotape is available upon request. The announcement of the meeting was published in the Milwaukee Journal Sentinel on May 5, 2002.

Public Disclosure

Public disclosure of this study was conducted using several different media formats. Copies of website information, newspaper notices and broadcast announcements are included as attachments.

A website (<http://www.mcw.edu/cardiac/index.html>) was established to provide the public with information about the study. This website includes a welcome page, frequently asked questions, a copy of the presentation given at the Community Consultation meeting, samples of the consent forms and surveys used in the trial, and a link for contacting investigators with questions or concerns.

Newspaper notices ran:

Newspaper/Newsletter	Date(s)
Milwaukee Journal Sentinel	June 2, 2002
Spanish Journal	July 17, 2002
Milwaukee Community Journal	July 19, 2002
Milwaukee Star	July 25, 2002
Milwaukee Courier	July 27, 2002
Milwaukee Times Weekly	August 8 – 14, 2002
50 Plus News Magazine	August 2002

Television announcements were broadcast:

Date	Station	Length	Viewing Area
July 2, 2002	WDJT-TV Channel 58	30-second announcement	Milwaukee County, WI
July 23, 2002	WISN-TV Channel 12	30-second announcement	Milwaukee County, WI
July 23, 2002	WTMJ-TV Channel 4	30-second announcement	Milwaukee County, WI
July 24, 2002	WTMJ-TV Channel 4	30-second announcement	Milwaukee County, WI
July 27, 2002	WTMJ-TV Channel 4	30-second announcement	Milwaukee County, WI
July 28, 2002	WTMJ-TV Channel 4	30-second announcement	Milwaukee County, WI

Community Consultation

Milwaukee J-Sentinel

SUNDAY, MAY 5, 2002

11A



Milwaukeeans Invited to Comment on Study to Test New Device in Cardiac Arrest Patients

The Medical College of Wisconsin is holding an informational meeting about a planned study to examine the effectiveness of the Resq-Valve™ used during CPR for patients suffering a cardiac arrest. The purpose of this public consultation is to get feedback from the community in which the research study will take place. The Food and Drug Administration requires this community consultation because informed consent cannot be obtained from a patient suffering a cardiac arrest.

May 8, 2002
Italian Community Center
631 E Chicago Ave., Milwaukee

5:00-5:45pm Light Buffet
5:45-6:05pm Research Presentation
6:05-7:00pm Discussion

For more information, please call
414-805-2573 or email lgrabows@mcw.edu.

125027



**MEDICAL
COLLEGE
OF WISCONSIN**

Medical College of
Wisconsin Announces

**ResQ-Valve™ Cardiac
Arrest Trial**

**For patients Suffering
from Cardiac Arrest**

Research to study the effectiveness of the ResQ-Valve™, a new biomedical device used during cardiopulmonary resuscitation (CPR) for adult patients suffering cardiac arrest, will begin in June 2002 in Milwaukee County. Initial studies indicate that the ResQ-Valve™ increases blood flow during CPR. Researchers at the Medical College of Wisconsin will compare survival rates and brain function for adult cardiac arrest patients receiving the standard of care versus the standard of care plus the use of the ResQ-Valve™. In addition, 20 adult cardiac arrest patients will also have carbon dioxide, chest pressure, oxygen, and blood pressure measured during CPR.

**Potential Risks/Benefits
for the Clinical Trial and
Hemodynamic Substudy**

The risks of this study include increased work of breathing, fluid buildup in the lungs, failure of the device, or lack of benefit of the device. A catheter placed in the large artery in the upper leg in the hemodynamic substudy is a standard procedure. Risks associated with this procedure include: 1) infection, 2) bleeding, 3) abnormal connection or hole between the artery and vein of the leg, or 4) blockage of blood flow to the leg. Surviving cardiac arrest with damage to the brain is a potential risk for any patient undergoing CPR. It is possible that survivors in one group may have more damage to the brain. This will be monitored on an ongoing basis and the study stopped if it occurs. There may also be some unknown or unanticipated risks because this device is relatively new and is an attempt to advance medical knowledge. Every precaution will be taken to assure personal safety.

The benefit, which may reasonably be expected from participating in this study, is possibly an increased chance of survival from cardiac arrest, but this is not guaranteed.

This study meets the FDA guidelines for waiver of informed consent under emergency circumstances because informed consent cannot be obtained from a victim of sudden cardiac arrest. For details on the risks and benefits, waiver of informed consent, and other aspects of the study please call Dr. Tom Aufderheide at (414) 805-2572, email at taufderh@mcw.edu, or visit the WEB site at www.mcw.edu/cardiac

Del 10 al 17 de julio 2002

Risk/Benefit Public Announcement

**ResQ-Valve™ Cardiac Arrest Trial
Public Notification:**

Research to study the effectiveness of the ResQ-Valve™, a new biomedical device used during cardiopulmonary resuscitation (CPR) for adult patients suffering cardiac arrest, has begun in Milwaukee County. Initial studies indicate that the ResQ-Valve™ increases blood flow during CPR. Researchers at the Medical College of Wisconsin will compare survival rates and brain function for adult cardiac arrest patients receiving the standard of care versus the standard of care plus the use of the ResQ-Valve™. In addition, 20 adult cardiac arrest patients will also have carbon dioxide, chest pressure, oxygen, and blood pressure measured during CPR.

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(Milwaukee Community Journal)

MCJ WEEKEND JULY 19, 2002 PAGE 9

Appendix F
Risk/Benefit Public Announcement

ResQ-Valve™ Cardiac Arrest Trial
Public Notification:

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Public Notification:

Research to study the effectiveness of the ResQ Valve™, a new bio-medical device used during cardiopulmonary resuscitation (CPR) for adult patients suffering cardiac arrest has begun in Milwaukee County. Initial studies indicate that the ResQ Valve™ increased blood flow during CPR.

Researchers at the Medical College of Wisconsin will compare survival rates and brain function for cardiac arrest patients receiving the standard of care versus the standard of care plus the use of the ResQ Valve™. In addition, 20 adult cardiac arrest patients will also have carbon dioxide, chest pressure, oxygen, and blood pressure measured during CPR.

This study meets the FDA guidelines for waiver of informed consent under emergency circumstances because informed consent cannot be obtained from a victim of sudden cardiac arrest. For details, on the risks and benefits, waiver of informed consent, and other aspects of the study please call Dr. Tom Aufderheide at (414) 805-2572; email at taufderh@mcw.edu; or visit the WEB site at www.mcw.edu/cardiac.



**MEDICAL
COLLEGE
OF WISCONSIN**

**ResQ-Valve™ Cardiac Arrest Unit
Public Notification:**

Research to study the effectiveness of the ResQ-Valve™, a new bio-medical device used during cardiopulmonary resuscitation (CPR), for adult patients suffering cardiac arrest has begun in Milwaukee County. Initial studies indicate that the ResQ-Valve™ increased blood flow during CPR.

Researchers at the Medical College of Wisconsin will compare survival rates and brain function for cardiac arrest patients receiving the standard of care versus the standard of care plus the use of the ResQ-Valve™. In addition, 20 adult cardiac arrest patients will also have carbon dioxide, chest pressure, oxygen, and blood pressure measured during CPR.

This study meets the FDA guidelines for waiver of informed consent under emergency circumstances because informed consent cannot be obtained from a victim of sudden cardiac arrest. For details, on the risks and benefits, waiver of informed consent, and other aspects of the study please call Dr. Tom Aufderheide at (414) 805-2572, email at taufderh@mcw.edu, or visit the WEB site at www.mcw.edu/cardiac.



August 8 - August 14, 2002

ResQ-Valve™ Cardiac Arrest Trial Public Notification:

Research to study the effectiveness of the ResQ-Valve™, a new biomedical device used during cardiopulmonary resuscitation (CPR) for adult patients suffering cardiac arrest has begun in Milwaukee County. Initial studies indicate that the ResQ-Valve™ increases blood flow during CPR. Researchers at the Medical College of Wisconsin will compare survival rates and brain function for cardiac arrest patients receiving the standard of care versus the standard of care plus the use of the ResQ-Valve™. In addition, 20 adult cardiac arrest patients will also have carbon dioxide, chest pressure, oxygen, and blood pressure measured during CPR. This study meets the FDA guidelines for waiver of informed consent under emergency circumstances because informed consent cannot be obtained from a victim of sudden cardiac arrest. For details, on the risks and benefits, waiver of informed consent, and other aspects of the study please call Dr. Tom Aufderheide at (414) 805-2572, email at taufderh@mcw.edu, or visit the WEB site at www.mcw.edu/cardiac.



ResQ-Valve™
Cardiac Arrest Trial
Public Notification

Research to study the effectiveness of the ResQ-Valve™, a new biomechanical device used during cardiopulmonary resuscitation (CPR) for adult patients suffering cardiac arrest, has begun June 12, 2002 in Milwaukee County. For details, on the risks and benefits, waiver of informed consent, and other aspects of the study please call Dr. Tom Aufderheide at (414)805-2572, e-mail at taufderh@mcw.edu or visit the web site at www.mcw.edu/cardiac.



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Appendix C

Brief Public Announcement

ResQ-Valve™ Cardiac Arrest Trial Public Notification:

Research to study the effectiveness of the ResQ-Valve™, a new biomedical device used during cardiopulmonary resuscitation (CPR) for adult patients suffering cardiac arrest, ~~will begin~~ ^{has begun} ~~in~~ 8, 2002 in Milwaukee County. For details, on the risks and benefits, waiver of informed consent, and other aspects of the study please call Dr. Tom Aufderheide at (414) 805-2572, email at taufderh@mcw.edu, or visit the WEB site at mcw.edu/cardiac.

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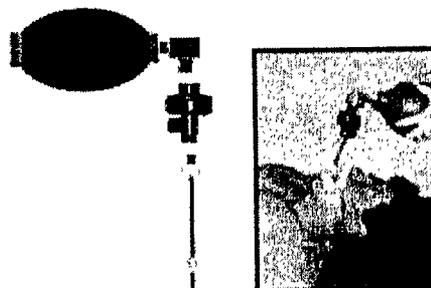
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CPR device may improve survival for victims of cardiac arrest

- [Welcome](#)
- [FAQs](#)
- [Research](#)
- [Consent forms](#)
- [Contact us](#)
- [MCW home](#)

Researchers at the Medical College of Wisconsin are testing a new biomedical device during CPR to determine if more people can be saved and the quality of their lives improved.



The new ResQ-Valve™ device is shown in blue between airbag and endotracheal tube in diagram (left) and in use with patient.

This is the first human trial of the device in the United States.

Other research shows the device can increase blood flow by 75%, significantly increase blood flow to the brain, improve survival and holds potential to reduce the risk of brain damage.

[FAQs on CPR and how this device works](#)



[Contact us](#)

Posted: 5.10.02

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It's called the ResQ-Valve™. It's a one-way valve that fits between the airbag -- used to introduce air into the cardiac arrest victim -- and the endotracheal tube placed into the patient's throat and lungs. The valve can also be used with a facemask that fits over the patient's nose and mouth and other resuscitation devices. During CPR the one-way valve creates a small vacuum within the victim's chest, increasing the return flow of blood to the heart.

Will this valve save lives?

Preliminary studies have demonstrated:

- A return flow of blood to the heart by 75%.
- Increased blood flow to the brain.
- An increased survival rate.

However, none of these benefits are guaranteed.

Why are we doing another study?

The valve has been successfully used on humans in Europe. But more study is needed. This will be the first study of cardiac arrest victims in the United States and the first study using standard CPR. It will be conducted by Medical College of Wisconsin physicians and Milwaukee County paramedics.

How will the Medical College of Wisconsin study be conducted?

The purpose of the study is to compare the outcome in victims of cardiac arrested who are treated with standard CPR techniques and those who are treated with standard CPR along with the new valve. Exactly 832 patients will be studied over the course of about a year. Physicians will measure two minutes of hemodynamic data -- blood pressure, pressure inside the chest, and oxygen and carbon dioxide levels -- in 20 of these patients during CPR.

The US Food and Drug Administration, the National Institutes of Health and the Institutional Research Board of the Medical College of Wisconsin have approved this study.

Which cardiac arrest victims will be treated with the valve?

This will be a randomized study. There is a 50-50 chance, similar to flipping a coin, that a cardiac arrest victim will receive standard CPR without the valve and standard CPR with the valve. Neither the victim nor the physician or paramedic will know whether the the valve is being used. Randomization is necessary to assure that research findings do not occur from bias or chance.

Who will be included in the study?

- The cardiac arrest patients must be at least 21 years old.
- The patient must be treated by Milwaukee County paramedics.
- Paramedics must be able to successfully place an endotracheal tube into the patient's lungs.

- Patients who received trauma, such as that from an automobile accident or gunshot, will be excluded from the study.
- Patients who have a pre-existing "do not resuscitate" order will be excluded.

Are there potential risks in the study?

Performing CPR, with or without the new valve device, can pose a risk. Surviving cardiac arrest with damage to the brain is a potential risk for any patient receiving CPR. The one-way valve that fits between the airbag -- used to introduce air into the cardiac arrest victim -- and the facemask placed over the patient's nose and mouth could fail and not provide any benefit to the victim.

The valve could become contaminated with bodily fluids and force paramedics to discontinue using it. There is the possibility the valve could cause an excessive buildup of fluids in the lungs. There may be unknown or unanticipated discomfort or risk from using the valve. Death from cardiac arrest is a potential risk for any patient receiving CPR.

Are there any risks in measuring a victim's blood flow and blood pressure while the patient is receiving CPR?

When paramedics begin CPR, they may insert a catheter into the femoral artery in the lower body. Femoral artery catheters are often inserted into the body in a hospital during or after cardiac arrest. This is done to monitor blood pressure. Inserting a catheter may cause infection or bleeding. It may create an abnormal connection between the femoral artery and the femoral vein. It can also block blood flow to the leg.

Will a cardiac arrest victim's records be kept confidential?

Yes, information gathered in the process of this study will remain confidential by the Medical College of Wisconsin research team, the Milwaukee County paramedics, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). The NIH is funding this study.

How can you get more information about the study?

Please contact Tom P. Aufderheide, MD, professor of emergency medicine at the Medical College of Wisconsin.

Phone: (414) 805-2572

E-mail: taufderh@mcw.edu

Fax: (414) 805-6464

Mailing address: Department of Emergency Medicine, Froedtert Hospital East, 9200 W. Wisconsin Ave., Milwaukee, WI 53226

For more information on Dr. Aufderheide, please follow this link: [Brief Bio](#)

How are cardiac arrest victims and their families informed about this research?

Obtaining an "informed consent" from victims of cardiac arrest is always impossible. To allow researchers to possibly improve the survival rate of

individuals suffering from cardiac arrest, the US Food and Drug Administration (FDA) has issued guidelines for the waiver of consent under emergency circumstances, as long as the research has the prospect of direct benefit to the patient. However, consent information is provided to the patient, legal representative and the family as soon as possible.

In an attempt to inform as many people as possible before the research begins, the researchers are required to disclose to the public the nature, risks and benefits of the study. This is being done through a variety of means:

- This website.
- Publicly announced meetings.
- Newspaper advertising.
- News stories.
- Consultation with survivors of cardiac arrest.
- Consultation with family members of survivors and non-survivors of cardiac arrest.
- Consultation with the administrative staff of the Milwaukee County Paramedics.
- Consultation with community leaders.
- Consultation with representatives of numerous other community organizations, such as the American Red Cross, the Visiting Nurse Association, Milwaukee Health Department, Wisconsin American Heart Association, Milwaukee area hospitals, churches and ethnic health organizations.

Why has the FDA changed its rules on informed consent?

The FDA has issued these regulations to allow research, designed to improve medical treatment, to occur under emergency circumstances in which obtaining informed consent is not feasible while doing everything possible to protect the rights and safety of human subjects.

Does the cardiac arrest study meet the FDA requirements for waiver of informed consent?

Yes, the Medical College of Wisconsin research study meets these requirements:

- A life-threatening situation with unproven or unsatisfactory treatment where research is necessary to improve outcome. Cardiac arrest is an immediately life-threatening condition with unsatisfactory treatment.
- Obtaining informed consent is not feasible because the patient is unresponsive and treatment must begin immediately if there is any hope for survival.

- Participation in research has the prospect of direct benefit because the situation necessitates an intervention, science supports the potential of direct benefit and the risks of the research are reasonable compared to the medical condition.
- The research could not practicably be done without waiver of informed consent.
- The potential therapeutic window is short (in the case of cardiac arrest just a few minutes).
- The Medical College of Wisconsin Research Board approves the consent document and procedures for the subject or legal representative.

Will the victim's family know that research was part of the CPR?

Information will be provided to the patient, legal representative and the family as soon as possible. Documentation will be kept on file according regulations.

Additional protections provided by FDA regulations include public disclosure prior to starting the study, public disclosure after completion of the study, and an attempt to contact family members whenever possible.

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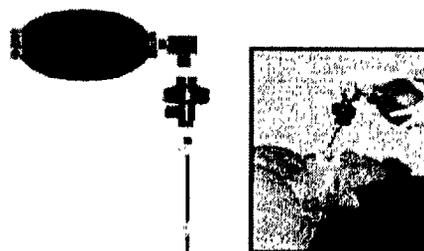
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Posted: 5.10.02

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Cardiac Arrest Research



The new ResQ-Valve™ device is shown in blue between airbag and endotracheal tube in diagram (left) and in use with patient.

Tom P. Aufderheide, MD, professor of emergency medicine at the Medical College of Wisconsin and an emergency medicine physician at the Froedtert & Medical College Emergency Center, described the research trial at a public meeting May 8, 2002, at the Italian Community Center in Milwaukee.

Dr. Aufderheide's presentation here includes his commentary and the text of slides he presented to the gathering.

[Begin the slide presentation.](#)

About one year after a cardiac arrest patient has been successfully resuscitated and discharged from a hospital, Dr. Aufderheide will send the patient and the family a letter asking the patient to fill out a short quality of life questionnaire.

Copies of the letter and questionnaire are [available here](#).

If you have any comments or questions about the research, you are welcome to contact [Dr. Aufderheide](#).

[Contact us](#)

Posted: 5.10.02

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Welcome

FAQs

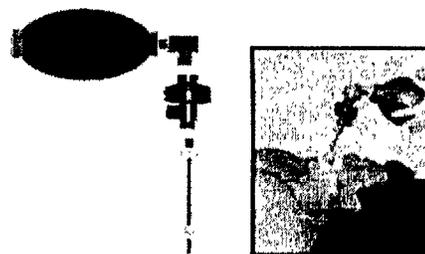
Research

Consent forms

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Consent Forms & Survey



The new ResQ-Valve™ device is shown in blue between airbag and endotracheal tube in diagram (left) and in use with patient.

Consent forms involving CPR and ResQ-Valve™ study

- [Statement of Volunteer Informed Consent for Clinical Study](#)
- [Statement of Volunteer Consent for Clinical Study after Waived Consent](#)
- [Statement of Volunteer Consent for Clinical Study for Family of Cardiac Arrest Victims after Waived Consent](#)
- [Statement of Volunteer Consent for Clinical Study after Family Consent](#)



Consent forms involving CPR and blood pressure study

- [Statement of Volunteer Consent for Hemodynamic Substudy](#)
- [Statement of Volunteer Consent for Hemodynamic Substudy after Waived Consent](#)
- [Statement of Volunteer Consent for Hemodynamic Substudy for Family of Cardiac Arrest Victims after Waived Consent](#)
- [Statement of Volunteer Consent for Hemodynamic Substudy after Family Consent](#)

Followup letter and quality of life survey

- [Letter to patients or relatives one year after cardiac arrest](#)
- [Quality of life survey one year after cardiac arrest](#)

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Welcome

FAQs

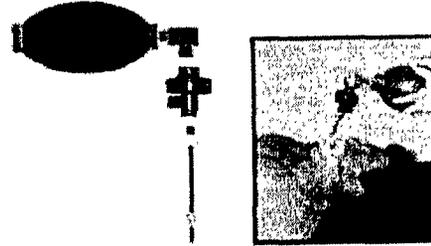
Research

Consent forms

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How to contact us



The new ResQ-Valve™ device is shown in blue between airbag and endotracheal tube in diagram (left) and in use with patient.



Please contact Tom P. Aufderheide, MD, professor of emergency medicine at the Medical College of Wisconsin and an emergency medicine physician at the Froedtert & Medical College Emergency Center.

Phon

(414) 805-2572

E-mail: taufderh@mcw.edu

Fax: (414) 805-6464

Mailing address: Department of Emergency Medicine, Froedtert Hospital East, 9200 W. Wisconsin Ave., Milwaukee, WI 53226

For more information on Dr. Aufderheide, follow this link: [Brief Bio](#)

Posted: 5.10.02

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Community Consultation Presentation

**Community Consultation
for the Proposed Cardiac Arrest Study**

"Comparison of Standard CPR versus Standard CPR plus
an Inspiratory Impedance Threshold Valve in Patients with
Out-of-Hospital Cardiac Arrest"
and "Hemodynamic Substudy"

DATE To Be Announced
LOCATION Italian Community Center
831 East Chicago Street
Milwaukee, WI 53202

PRESENTER: Tom P. Aufderheide MD, FACEP
Associate Professor of Emergency Medicine
Froedtert Memorial Lutheran Hospital
Medical College of Wisconsin

1

Community Consultation Participant List

- 1 Survivors of cardiac arrest
- 2 Family members of survivors of cardiac arrest
- 3 Family members of non-survivors of cardiac arrest
- 4 Individuals with risk factors for heart disease
- 5 Community leaders
- 6 Interested members of the public
- 7 Milwaukee County EMS Medical Director
- 8 Milwaukee County EMS Associate Medical Director
- 9 WI State EMS Director
- 10 Vice-President of Public Advocacy
- 11 Director, Diabetes Control Program

2

Community Consultation Participant List

1 American Red Cross	26 Milwaukee Health Department
2 Visiting Nurses Assoc	27 Milwaukee Academy of Medicine
3 Milwaukee Chapter of the Black Nurses' Assoc	28 WI American Heart Assoc
4 Black Health Coalition	29 Hmong American Women's Assoc
5 La Guadalupe Senior Center	30 Hmong Christian Community United Methodist Church
6 Department on Aging	31 Sixteenth Street Community Health Center
7 Paramedic Training Center	32 American Diabetes Assoc
8 Milwaukee County Health Care Programs	33 American Lung Assoc
9 Southeast Asian Consulting Services	34 St Anthony's Church
10 South Medical Services	35 Family Services of Milwaukee
11 LW-M Silver Spring Clinic	36 Village Adult Services
12 Harambee Urgent Care	37 Aging Commissioner of Health
13 Shaif Medical Center, SC	38 ADSP
14 Johnson Primary Care Clinic	39 MCW Faculty Physicians and Clinics
15 Rainbow Community Health Center	40 Latino Health Organization
16 Isaac Coggs Health Center	41 WI Health and Hospital Assoc
17 Healthcare for the Homeless	42 St Francis Hospital
18 Milwaukee Women's Center	43 St Joseph's Hospital
19 Dept of Human Services	44 Medical Society of Milwaukee County
20 SET Ministry	45 Medical Society of Milwaukee County
21 St Michael's Hospital	46 Milwaukee Jewish Home
22 American Heart Assoc	47 St Ben's Clinic
23 Milwaukee Hospital Assoc	48 Healthreach Community Advocates
24 Cream City Medical Society	49 Sene Semanin Medical Center
25 St Mary's Hospital	

3

**Cardiac Arrest
Research Presentation**

4

Community Consultation

"Comparison of Standard CPR versus Standard
CPR plus an Inspiratory Impedance Threshold
Valve
in Patients with Out-of-hospital Cardiac Arrest"
and "Hemodynamic Substudy"

Tom P. Aufderheide MD, FACEP
Professor of Emergency Medicine
Froedtert Memorial Lutheran Hospital
Medical College of Wisconsin

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Agenda

■ 6:00 pm -- 6:20 pm	■ Cardiac arrest research presentation
■ 6:20 pm -- 7:30 pm	■ Community consultation & discussion

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Cardiac Arrest: Extent of the Problem

- 500,000 cardiac arrest in U.S.
- 350,000 occur outside the hospital
- 1,000 occur in Milwaukee each year

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Cardiac Arrest

- Definition: heart suddenly stops beating
- Treatment: immediate CPR
- CPR is poorly effective
 - Forward blood flow during CPR is less than 25% of normal

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Cardiac Arrest

- Treatment of cardiac arrest unsatisfactory
- Milwaukee County paramedics one of the best in the U.S.
- Survival rate in Milwaukee
 - Best circumstances = 24%
 - Overall survival = 9%
- Outcome from cardiac arrest dismal

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Bag-Valve Mask, ITV and Endotracheal Tube

[Insert picture of ITV in respiratory circuit]

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Cardiac Arrest Study

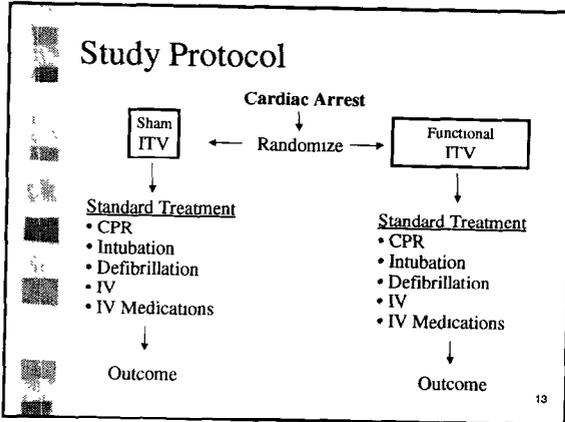
- Preliminary information
 - In animal studies
 - Vital organ blood flow improved
 - Increase in blood pressure
 - Coronary perfusion pressure significantly increased

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Cardiac Arrest Study

- Information to date is encouraging BUT...
- Unknown if improved blood flow with the ITV results in improved outcome for victims of cardiac arrest
- Purpose of study:
 - To evaluate outcome in victims of cardiac arrest treated with standard CPR versus standard CPR plus the ITV
 - To obtain hemodynamic information: blood pressure, pressure inside the chest, oxygen and carbon dioxide levels

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Randomization

- A 50 - 50 chance, similar to “flipping a coin”
- “Blinded” randomization
- Randomization is necessary to assure research findings reflect the study intervention and do not occur from bias or chance

- ### Study Protocol
- Subject inclusion
 - Adult cardiac arrest patients (21 years old or greater)
 - Treated by Milwaukee County paramedics
 - Successfully intubated
 - Subject exclusion
 - Less than 21 years old
 - Trauma
 - Not successfully intubated
 - Known pre-existing “do not resuscitate” orders
 - CPR cannot be performed
 - Patients already successfully resuscitated
 - Patients entered into the hemodynamic substudy

Profile of Cardiac Arrest Patients

Race

Race	Number	Percent
Unknown	21	6%
Black	81	22%
Hispanic	4	1%
Native American	3	0.8%
Asian	1	0.2%
White	262	70%
TOTAL	372	100%

Gender

Gender	Number	Percent
Female	145	39%
Male	227	61%
TOTAL	372	100%

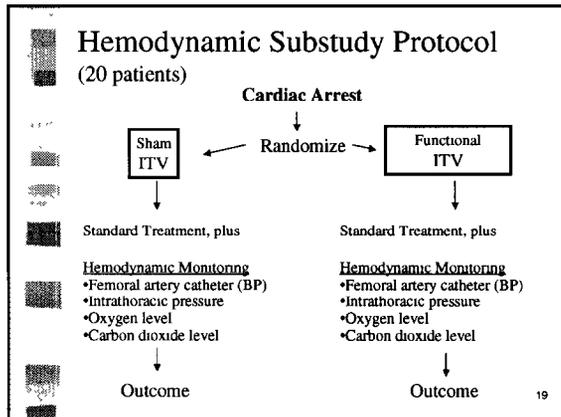
Profile of Cardiac Arrest Patients

Age	Number	Percent
18 - 29	6	1.6%
30 - 39	16	4.3%
40 - 49	27	7.2%
50 - 59	56	15.0%
60 - 69	80	21.5%
70 - 79	105	28.3%
80 - 89	68	18.3%
90 - 99	13	3.5%
100 - 110	1	0.3%
TOTAL	372	100%

Profile of Cardiac Arrest Patients

Geographic Location of Cardiac Arrest Within the Area Served by the Milwaukee County EMS System

Location	Number	Percent
Wauwatosa	24	6.5%
Milwaukee	221	59.4%
North Shore	29	7.8%
Greenfield	33	8.9%
South Milwaukee	31	8.3%
Franklin	7	1.9%
West Allis	27	7.2%
TOTAL	372	100%



- ### Study Procedures
- Randomized (a 50 - 50 chance, similar to “flipping a coin”) to receive either standard CPR or standard CPR plus the ITV
 - Results of resuscitation efforts and hospital outcome documented and scientifically reviewed
 - Experimental aspect of study is that it is unknown if CPR with ITV improves outcome
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- ### Substudy Procedures
- Same procedures, plus
 - Femoral artery catheter (to measure BP)
 - Monitoring of
 - Pressures inside the lungs
 - Level of carbon dioxide exhaled
 - Level of oxygen
 - Presence of a pulse during CPR
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- ### Potential Study Risks
- If successful resuscitation
 - Increased work of breathing
 - Fluid buildup in the lungs
 - Failure of the device
 - Lack of benefit of the device
 - Surviving cardiac arrest with damage to the brain is a potential risk for any patient receiving CPR
 - Death from cardiac arrest is a potential risk for any patient receiving CPR
 - Unknown or unanticipated discomfort or risks
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- ### Potential Risks Associated with the Investigational Device (Impedance Threshold Valve)
- Mechanical failure of the device
 - Discontinued use due to fluid contamination
 - Excessive fluid buildup in lungs
 - Increased number of patients resuscitated who are neurologically impaired
 - Unknown or unanticipated discomfort or risks
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- ### Potential Substudy Risks
- Same as already reviewed, plus
 - Possible complications from the femoral artery catheter
 - Infection
 - Bleeding
 - Creating of an arteriovenous fistula (an abnormal connection between the artery and vein)
 - Blockage of blood flow to the leg
 - Unknown or unanticipated discomfort or risks
 - Femoral artery catheters are often placed in the hospital during or after cardiac arrest
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Study Monitoring

- Clinical Events Committee
 - Review all adverse events
 - Study
 - ITV
 - Substudy
- Data Safety Monitoring Board
 - Monitor differences in the two groups
 - Adverse events
 - Rate of pulse return
 - Neurologic outcome
 - Carbon dioxide levels
 - Survival at one hour, ICU admission, 24 hours, hospital discharge, 30 days, 1 year

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Potential Benefits (Study)

- Improved outcome
- Improved effectiveness of CPR
- Helpful to others
- Useful scientifically
- Benefits not guaranteed

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Potential Benefits (Substudy)

- Improved outcome
- Improved effectiveness of CPR
- Improved treatment during CPR
- Helpful to others
- Useful scientifically
- Benefits not guaranteed

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Study Protocol

- Financial benefits: none
- Alternative procedures: none
- Confidentiality
 - Information will remain confidential
 - Access to medical records
 - Food and Drug Administration (FDA)
 - National Institutes of Health
 - CPRx LLC
 - Research team
- Further information
 - Tom P. Aufderheide, MD (414-805-2572)

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Study Protocol

- Study end points: comparison between the 2 groups of:
 - Carbon dioxide levels
 - Frequency of pulse return
 - Survival at: one hour, ICU admission, 24 hours, hospital discharge, 30 days, 1 year
 - Neurologic recovery in survivors
 - Quality of life at one year
- Study duration
 - 832 patients total or about 12 months duration

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Substudy Protocol

- Study end points: comparison between the 2 groups of
 - Carbon dioxide levels
 - Chest pressure levels
 - Bloodstream oxygen levels
 - Blood pressure
 - Presence of a pulse during CPR
 - Same endpoints in larger study
- Study duration
 - 20 patients total or about 3 months duration

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Study Protocol

- Study will not proceed without
 - Approval by Human Research Review Committee at MCW
 - Approval by receiving hospitals to review records
 - Investigational device exemption (IDE) from Food and Drug Administration

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Differences Between Treatment and Research

- Treatment
 - Proven to be effective
 - Established as acceptable practice
 - Involves risks and benefits
- Research
 - Attempts to advance knowledge and improve treatment
 - Unproven (experimental) intervention
 - Randomize
 - Involves risks and benefits

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Waiver of Informed Consent Under Emergency Circumstances

- Informed consent
- Exception issued by Food and Drug Administration (FDA)
 - Waiver of informed consent under emergency circumstances

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Food and Drug Administration (FDA) Requirements for Waiver of Informed Consent

A. IRB with concurring physician finds and documents

1. Life threatening situation with unproven or unsatisfactory treatment and research is necessary
2. Obtaining informed consent is not feasible
3. Participation in research has prospect of direct benefit because
 - i. Situation necessitates intervention
 - ii. Science supports potential of direct benefit
 - iii. Risks are reasonable compared to medical condition
4. Research could not practicably be done without waiver
5. Potential therapeutic window is short
6. IRB approves consent document and procedures for subject or legal representative

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Food and Drug Administration (FDA) Requirements for Waiver of Informed Consent

B. Information provided to subject, legal representative, and/or family as soon as possible

C. Documentation will be kept on file in accordance with IRB regulations

D. Separate investigational device exemption (IDE) obtained from FDA

E. Additional protections

- i. Public disclosure prior to initiation
- ii. Public disclosure after completion
- iii. Independent Data and Safety Monitoring Board
- iv. Attempt to contact family member when possible
- v. Community consultation

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Community Consultation

- Present today include
 - Survivors of cardiac arrest
 - Family members of survivors and non-survivors of cardiac arrest
 - Individuals at risk for heart disease
 - Community leaders
 - Representatives of community organizations
 - Interested members of the general public

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Community Consultation Presentation

Community Consultation

- Feedback
- Comments
- Discussion

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With further questions or comments please contact:

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Fax: (414) 805-6464
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Notes

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**Statement of Patient's
Voluntary Informed Consent
for Clinical Outcome Study**

Note: Waiver of this Informed Consent is necessary and required for this study.

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**Statement of Patient's
Voluntary Informed Consent
for Concurrent Hemodynamic Study**

Note: Waiver of this Informed Consent is necessary and required for this study.

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CDRH SUBMISSION COVER SHEET

Date of Submission: October 23, 2002

FDA Document Number: G980125

COPY

Section A Type of Submission

<p>PMA</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p>PMA Supplement</p> <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<p>PDP</p> <input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<p>510(k)</p> <input type="checkbox"/> Original submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<p>Meeting</p> <input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
<p>IDE</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Supplement	<p>Humanitarian Device Exemption</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<p>Class II Exemption</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<p>Evaluation of Automatic Class III Designation</p> <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<p>Other Submission</p> <p>Describe submission.</p>

Section B Applicant or Sponsor

Company / Institution name: CPRx LLC	Establishment registration number: 3003477173
Division name (if applicable):	Phone number (include area code): (952) 947-9570
Street address: 7615 Golden Triangle Drive, Suite A	FAX number (include area code): (952) 942-8336
City: Eden Prairie	State / Province: MN 55344
Country: USA	
Contact name: Ms. Terry Provo	
Contact title: Director of Clinical Trials	Contact e-mail address: tprovo@resqcpr.com

Section C Submission correspondent (if different from above)

Company / Institution name:	Establishment registration number:
Division name (if applicable):	Phone number (include area code): ()
Street address:	FAX number (include area code): ()
City:	State / Province:
Country:	
Contact name:	
Contact title:	Contact e-mail address:

Section D1**Reason for Submission — PMA, PDP, or IDE**

- | | | |
|---|---|---|
| <input type="checkbox"/> New device
<input type="checkbox"/> Withdrawal
<input type="checkbox"/> Additional or expanded indications
<input type="checkbox"/> Licensing agreement

<input type="checkbox"/> Process change
<input type="checkbox"/> Manufacturing
<input type="checkbox"/> Sterilization
<input type="checkbox"/> Packaging
<input type="checkbox"/> Other (specify below)

<input type="checkbox"/> Response to FDA correspondence:
<input type="checkbox"/> Request for applicant hold
<input type="checkbox"/> Request for removal of applicant hold
<input type="checkbox"/> Request for extension
<input type="checkbox"/> Request to remove or add manufacturing site

<input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in design, component, or specification:
<input type="checkbox"/> Software
<input type="checkbox"/> Color Additive
<input type="checkbox"/> Material
<input type="checkbox"/> Specifications
<input type="checkbox"/> Other (specify below)

<input type="checkbox"/> Labeling change:
<input type="checkbox"/> Indications
<input type="checkbox"/> Instructions
<input type="checkbox"/> Performance Characteristics

<input type="checkbox"/> Shelf life
<input type="checkbox"/> Trade name
<input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Location change:
<input type="checkbox"/> Manufacturer
<input type="checkbox"/> Sterilizer
<input type="checkbox"/> Packager
<input type="checkbox"/> Distributor

<input type="checkbox"/> Report submission:
<input type="checkbox"/> Annual or periodic
<input type="checkbox"/> Post-approval study
<input type="checkbox"/> Adverse reaction
<input type="checkbox"/> Device defect
<input type="checkbox"/> Amendment

<input type="checkbox"/> Change in ownership
<input type="checkbox"/> Change in correspondent |
|---|---|---|

Section D2**Reason for Submission — IDE**

- | | | |
|---|--|---|
| <input type="checkbox"/> New device
<input type="checkbox"/> Addition of institution
<input type="checkbox"/> Expansion / extension of study
<input type="checkbox"/> IRB certification
<input type="checkbox"/> Request hearing
<input type="checkbox"/> Request waiver
<input type="checkbox"/> Termination of study
<input type="checkbox"/> Withdrawal of application
<input type="checkbox"/> Unanticipated adverse effect
<input type="checkbox"/> Notification of emergency use
<input type="checkbox"/> Compassionate use request
<input type="checkbox"/> Treatment IDE
<input type="checkbox"/> Continuing availability request

<input checked="" type="checkbox"/> Other reason (specify):
<i>Public Disclosure</i>
<i>Submission</i> | <input type="checkbox"/> Change in:
<input type="checkbox"/> Correspondent
<input type="checkbox"/> Design
<input type="checkbox"/> Informed consent
<input type="checkbox"/> Manufacturer
<input type="checkbox"/> Manufacturing process
<input type="checkbox"/> Protocol – feasibility
<input type="checkbox"/> Protocol – other
<input type="checkbox"/> Sponsor

<input type="checkbox"/> Report submission:
<input type="checkbox"/> Current investigator
<input type="checkbox"/> Annual progress
<input type="checkbox"/> Site waiver limit reached
<input type="checkbox"/> Final | <input type="checkbox"/> Response to FDA letter concerning:
<input type="checkbox"/> Conditional approval
<input type="checkbox"/> Deemed approved
<input type="checkbox"/> Deficient final report
<input type="checkbox"/> Deficient progress report
<input type="checkbox"/> Deficient investigator report
<input type="checkbox"/> Disapproval
<input type="checkbox"/> Request extension of time to respond to FDA
<input type="checkbox"/> Request meeting |
|---|--|---|

Section D3**Reason for Submission — 510(k)**

- | | | |
|--|--|--|
| <input type="checkbox"/> New device
<input type="checkbox"/> Additional or expanded indications
<input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in technology
<input type="checkbox"/> Change in design | <input type="checkbox"/> Change in materials
<input type="checkbox"/> Change in manufacturing process |
|--|--|--|

Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed.

Summary of, or statement concerning, safety and effectiveness data.
 510(k) summary attached
 510(k) statement

1	2	3	4
5	6	7	8

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information — Applicable to All Applications

Common or usual name or classification name:
 Impedance threshold valve

Trade or proprietary or model name	Model number
1 ResQValve	0900
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1 G980125	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: Laboratory testing Animal trials Human trials

Section G Product Classification — Applicable to All Applications

Product code	C.F.R. Section:	Device class: <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification panel: Not yet determined		

Indications (from labeling):
 The ResQValve is a single-use device intended for use during the performance of cardiopulmonary resuscitation (CPR) on adult patients in cardiac arrest.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number: G980125

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

Original
 Add Delete

FDA establishment registration number

Manufacturer Contract sterilizer
 Contract manufacturer Repackager / relabeler

Company / Institution name:

Establishment registration number:

Division name (if applicable):

Phone number (include area code):
()

Street address:

FAX number (include area code):
()

City:

State / Province:

Country:

Contact name:

Contact title:

Contact e-mail address:

Original
 Add Delete

FDA establishment registration number

Manufacturer Contract sterilizer
 Contract manufacturer Repackager / relabeler

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Contact title:

Contact e-mail address:

Original
 Add Delete

FDA establishment registration number

Manufacturer Contract sterilizer
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City:

State / Province:

Country:

Contact name:

Contact title:

Contact e-mail address: