

CORPORATE PROFILE

Founded in Minneapolis, Minnesota in 2015 by an experienced team that previously developed multiple novel resuscitation technologies currently in widespread clinical practice, AdvancedCPR Solutions™ is an early stage medical device firm focused on the development and commercialization of delivery mechanisms, methods and devices that support the practice of the ElevatedCPR™ method to potentially improve survival of cardiac arrest. The ElevatedCPR method is a broad, patent-protected and technologically-advanced technique for performing device-assisted head up CPR that incorporates raising the head, heart, and thorax in a multi-level elevation, in a controlled sequence, in conjunction with the best practice standards of resuscitation protocols. Preclinical studies have demonstrated a number of benefits associated with the ElevatedCPR method relative to intracranial pressure (ICP),^{1,2,3} cerebral perfusion pressure (CerPP),^{1,2,3,4,5,6,7} and coronary perfusion pressure (CorPP).^{2,3,4,5,6,7} The company's initial device, the EleGARD™ Patient Positioning System, is the only device that precisely and consistently elevates a patient's head and thorax from supine to multi-level positioning and could support the practice of the ElevatedCPR method⁸ in the pre-hospital and hospital settings.

The EleGARD™ Patient Positioning System is intended to assist in elevating the head and the thorax of a patient from a supine position into a multi-level elevated position with the head above the thorax and the thorax above the lower body and extremities, and may be used during various procedures, i.e., airway management, CPR, etc.

1 Debaty, *Resuscitation* 2015

2 Ryu, *Resuscitation* 2016

3 Moore, *Resuscitation* 2018

4 Kim, *Resuscitation*, 2017

5 Moore, *Circulation* 2018

6, Rojas, *NAEMSP* 2019

7 Frascone, *Gathering of Eagles* 2019

8 Scheppke, *Prehospital Emergency Care* 2020

ABOUT SUDDEN CARDIAC ARREST (SCA)

Sudden cardiac arrest, the abrupt loss of heart function that occurs when the heart's electrical system malfunctions, is a leading cause of death globally, claiming a life every 90 seconds and taking more lives annually than breast cancer, lung cancer and HIV/AIDs combined.⁹

In the US alone, there are approximately 356,000 out-of-hospital cardiac arrests (OHCA) annually, and another 357,900 in-hospital cardiac arrests (IHCA) in adults.^{9 10} Overall survival rates are dismal, with approximately eight percent of OHCA and 24 percent of IHCA¹¹ cardiac arrest patients surviving with neurological function intact.

Despite a number of standard of care updates to improve outcomes of cardiac arrest over the last 50 years, the survival rates are shockingly low. While we have begun to address SCA as a public health crisis with continued education about bystander CPR and the growing placement of automated external defibrillators (AEDs), there remains an unmet need to implement new technologies, bundles of care and protocols within the pre-hospital and hospital settings to improve the potential for survival. Preclinical evidence is growing that shows device-assisted head up CPR using the ElevatedCPR™ method could be an important part of this next-generation approach.

⁹ <https://www.hrsonline.org/Patient-Resources/Heart-Diseases-Disorders/Sudden-Cardiac-Arrest-SCA>

¹⁰ "Annual Incidence of Adult and Pediatric In-Hospital Cardiac Arrest in the United States". *Circulation: Cardiovascular Quality and Outcomes*, July 2019.

¹¹ American Heart Association Statistics, Update 2018

WHAT IS THE ELEVATEDCPR™ METHOD?

The ElevatedCPR method is a technologically-advanced technique for performing device-assisted head up CPR that incorporates raising the head, heart, and thorax in a multi-level elevation, in a controlled sequence, in conjunction with the best practice standards of resuscitation protocols. This positioning allows the body to drain venous blood from the brain while CPR is being performed; and the positioning of the patient, the speed at which the patient is elevated after initial supine CPR priming, and the height to which the head is elevated over the heart, and the heart over the lower part of the body, are all important elements of the ElevatedCPR method.^{12 13 14} The ElevatedCPR method is used in conjunction with best practices standards including active compression-decompression CPR (ACD-CPR) or mechanical CPR devices and an impedance threshold device (ITD) to help regulate intrathoracic pressure while CPR is being performed.

Preclinical studies exploring the ElevatedCPR method as part of this bundle of care have shown a strong potential to improve resuscitation and survival from sudden cardiac arrest.

^{12 15 16 17}

¹² Moore, *Circulation* 2018

¹³ Rojas, *NAEMSP* 2019

¹⁴ Frascione, *Gathering of Eagles* 2019

¹⁵ Debaty, *Resuscitation*, 2015

¹⁶ Ryu, *Resuscitation*, 2016

¹⁷ Schepke, *Prehospital Emergency Care* 2020

EVIDENCE-BASED BENEFITS OF THE ELEVATED CPR™ METHOD

The ElevatedCPR method is the first major CPR breakthrough in decades and may potentially offer a significant opportunity to improve the chances for survival of cardiac arrest when implemented with the proper bundle of devices.^{18 19 20 21 22 23 24 25}

Preclinical studies have demonstrated that the ElevatedCPR method when used with an ITD and ACD-CPR or mechanical CPR:

- doubled blood flow to and through the brain and other vital organs compared to today's best-of-class CPR techniques and devices;¹⁸
- significantly increased cerebral perfusion pressure to greater than 80 percent of normal and coronary perfusion pressure to greater than 70 percent of normal when two minutes of priming in the lowered position preceded slowly raising the head and thorax to the elevated positions over a two-minute period;^{19 20 21}
- immediately and significantly reduced intracranial pressure,^{19 22 23} mitigating the "brain concussion with every compression" seen in standard CPR. Conventional (head flat) CPR increases ICP, effectively causing a concussion with every compression.

Human cadaver studies with ACD-CPR with an ITD and with mechanical CPR devices with an ITD show physiologic results that are consistent with these preclinical animal studies.²⁴ In addition, first user evaluations show an achieved ROSC rate in PEA and Asystole patients of 43 percent when using this method compared to 30 percent with simple rapid head elevation.²⁵

Research into the many potential benefits of the ElevatedCPR method continues, with a number of publications and presentations scheduled for completion or in development.

¹⁸ Moore, *Resuscitation*, 2017

¹⁹ Moore, *Circulation* 2018

²⁰ Rojas NAEMSP 2019

²¹ Frascone, *Gathering of Eagles* 2019

²² Debaty, *Resuscitation* 2015

²³ Ryu, *Resuscitation* 2016

²⁴ Moore *Resuscitation* 2018

²⁵ Scheppke, *Prehospital Emergency Care* 2020

ORIGIN OF THE ELEVATEDCPR™ METHOD

In the early 2010's, Korean clinicians faced the challenge of extracting cardiac arrest victims from the small elevators pervasive in Asian apartment complexes, and determined that a change in patient positioning might provide a solution. The physicians were working with a patient stretcher that could be tilted to fit into the elevator without stopping CPR and recommended tilting the head of the patient down during extrication, based on a theory that blood draining from the lower trunk and legs from the force of gravity would increase blood flow to the heart and brain and produce better outcomes.

In 2014, Keith Lurie, MD, AdvancedCPR Solutions' founder and a globally-respected expert and researcher in resuscitation, and his team analyzed the impact of head down positioning on patient physiology and hemodynamics. Dr. Lurie and his team used their proven cardiac arrest animal model, monitoring systems and an automated CPR device with a tilt table that could tilt the entire body up or down. They first replicated the Korean recommendation for head down CPR and saw an immediate, profound and dangerous increase in intracranial pressure and a corresponding decrease in cerebral perfusion pressure – exactly the opposite of what was expected and needed.

The team decided to investigate what would happen if the patient were tilted the other direction – into a head up or elevated position. Surprisingly, the exact opposite of what was expected occurred – both the intracranial pressure fell and cerebral perfusion pressure increased by statistically significant levels.

Their research into head up positioning and controlled sequential elevation of the head, heart and thorax continued forward and is the basis for the ElevatedCPR method. Lurie and his team have published numerous scientific papers about the ElevatedCPR method and its potential benefits as an additional recommendation to address SCA.

PRODUCT SUMMARY – ELEGARD™ PATIENT POSITIONING SYSTEM

Preclinical studies have demonstrated that the ElevatedCPR™ method, using precise positioning in a multi-level elevation and a controlled elevation sequence along with the use of an impedance threshold device (ITD) and active compression-decompression CPR (ACD-CPR) or mechanical CPR dramatically enhances the potential outcomes of resuscitation.^{26 27 28} The positioning of the head, heart and thorax; the speed at which the head is elevated into position after initial supine CPR priming; and the height to which the head is elevated over the heart and the heart over the lower part of the body are all important elements to produce the most advantageous physiological response to the ElevatedCPR method.

The EleGARD Patient Positioning is the only device that precisely and consistently elevates a patient's head and thorax from supine to multi-level positioning and could support the practice of the ElevatedCPR.²⁹ It is intended to assist in elevating the head and the thorax of a patient from a supine position into a multi-level elevated position with the head above the thorax and the thorax above the lower body and extremities, and may be used during various procedures, i.e., airway management, CPR, etc.



The EleGARD System's multiple-patented design was developed to meet the stringent needs of first responders, emergency department, ICU, Cath Lab, OR and PACU personnel for dependability, precision and user-friendliness. The EleGARD launched in early 2019, and is being used in multiple sites across the US and is cleared for sale and use in EU countries.

²⁶ Moore, *Circulation* 2019

²⁷ Rojas, *NAEMSP* 2019

²⁸ Frascone, *Gathering of Eagles* 2019

²⁹ Scheppke, *Prehospital Emergency Care* 2020

MILESTONES

- 2015 - Founded as Minnesota Resuscitation Solutions.
- 2015 – EleGARD™ Patient Positioning System (formerly known as MRS 525) received clearance from US FDA under a 513(g) Regulatory Requirements Review as Class 1, 510(k) exempt device which allows for immediate marketing.
- 2017 - First patent issued by US PTO.
- 2017 - Company received \$225,000 grant from the National Institutes of Health Small Business Innovation Research (SBIR) Program.
- 2018 – Broad method patent issued by US PTO.
- 2018 – Design and development of first generation EleGARD System completed.
- 2018 – Global headquarters established in Edina, Minnesota.
- 2019 – EleGARD Patient Positioning System launched in first evaluation sites and achieved first revenue.
- 2019 – USPTO issued three additional broad method patents and two additional device patents.
- 2019 - ACS completed requirements to apply CE mark to EleGARD System, enabling clinical use and commercialization in European Union and other CE mark geographies.
- 2019 – ACS engaged MED Alliance International, LLC to handle logistical and fulfillment needs for EleGARD System.
- 2020 – First user evaluations show an achieved ROSC rate in PEA and Asystole patients of 43 percent when using EleGARD System compared to 30 percent with simple rapid head elevation.³⁰
- 2020 – ACS receives 510(k) clearance from the US FDA for updated indications for use of the EleGARD Patient Positioning System.

³⁰ Scheppke, *Prehospital Emergency Care* 2020

OFFICERS AND DIRECTORS

Phil Faris - Founder & CEO

A serial entrepreneur with over 35 years of successful CEO and board experience. He has led over 30 major novel medical product introductions in the pharma, med-tech, clinical informatics spaces. Currently Managing Director ProSavant International, LLC. Previously, Chairman, Flashback Technologies, Inc.; Executive Chairman, Innovative Trauma Care; CEO, President and Director Vidacare Corporation (sold to Teleflex); Lead Director Advanced Circulatory Systems, Inc. (sold to ZOLL Medical).

Keith Lurie, MD - Founder, Chief Medical Officer

A prolific inventor, successful entrepreneur, electro-physiologist and world-renowned expert in the resuscitation of patients suffering sudden cardiac arrest. Dr. Lurie founded Advanced Circulatory Systems, Inc. (ACSI) in 1997 to make perfusion on demand a standard of care. ACSI was sold to ZOLL Medical in January 2015. He is also Professor of Emergency Medicine at the University of Minnesota School of Medicine and director of a NIH funded research laboratory at Hennepin County Medical Center, Minneapolis MN.

Glen Robinson - Chief Financial Officer

A skilled financial executive with over 35 years' experience in corporate and public accounting and financial management. Currently Leader of Financial Management Practice, ProSavant International, LLC, Partner and CFO Regent Coach Line, LTD. Formerly VP Finance Innovative Trauma Care, Inc.

Philip Tetzlaff - Chief Technology Officer

Highly skilled medical technology executive with over 25 years' experience in product development, quality and operations management, with over 40 issued patents. Prior to joining AdvancedCPR he was Vice President R & D, Operations and Quality for TVA Medical (acquired by Becton Dickinson); Senior Director R & D for Arthrocare (acquired by Smith & Nephew); and Head of Development at Cardio-Optics (acquired by Olympus).

Kim Marie Macygin, MSN - VP Clinical Education

A Master's prepared registered nurse with over 20 years of clinical experience and over 10 years' experience as an educator for market leading and emerging technologies in pre-hospital, emergency, trauma and critical care medicine with Vidacare Corporation, Teleflex, Inc., Innovative Trauma Care, and Minnesota Resuscitation Solutions, LLC.

Lisa Owens – VP Marketing, Strategy and Communications

Nearly 30 years' experience in providing strategic public relations and marketing communication for high science, pharma, biotech and medical device firms in pre-hospital, emergency medicine, oncology, cardiology, nephrology, health IT and other sectors. She has a history of moving emerging novel technologies to global commercialization with success and efficiency. She has worked with a number of leading medical device firms including Vidacare Corporation, Advanced Circulatory Systems Inc / ZOLL Medical, Attune Medical and more.

David Benditt, MD, Director

A world-renowned electro-physiologist and Professor of Medicine at the University of Minnesota. He served as a director of Advanced Circulatory Systems, Inc. prior to its sale to ZOLL Medical, and served as a new product consultant to St. Jude Medical, 3M, Medtronic, Cardionet, Transoma, and Nanostim. He brings expertise in device development, clinical trial design and regulatory affairs.

Robert K. Eddy, Director

The former Chairman and President of Sherburne Tele Systems, Inc., Bob is an active philanthropist and entrepreneur and endowed the R.K. Eddy Endowed Chair in Cardiovascular Resuscitation at the medical school of his alma mater, the University of Minnesota, in 2013.

Barbara Gold, MD, Founder, Director

Executive Vice President of Medical Affairs and Professor of Anesthesiology of Minnesota Health (M-Health), Professor of Anesthesiology at the University of Minnesota. She is a founding member of AdvancedCPR Solutions and co-inventor of a number of important devices and methods to improve outcomes from cardiopulmonary resuscitation. Dr. Gold's special interests are focused on improving clinical performance and patient outcomes using systems-based approaches.