

# ADVANCEDCPR

## SOLUTIONS®

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August 29, 2022

Mark A. Lamphiear, MBA, NRP, CEMSO  
Chief  
Gaston County Emergency Medical Services  
615 Highland Street, PO Box 1475  
Gastonia NC 28053-1475

**RE: Sole Source Status of the  
EleGARD™ Patient Positioning System**

Dear Chief Lamphiear:

Melissa Bahr requested that I provide an updated sole source letter.

**Clinical Rationales:**

As you know from your meetings with Melissa Bahr and from the virtual visit to ACS' research lab in Minneapolis, the road from our discovery of the concept of "head up CPR" to the development of what is now being called neuro-protective CPR (NP-CPR) has taken >7 years of dedicated pre-clinical and clinical research, product development and an investment of millions of dollars – all aimed at materially improving the persistently terrible neurologically intact survival rates from out of hospital sudden cardiac arrest.

The EleGARD™ Patient Positioning System was developed in parallel with the evolving science and went through a number of major iterations to maximize the physiologic effect of precise reproducible sequential positioning of the patient during CPR across the wide spectrum of body shapes and sizes. *The current commercial EleGARD product is the only device that supports the elevation of the head and thorax in the precise sequence and*

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Edina, MN 55436

**office:** 763.259.3722

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*elevation speed required to deliver what is now being classified as "neuro-protective Head Up CPR" by leading clinicians.*

### **Intellectual Property Rationales:**

Both the method of NP-CPR and the EleGARD Patient Positioning System are currently covered by 19 issued patents and 100's of allowed claims. Additional US and foreign patents are pending examination by the respective patent granting bodies.

*The broad method and device coverages afforded by the issued and pending patents would require any manufacturer considering production of a competitive device to either seek a license from ACS or risk patent infringement. To date we know of no such companies.*

### **Interoperability with Gaston County's Equipment Rationales:**

Changing the position of the cardiac arrest patient from supine to the elevation of the thorax and head afforded by the use of the EleGARD System requires very high-quality chest compressions with active decompression and the use of a circulatory enhancing device called an Impedance Threshold Device or ITD. Gaston County EMS uses the LUCAS Automated Chest Compression System to provide mechanical chest compressions. The LUCAS device uses a suction cup to provide active chest decompression that, when used with an ITD, provides enhanced circulation. The EleGARD Patient Positioning System was designed to interoperate with the LUCAS device and incorporates the LUCAS backplate in each EleGARD device to facilitate rapid deployment of the LUCAS device during resuscitation. ACS has FDA 510(K) clearance for the use of the EleGARD device during manual CPR, manual CPR adjuncts, and CPR with the LUCAS Chest Compression System.

*No other product is available that is designed to interoperate with Gaston County EMS' existing equipment and/or has regulatory clearance to interoperate with Gaston County EMS' existing equipment.*

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## Clinical Support and Education Rationale:

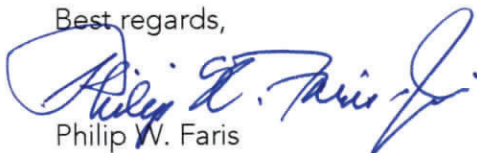
ACS discovered the effect of elevating the head and thorax in a controlled sequential manner during CPR in its quest to improve the decades long neurologically intact survival rate of less than 8% for out of hospital cardiac arrests. That discovery has been further refined and developed through years of pre-clinical research and, since mid 2019, clinical use in the US and Europe. That knowledge and experience is embodied in the company's commitment to assisting its customers understand the science and properly implement NP-CPR. ACS also offers participation in one of two IRB approved registry options to those customers wanting to track their performance after implementing NP-CPR with the EleGARD System. *No other vendor offers this base of value-added services.*

## Summary

The EleGARD Patient Positioning System is a sole source product available to Gaston County Emergency Medical Services through AdvancedCPR Solutions' exclusive fulfillment partner for the US, Med Alliance Group, Inc. (MAGI). Med Alliance is an ISO 13485 approved medical products distribution and manufacturing company and is an approved vendor to over 3000 health care customers in the United States. The actual purchase, when approved by Gaston County EMS will be with Med Alliance Group, Inc. Med Alliance ships the EleGARD products from its logistics facilities in Sycamore Illinois.

Please let me know if we need to supply any additional information to support the consideration by your City Council.

Best regards,



Philip W. Faris  
Chief Executive Officer

cc: Melissa Bahr

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