



STATE OF NEW YORK  
DEPARTMENT OF HEALTH

433 River Street, Suite 303 Troy, New York 12180-2299  
Antonio C. Novello, M.D., M.P.H., Dr. P.H.  
Commissioner

Dennis P. Whalen  
Executive Deputy Commissioner

May 19, 2003

Mr. Raymond W. Cohen, President & CEO  
Cardiac Science, Inc.  
1900 Main Street, Suite 700  
Irvine, CA 92614

Dear Mr. Cohen:

This letter is to advise Cardiac Science of the results of the State Emergency Medical Advisory Committee (SEMAC) meeting with regards to the Powerheart AED manufactured by your company and marketed to Public Access Defibrillation (PAD) programs and EMS services within the State of New York.

As we advised you previously, the main concern of the SEMAC and the Department is the Powerheart's capability of cardioverting Supraventricular Tachycardia (SVT). Current protocols for PAD programs in New York State do not include SVT but rather are aimed at treating ventricular fibrillation and ventricular tachycardia. In addition, the physicians who are members of the SEMAC, as well as the NYS EMS for Children Committee whose members include pediatricians, remain concerned that an AED be able to distinguish SVT from ventricular fibrillation or ventricular tachycardia and not shock the SVT when it is identified. This issue was accentuated during the development of SEMAC Advisory 02-02, allowing patients under the age of 8 and less than 55 pounds to be defibrillated with an AED in the prehospital EMS system. This was of even greater concern for use in PAD programs.

In addition, the SEMAC requests that the default setting for defibrillation for children be your protocol #5, which according to your literature was the protocol approved by the FDA for small children and infants.

After careful consideration and review of data provided by your company, the SEMAC voted on May 14<sup>th</sup>, 2003 to require the following:

1. All AED units sold within the State of New York for use in prehospital EMS systems and PAD programs, must **not** be capable of defibrillating/cardioverting an SVT rhythm at the time the AED is sold. This will require Cardiac Science to set the "default setting" for SVT to "off", so SVT can not be defibrillated/cardioverted. Currently, the only approved "shockable" rhythms are Ventricular Fibrillation and Pulseless Ventricular Tachycardia.
2. Cardiac Science must notify all EMS and PAD organizations that have previously purchased the Powerheart AED that the AED must be reset so that the SVT setting is set to "off". A

copy of this letter must be provided to this Department, Bureau of EMS.

3. Cardiac Science must notify entities owning a Powerheart AED, that the factory default setting for defibrillation protocols must be set to protocol number 5 (as provided through documentation from Cardiac Science), if the unit will be used on patients under the age of 8 or below 55 pounds in the prehospital EMS system or PAD organization. All units sold to prehospital EMS or PAD organizations must be factory set to protocol number 5.
4. Cardiac Science must notify entities purchasing their AEDs that all AED units purchased for use in the State of New York in an EMS program or Public Access Defibrillation (PAD) program, must follow New York State Basic Life Support Protocols for the implementation and use of an AED.

Physicians who oversee Emergency Medical Service and PAD programs do have the ability to change the factory default settings, if they so wish. However, EMS programs as well as PAD programs, must follow the NYS Basic Life Support Protocol with regards to the use of AEDs. The above requirements only affect EMS and PAD programs. They do not affect in-hospital use or use in non-EMS systems or PAD programs.

The Bureau of EMS has notified the NYS Education Department and the 18 NYS Regional EMS Councils of this SEMAC decision. We appreciate your compliance with the SEMAC's request that all Cardiac Science AEDs are configured and utilized in a manner consistent with NYS and Regional EMS protocols.

If you have any questions please contact me at (518) 402-0996, Ext. 4.

Sincerely,

Edward G. Wronski  
Director  
Bureau of Emergency Medical Services

cc: REMSCOS  
REMACS  
State Education  
Approved PAD State Ed programs