



HeartSine®

Inventor. Innovator. Lifesaver.

19th February 2013

FIELD SAFETY NOTICE

Advice regarding TRAINING, USE and MAINTENANCE, and MONITORING of ALL HEARTSINE AEDs

Dear Sir or Madam,

HeartSine Technologies has been requested by the Health Care Inspectorate, *Ministry of Health, Welfare and Sport*, The Netherlands, to issue this Field Safety Notice to all owners of HeartSine Technologies AEDs in the Netherlands. The purpose of this notice is to emphasize the importance of adherence to the recommendations contained in the user manuals supplied with the devices, relating to TRAINING, USE and MAINTENANCE, and MONITORING of all HeartSine AEDs.

The recommendations in the User Manual relating to these issues are as follows:

TRAINING: - HeartSine Technologies recommends that potential users of an AED are trained in cardiopulmonary resuscitation (CPR) and the use of an Automated External Defibrillator. It is recommended that this training be kept up to date by means of regular refresher courses as and when recommended by your training provider.

USE: - HeartSine Technologies AEDs are indicated for use on victims of sudden cardiac arrest who are exhibiting the following signs:

- a) Unconscious
- b) Not Breathing
- c) No life signs

HeartSine Technologies recommends that AEDs are stored in a wall case and in a safe visible location. The device should be kept in a convenient central location. Ideally it should be stored alongside other emergency equipment such as first-aid, CPR preparation kits or fire extinguishers etc. If possible the storage location should be located close to a telephone so that the user can call the emergency services and retrieve the AED without wasting time.

1. Make all necessary arrangements to ensure that the AED is easily accessible at all times.
2. The storage location should be clean and dry.
3. The storage location should ideally be maintained at room temperature. Do not select locations where the AED could be exposed to extreme temperatures even for a small period of time.
4. Where possible the AED should be stored with other appropriate CPR accessories such as: CPR mask, razor, scissors etc.
5. Ensure that the AED status indicator can be clearly seen
6. Inform all potential user of the location of the AED.

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MAINTENANCE: - HeartSine Technologies recommends that users perform regular maintenance checks. A suggested maintenance routine would be:

- a) Check the status indicator. If the status indicator is not flashing or flashing **RED**, a problem has been detected.
- b) Check the expiration date of the device (where appropriate) and/or accessories.
- c) Check supplies, accessories and spares for damage or expiration.
- d) Check the exterior of the AED for cracks or other signs of damage
- e) Check that the trained responders are aware of the AED's location and that it is accessible to those responders at all times
- f) Ensure that trained responders have up to date training for both CPR and AED use.

MONITORING: - HeartSine Technologies' AEDs are fitted with a status indicator. This is an indicator which will flash green approximately once every five seconds. When it is flashing green it is an indication that the AED is ready for use. If this indicator is flashing RED or not flashing at all, there is a problem with the device.

HeartSine Technologies' AEDs perform a weekly self-test at midnight (GMT) on Sunday. During this self-test period the status LED blinks red but returns to green on successful completion of the test. The self-test takes no more than 10 seconds to complete.


HeartSine Technologies recommend that users do not activate the AED on a regular basis to check its functionality as this will deplete the battery prematurely. Regular switching the device on and off is not necessary as the status indicator informs the user if there is a problem with the device.

HeartSine Technologies strongly recommends that all users of AEDs pay attention to the contents of this Field Safety Notice. Appropriate training, use, maintenance and monitoring of the device should ensure that it is fully operational when required in a Sudden Cardiac Arrest event.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where AEDs have been transferred.

Please maintain awareness on this notice and any resulting action(s)

Sincerely,


Declan O'Mahoney
President and CEO
HeartSine Technologies Ltd.

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