Medtronic

April 2007

FIELD SAFETY CORRECTIVE ACTION

LIFEPAK® 20 Defibrillator/Monitor

Dear Customer,

Physio-Control, Inc., a division of Medtronic Inc. is notifying customers that a limited number of LIFEPAK® 20 Defibrillator/Monitors with specific operating software can experience a "White Screen", lock-up condition when the machine is being powered on. This condition could cause a delay in the delivery of a defibrillating shock, possibly resulting in a failure to resuscitate a patient.
There has been one confirmed, customer occurrence duplicating this situation. There have been no confirmed occurrences during patient use.

Defibrillators with operating software version 48 or version 52 are susceptible to this "White Screen" issue. Only when attempting to power on the defibrillator, a timing error can occur causing the display to turn white, which prevents completion of the power-on sequence.
Turning the defibrillator power off and back on can restore normal operation.
Once the defibrillator is successfully powered on, there is no risk of a white screen lock-up condition.

We have identified 1.014 affected defibrillators worldwide. Our records indicate you own at least one of the identified LIFEPAK® 20 defibrillator/monitors (*See attached list that references the specific serial number affected for your location).*

Recommendation

- Turn the defibrillator power off and back on to restore normal operation in the event of a white screen condition.
- Routine defibrillator user tests will detect electrical or mechanical errors, such as this white screen lock-up condition.
- Keep the defibrillator in service.

A Physio-Control representative will contact you and make arrangements to provide a Free software upgrade to correct the issue.

Please assure all defibrillator users at your facility, including off-site users, are made aware of this correction immediately. If you have transferred this device to another facility, please forward a copy of this notice to them and notify us as soon as possible.

This device correction has been made with the knowledge of {Name of Authority}.

Medtronic is committed to ensuring our products meet the highest quality standards and that our customers are fully supported.

If you have any questions regarding this notification, please call Technical Support at {local contact phone number} or visit our website at www.Physio-Control-notices.com/LP20screen.

Sincerely,