URGENT FIELD SAFETY NOTICE

Physio-Control, LIFEPAK®9 and LIFEPAK 9P, Internal Paddles (PN: 802154-10 thru -19) **and Handles without Discharge Button** (PN: 800441-03 thru -06, 800441-36 thru-39)

Discontinuation of use

February 2009

Medtronic reference: FA424

Dear Customer,

Physio-Control, Inc. a division of Medtronic is notifying customers who have purchased Internal Defibrillation Paddles and Handles without discharge control (i.e., hands free internal paddles requiring a defibrillation adapter) for use with a LIFEPAK 9, or LIFEPAK 9P defibrillator/monitor. Recent retesting of sterilization methods can no longer support our existing guidelines listed below and require that we discontinue our recommendations for STERRAD® 100 and 100% Ethylene Oxide.

The LIFEPAK 9 / 9P internal handles without discharge control and associated specific internal paddles were first released in 1989 and discontinued from distribution in August 2008.

The dark grey internal electrodes (paddles) are metal with threaded ends and are various sizes. They are specifically designed for and twist into the white, plastic handles without discharge control that is hardwired to the LIFEPAK 9 therapy cable. Internal Electrode PN: 802154 / Handle assembly PN: 800441. Part numbers may not be evident if labels have been removed.

Existing guidelines recommend the following sterilization methods:

- STERRAD® 100
- 100% Ethylene Oxide (EO)
- 12/88 EO *(has since been phased out of the market by industry standards)*

We are instructing customers to discontinue use of these products and to remove them from service since there is no sterilization method that can be supported by current data. There have been no adverse events related to this issue.

A Medtronic Representative will contact you in order to confirm that all available products have been removed from use and to discuss replacement options.

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

Medtronic is communicating this information to the appropriate regulatory agency in your country.

If you have any questions, please call your local representative <insert local contact details>. We regret any inconvenience this action may cause.

Country Manager title & signature