

# *PACE* Medical, Inc.

September 14, 2012

## REF 4580 DEFIBRILLATION FIELD SAFETY NOTICE

Dear Pace Medical Customer:

This letter is to advise you that Pace Medical has observed in the REF 4580 that in a specific use of the device the defibrillation protection circuitry may not function as well as intended. If the device is used on a patient, with heart wires and the patient's heart is defibrillated directly on the heart, there may be a chance that the device will be damaged from the defibrillation output current. This has been observed in one device. Pace Medical has designed and validated a new defibrillation protection circuit which will eliminate the potential for this to occur.

### Description:

It has been reported to the Company that a User of the REF 4580 encountered the failure of a MOSFET, which can affect the output of the device, following defibrillation of the heart using paddles directly on the heart with a patient also having heart wires in place. Output was compromised on one channel of the device. Devices with this potential have been identified by serial number. You are receiving this letter because our information indicates that you have received a device(s) with this potential problem.

### Solution:

Pace Medical requests that you contact our office in England, APC Medical Ltd, telephone +44 1707 327641, and arrange to have your device(s) returned for retrofit. A simple hardware change eliminates the potential for this occurrence.

It is our recommendation that you promptly return your device(s) to the Company for a complimentary upgrade. **Pace Medical recommends that the device not be used in cardiac surgical theaters where heart wires are used and defibrillation is applied directly to the heart tissue.** You may use the REF 4580 in other procedures while scheduling your return to our facility, it is also recommended that patients are monitored while the device is in use and that a backup device is on hand.

If you have any questions, please contact your local Distributor or APC Medical directly.

Pace Medical and APC Medical regret any inconvenience this may have caused you and your hospital; however it is our intention to service your pacemaker and correct this issue as quickly as possible.

Sincerely,



Steven E. Hanson  
President & CEO  
Pace Medical, Inc.