

September 3, 2015

Dear Parks Medical Electronics Incorporated (PMEI) Customers,

PMEI devices are registered as "Class II" devices by the Food and Drug Administration (FDA). Their proper use presents minimal risk to patients. Our Class II devices are non-invasive diagnostic equipment and are not to be used subcutaneously (under the skin).

The use of PMEI equipment subcutaneously is contraindicated and presents an intolerable risk of patient infection.

In the coming months PMEI will be reviewing its labeling with the intent of strengthening this contraindication language where necessary.

Please consider this information when determining your diagnostic equipment needs.

Sincerely,

PMEI