

August 23, 2000

Prizm Medical  
3400 Corporate Way, Suite I  
Duluth, Georgia 30096

Attention: Jim 

Dear Jim:

It is my pleasure to write this letter to you in support of your excellent electrical stimulation product. As you know, I was formerly tenured associate professor in the Department of Orthopedics at the University of Texas Health Science Center in San Antonio, where I devoted both my clinical and research efforts to high-risk diabetic patients with lower extremity complications. The research group at the University of Texas during my tenure as the director of research was probably the single most published group regarding diabetic foot complications in the United States. In the past two years, I have been the medical director of a diabetes disease management company in Texas called Diabetex.

In both professional settings, I have had the opportunity to use electrical stimulation for neuromuscular pathology and to facilitate wound healing. At the University, we conducted three studies to evaluate the effectiveness of your product to treat patients with painful diabetic neuropathy, to evaluate the improvement in peripheral blood flow as a result of using electrical stimulation, and to evaluate the effectiveness of electrical stimulation to enhance wound healing in patients with diabetic foot ulcers. As you know, perhaps the most dramatic clinical responses are from patients with severe, painful diabetic sensory neuropathy. Many of these patients have constant and severe burning in their feet. Most of them have gone through a myriad of narcotics, antidepressants, seizure medications, and analgesics without any improvement whatsoever. For many of these people, their life has been completely disrupted because of their severe and constant pain. They cannot sleep or function because the focus of their life is pain due to their neuropathy.

Motor neuropathy and motor wasting: Another very common clinical problem in patients with diabetes is motor neuropathy that contributes to wasting of the intrinsic muscles in the foot and hands. In the lower extremity, this contributes to instability of the muscles in the forefoot. The intrinsic muscle function is to stabilize the toes against the first metatarsophalangeal joints, and with muscle weakness and wasting, there is often subluxation and dislocation at the level of the metatarsophalangeal joints and subsequent clawing of the toes. This contributes to severe and progressive foot deformities. Subsequently, in the presence of neuropathy, these patients become extremely high-risk patients for ulceration and re-ulceration due to the combination of severe rigid foot deformities, peripheral sensory neuropathy, and motor neuropathy.

As you know, electrical stimulation has been shown to be effective for this specific type of pathology. Your design makes the application and delivery of electrical stimulation practical for patients to do at home without the added cost of home health care.

The emerging data on electrical stimulation and wound healing I believe will be

dramatic. Several studies are pending. Electrical stimulation has been shown to enhance perfusion in animal and human models. In my research, electrical stimulation was more effective than previous reports with Regranex and Dermagraft in a similar patient population. I believe that other studies that are nearing completion will demonstrate the same types of excellent outcomes. My frustration has been overcoming red tape to get your device to people that have a high risk of amputation. The basic technology has been used for many years. Physical therapists are paid to provide the services three times a week, but I cannot get a patient friendly device, such as the Prizm design, that could be used in the patient's home every day. How many electrical stimulation units would we have to pay for to equal the cost of an amputation, hospitalization and prosthetic limb?

Lawrence [REDACTED], DPM MPH  
Medical Director  
DIABETEX, diabetes disease management corporation