

Compatibility of Electrodes used
in Neuromuscular Electrical Stimulation
Therapy for the Treatment of Dysphagia

Testing and analysis performed by

Weddendorf Design, Inc.

14060 Valley Vista Drive- Huntsville AL 35803

Date of Publication: February 8, 2014

Purpose:

This document is to document the compatibility of eSwallow electrodes used in conjunction with VitalStim stimulator units, in the treatment of dysphagia.

Background:

From the beginning of eSwallow in January 2009 until the eSwallow stimulation unit received FDA 510k approval for use in dysphagia therapy, eSwallow sold electrodes to thousands of customers for use with VitalStim stimulation units. The electrodes were specifically designed to work with the VitalStim unit, and provide equal or superior therapy to the VitalStim electrodes, and served in this role for over two years. Of the thousands of patients treated, the only complaints were from a few users with VitalStim units that would occasionally fail to operate when amperage was increased over 10 milliamps. This was determined to be a fault with early versions of the VitalStim unit, which had an overly sensitive open circuit detection feature. Testing of an example unit revealed the fault condition was equally likely to occur with VitalStim electrodes as with eSwallow electrodes.

The eSwallow electrodes are designed to provide equivalent or lower impedance and superior dispersion to the VitalStim electrodes, as well as equal or better skin adhesion, as demonstrated in testing. See the reference documents: “Dispersion Testing” which shows this pictorially, and the tabulated impedance results in “Comparative Analysis of Electrodes used in Neuromuscular Electrical Stimulation for the Treatment of Dysphagia” for more data proving compatibility and superiority of the eSwallow electrodes. Also, see the document: “Electrical Stimulation for Swallowing: Satisfaction and Outcomes with eSWALLOW” by Susan Almon of Aegis Therapies, November 16, 2012, which addresses this topic directly.

Conclusions:

1. The eSwallow electrodes were designed to interchange with VitalStim electrodes on VitalStim stimulation units for the treatment of dysphasia.
2. Treatment specialists used the eSwallow electrodes with the VitalStim unit for treatment of dysphasia in thousands of cases over a two-year period.
3. Use of eSwallow electrodes produced similar treatment results to the VitalStim electrodes when used with either the eSwallow stimulator unit or the competing VitalStim stimulator unit.