**Title: A User Study of the Soniflow System for Nasal Congestion Relief**

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Sponsor: Sound Health Systems

## 1. STUDY PROTOCOL

### 1.1 Objectives
This study was designed to evaluate the safety and efficacy of the Soniflow System for the treatment of nasal congestion.

### 1.2 Study Design
This study is a prospective, single-center, interventional cohort study of acoustic resonance therapy (ART) for the treatment of nasal congestion using the Soniflow System. Subjects with nasal congestion as determined by the Total Nasal Symptom Score (TNSS) were consented and screened for study eligibility (score of 2 or 3 on the nasal congestion subdomain). Eligible subjects who consented to the study were mailed the device as well as provided a link to download the associated smartphone app. Subjects self-performed the treatment without assistance from the staff after reading the included instructions. The intervention consisted of two sequential 10-minute treatment sessions, with treatment time automatically tracked by the app. Subjects reported their baseline TNSS, including subscores for each of the 4 subdomains, prior to any intervention and immediately after each of the two 10-minute treatment sessions. In order to assess whether use of the product led to pain or discomfort, visual analog scales (VAS) for headache and facial pain were assessed at baseline and after each treatment session, with higher scores indicating increased symptom burden.

### 1.3 Study Endpoints
Safety and efficacy were evaluated by the following primary and secondary endpoints.
Primary Endpoints

- Safety as evidence by an assessment of serious acute serious adverse events potentially associated with device
- Effectiveness as defined by improvement in nasal symptoms using the TNSS after one 10 minute treatment
- Use-ability for self-treatment

Secondary Endpoints

- Visual Analog Scale (VAS) for Headache
- Visual Analog Scale (VAS) for Facial Pain
- Percent of subjects requiring additional treatment and their subsequent change in TNSS

## 2. STATISTICAL PLAN
Descriptive statistics and graphical summaries were used to summarize the data. For categorical variables, counts and percentages were calculated. For continuous variables, means, standard deviations or standard error were calculated. Changes in symptom scores and nasal congestion from baseline were evaluated using a paired t-test examining the distribution of within-patient changes from baseline to each of the two post-treatment intervals. A clinically meaningful change in TNSS from baseline was defined as the minimal clinically important difference (MCID) identified using anchor-based methods in allergic rhinitis, with a value of 0.28.