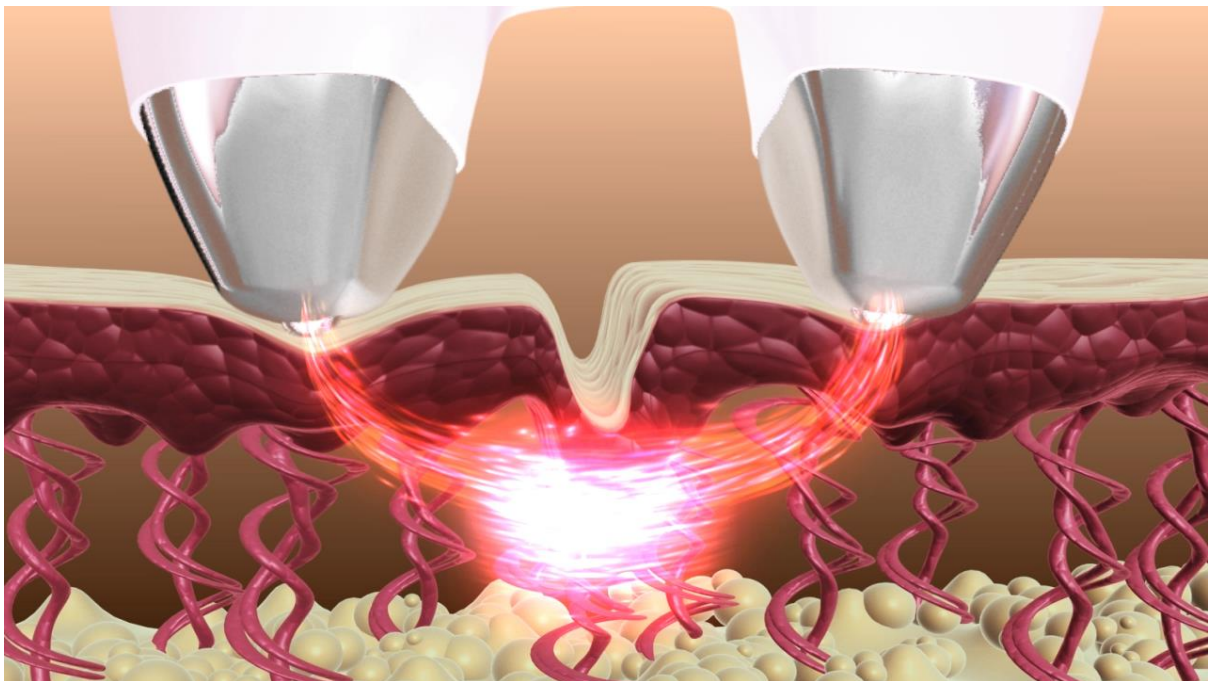


# SENSICA

## Sensilift Safety and Effectiveness Study



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# 1 Scope

The document herein presented summarizes the clinical study of the Sensilift device for marketing needs. The purpose of the study was to assess the safety and effectiveness of the Sensilift, when used by naïve lay users in their homes and to establish the most optimal treatment protocol.

## 2 Applicable Documents

Document #	Revision	Document Name
RD 11086	Latest Approved	Sensilift Safety and Efficacy Study Protocol
RD 11112	Latest Approved	Sensilift Safety and Efficacy Study- a five months report

## 3 Acronyms

3.1 *FU* – Follow Up

3.2 *PI* – Principle Investigator

3.3 *RF* – Radio Frequency

## **4 "Sensilift" Safety and Effectiveness Study – white paper**

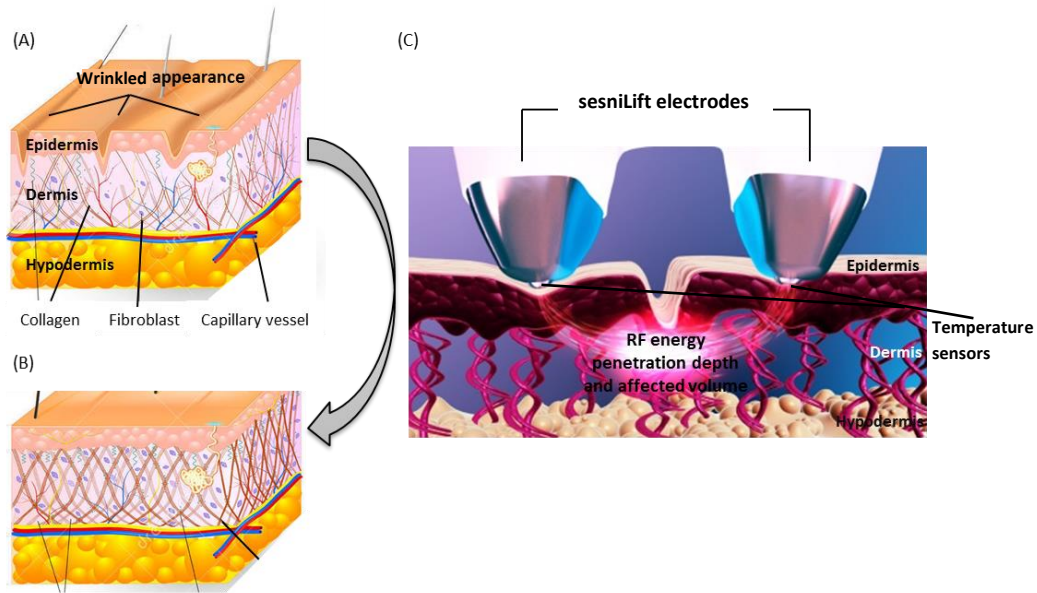
### **4.1 Introduction**

Skin aging, as manifested by rhytides, wrinkles, elastosis (yellow and thick appearance), skin laxity and sagging, occur chronologically. Such intrinsic aging, is related to both time and genetics, and is enhanced by environmental factors, such as sun exposure and smoking. The additive result is dermal damage due to reduction in collagen quantity and quality.<sup>1</sup> Skin rejuvenation treatments are gaining popularity, with a constant quest for anti-aging treatments which will be with high safety and efficacy, allowing self-use at home.<sup>2</sup>

One of the most advanced and well established technologies for non-invasive skin rejuvenation existing today is Radio-Frequency (RF).<sup>3,4</sup> RF is a form of electromagnetic energy that enables efficient biological tissue heating, in a local and safe manner, and therefore is widely used in medicine. The thermal effect, produced by RF energy, is commonly termed selective electrothermolysis, due to its local nature.<sup>2,3</sup> RF thermal stimulation of the dermal layer, while sparing the epidermis from ablation, leads to immediate contraction of collagen fibers and later on to their de-novo synthesis, known also as neo-collagenesis, as well as enhanced synthesis of elastin fibers and other components of the extracellular matrix. Altogether, the RF induced process enhances young, firm and less wrinkled appearance of the skin.<sup>2-4</sup>

### **4.2 Sensilift device**

The Sensilift device features Sensica's proprietary Dynamic RF™ technology. Dynamic RF™ is a combination of facial massage and bipolar RF (frequency of 1MHz). The unique moving electrodes of the Sensilift enable RF energy to reach wide range of skin layers simultaneously, while enjoying the benefits of a gentle massage, leading to a more intense and effective treatment. Sensilift has 3 RF energy levels and 2 massage speed levels that are selected by the user, according to their personal comfort and tolerance. Optimal results can be achieved with all energy levels, since the effective treatment temperature of 40°C/ 104°F will be achieved for all levels. Furthermore, Sensilift is equipped with two safety mechanisms. First, two redundant real-time temperature sensors that deactivate the RF when skin temperature reaches 40°C/104°F (Figure 1) and RF delivery is re-activated when skin temperature is lowered to 39.5°C/103.1°F. Second, skin contact sensors ensure RF is delivered only when the electrodes are in full skin contact. In addition, the movement function of the electrodes serves as additional layer of safety, preventing local overheating in case if the user does not move the device by herself, as directed in the instructions for use.



**Figure 1. Schematic illustration of Sensilift device contribution for wrinkles treatment.** (A) Low quality and quantity of collagen fibers, results in wrinkled appearance of the epidermis layer. (B) After collagen remodeling and neo-collagenesis induced by the Sensilift Dynamic RF™ technology, the wrinkled appearance is flattened. (C) The Sensilift device's RF penetration into the dermal layers. The Dynamic RF™ electrodes are equipped with temperature sensors, preventing overheating and enabling safe treatment.

### 4.3 Study design

Safety and effectiveness of the Sensilift device, for the non-invasive treatment of facial wrinkles and rhytides, were assessed in 37 women (40-64 years old). All participants were enrolled to the study (approved by the local ethics committee), by the Principle Investigator (PI), after signing an informed consent. Participants treated 2-3 facial areas, according to the standard instructions for use; once a week for 8 weeks, 5 minutes per treatment area, after application of a thin layer of the Base Gel on a clean and dry skin.

Clinical safety was assessed by monitoring adverse events during and after treatments, when success criterion was defined as no severe adverse events occurrence. Clinical effectiveness was assessed both objectively, by independent and blinded board-certified dermatologists and plastic surgeons (also referred to as "reviewers") and subjectively, by the participants themselves. Objective assessment of wrinkles and elastosis appearance was according to the widely used and validated Fitzpatrick Wrinkles Severity Scale.<sup>5</sup> Improvement was defined as decrease of at least one score in the Scale, and success criteria were predefined as improvement in at least 85% of participants as agreed by at least 2 of the 3 independent and blinded reviewers. This assessment was conducted using standardized photographs taken at baseline (pretreatment, T0) and at the end of the active treatment regimen (T8, after 8 Sensilift treatments), 1 and 3 months after the last treatment (follow-up period FU1 and FU2,

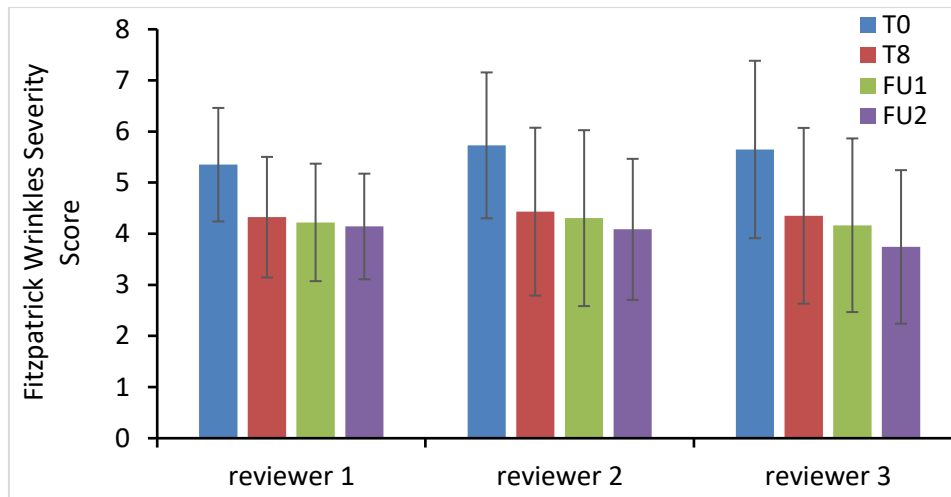
respectively). In addition, the participants answered a satisfaction questionnaire, including treatment effectiveness, safety, ergonomics and general impression (subjective assessment).

#### **4.4 Results**

After the completion of the active treatment regimen (8 treatments), 89%, 95% and 95% of the study participants (as assessed by 3 reviewers, respectively) have shown improvement in overall facial wrinkles appearance, with 97% of the participants showing improvement according to agreement of at least 2 out of the 3 reviewers. The average decrease of wrinkles was  $1.21 \pm 0.15$  in the Fitzpatrick Wrinkles Severity Scale (Figure 2). At the end of the Follow-up regimen, 3 months after the last treatment, the reviewers had detected in 97-100% of the participants a decrease in wrinkles (average decrease of  $1.5 \pm 0.33$  in the Fitzpatrick Wrinkles Severity Scale) (Figure 2).

Moreover, an improvement in skin elastosis has been assessed and detected by the PI (live) and 2 additional independent reviewers (from photographs), with 89%, 94% and 100% of the study participants showing at least 1 score decrease in elastosis, according to agreement between at least 2 out of the 3 reviewers, at T8, FU1 and FU2, respectively (with an average decrease of  $1.76 \pm 0.17$  in the Fitzpatrick Wrinkles Severity Scale). Importantly, worsening in the degree of wrinkling and elastosis never occurred during neither the active treatment nor the follow-up period.

The safety profile of the Sensilift device was demonstrated in this study. No severe or unexpected adverse events occurred during and after the study, meaning that the success criterion for safety was met. Only 3 minor, transient and local side effects, as described in the user manual, occurred (local and transient skin sensitivity and redness).



**Figure 2. Fitzpatrick Wrinkles Severity Score as assessed by 3 independent reviewers before the treatment (T0), after the last treatment (T8), and at the 1 and 3 months follow-ups (FU1 and FU2, respectively) after the last active treatment.** Error bars represent standard deviation. All results are statistically significant ( $p < 1E-11$ ), as tested per reviewer- comparison between baseline (T0) to each follow up (T8/FU1/FU2), using paired two-tailed *t*-test.

Photographic examples of improvement in facial skin's appearance and wrinkles, are shown in Figures 3-5.



**Figure 3. Wrinkles reduction and overall improvement in facial skin after 8 treatments with Sensilift was sustained and further improved during follow-up period.** 46 year old participant that treated the perioral, periorbital and between the eyebrows (frown lines) areas. (A) Represents the baseline photograph (T0). In (B-D) images obtained after 8 treatments (T8), 1 month post 8<sup>th</sup> treatment (FU1) and 3 months post last treatment (FU2), respectively, are shown. Blue arrows mark the area with the most prominent improvement. Note that the frown lines became shallower (blue rectangular) and the face generally looks "lifted". Participant kept stable weight.



**Figure 4. Perioral Wrinkles reduction already after 4 treatments with the Sensilift and further improvement after 8 treatments.** 47 year old participant that treated the perioral and periorbital areas. (A) Represents the baseline photograph (T0). In (B, C) images obtained after 4 treatments (T4) and after 8 treatments (T8), respectively, are shown.



**Figure 5. Periorbital texture and wrinkles improvement after 8 Sensilift treatments.** In (A) and (B) a 44 year old participant is shown at baseline (T0) and after 8 treatments (T8), respectively. Participant had significant improvement in the periorbital area, as marked by the red circles.

All the participants were highly satisfied with the device at the end of the study and stated that they would recommend the device to a friend or relative. 89% reported on improvement in their skin's appearance and 91% noticed an improvement in the texture of their facial skin. 100% of the participants found the Sensilift easy to use and 97% declared that the treatment is comfortable. Importantly, the level of pain and discomfort felt by the users during treatments was very low to almost non-existing at all. The general impression of the participants was great and included statements such: "*I feel a very significant lifting effect, amazing!*", "*great decrease in wrinkles depth*", "*the treatment is very pleasant*", "*great to use before special events, since it has an amazing immediate effect*", "*I feel like the glow came back to my face*", and more. In addition, some participants have noticed that their facial skin has a more even complexion and decreased pigmentation in the areas that were treated.

To summarize, improvement in facial skin's appearance and wrinkles was stable and even further improved at the long-term follow-ups (as measured at 1 and 3 months post last treatment), demonstrating that the Sensilift is both safe and effective for its intended use of at-home aesthetic treatment.



## 4.5 Discussion & Conclusions

The Sensilift home-use device, was found to be both safe and effective, when treatments are performed independently by the users in a home setting according to instructions for use.

According to objective evaluation (by board-certified physicians), improvement in the aesthetic outcome was detected in almost all the participants by all the reviewers after treatments. The results of wrinkles and elastosis reduction gradually improved during the treatment regimen and even 3 months after completion of treatments, during the follow-up regimen. A possible explanation to the continued improvement without additional active treatments is the long-term effect of the RF treatments. RF is known to induce collagen remodeling process as well as later neo-collagenesis (production of new collagen). The heat produced by the RF waves in the dermis, causes denaturation of collagen triple helixes, leading to collagen shrinkage, thus creating immediate response of skin tightening. As a longer term effect it is believed to influence the fibroblasts to synthesize new collagen and elastin, which leads to continuation of improvement of skin tightening and dermal thickening after treatment.<sup>2-4</sup>

In addition, the high satisfaction and positive self-assessment results all indicate that treatments with the Sensilift are perceived as effective by the naïve lay users, which is of very high importance in the field of aesthetics and beauty treatments.

To conclude, the Sensilift device is both safe and effective for wrinkles reduction and for general facial skin appearance improvement, offering painless and comfortable treatment at home.

## 4.6 References

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