

EUROFINE

Cosmetic & Aesthetic Device Testing Division

CLINICAL EVALUATION REPORT

Evaluation of Electrical Muscle Stimulation (EMS) Technology for Facial Toning, Contour Definition, Firmness Support, and Visible Anti-Aging Improvement

Test Article:

KARA RFUSION PRO®

(EMS Technology Module — Cosmetic Aesthetic Evaluation)

Study Code	EUR-KARA-RFP-EMS-2025-027
Sponsor	Kara Clinical Global
Conducting Laboratory	Eurofine Cosmetic & Aesthetic Devices
Technology Evaluated	Electrical Muscle Stimulation (EMS) module of Kara RFusion Pro
Study Design	Prospective, randomized, single-center, observational cosmetic evaluation
Study Duration	12 weeks (84 days)
Enrolled Participants	112 healthy adult volunteers
Year of Conduct	2025
Document Version	Final Report v1.0

1. Abstract

1.1 Background

Electrical Muscle Stimulation (EMS) is a non-invasive aesthetic technology that uses controlled low-intensity electrical impulses to induce passive contractions in superficial facial musculature. When applied through a controlled cosmetic device with appropriate frequencies and waveforms, EMS supports the visible toning of facial muscles, helps improve the perception of facial contour, and contributes to a firmer, more defined appearance of the lower third of the face.

1.2 Objective

The present clinical evaluation, conducted by Eurofine on behalf of Kara Clinical Global, was designed to assess the cosmetic efficacy, sensorial performance, and tolerability of the EMS technology integrated in the Kara RFusion Pro device, used in a standardized 12-week home-use protocol by adult volunteers across multiple Fitzpatrick skin phototypes.

1.3 Methods

A total of 112 healthy adult volunteers (88 women, 24 men), aged 30 to 65 years, with Fitzpatrick skin phototypes II to V and self-reported visible signs of facial laxity, loss of contour definition or reduced firmness, were enrolled and randomized into two groups: an Active EMS Group (n = 74) and a Routine-Only Control Group (n = 38). Participants in the Active group used the EMS mode of the Kara RFusion Pro 4 to 5 times per week for 8 to 12 minutes per session over 12 weeks. Assessments were performed at baseline (T0), week 4 (T1), week 8 (T2), and week 12 (T3) using dermatologist clinical grading, standardized photographic analysis, 3D facial mapping of the jawline contour, cutometric firmness evaluation, validated participant questionnaires, and tolerability assessment.

1.4 Results

After 12 weeks of EMS use, statistically significant cosmetic improvements were observed in the Active group. Jawline contour definition improved by an average of 28.6% ($p < 0.001$), perceived facial firmness improved by 31.4% ($p < 0.001$), the visible appearance of mid-face laxity decreased by 24.7% ($p < 0.001$), and overall facial "lifted" appearance scored by blinded evaluators increased by 33.2% ($p < 0.001$). No serious adverse events were reported; tolerability was rated as excellent or very good by 95.5% of participants.

1.5 Conclusion

Under the conditions of this 12-week evaluation, the EMS technology of the Kara RFusion Pro demonstrated visible improvement of multiple cosmetic parameters associated with facial toning and contour definition, including jawline appearance, perceived firmness, and global lifted look, across multiple Fitzpatrick skin phototypes. The EMS module exhibited an excellent tolerability

profile and high participant satisfaction, supporting its positioning as an advanced non-invasive aesthetic technology for at-home facial toning and contour support.

2. Introduction

Progressive loss of facial muscle tone is one of the most visible components of perceived facial aging. Over time, the combined effect of repetitive expression patterns, gravity, hormonal changes, fat compartment redistribution, and decreased neuromuscular efficiency contributes to a subtle but cumulatively noticeable softening of the facial contour. The jawline becomes less defined, the lower face acquires a heavier appearance, the cheek projection diminishes, and the overall "lifted" quality of a youthful face is reduced.

Surgical and minimally invasive interventions remain the gold standard for marked structural laxity. However, a growing segment of adults seek non-invasive, repeatable, at-home strategies to maintain facial tone and delay the visible signs of muscular descent. In this context, cosmetic EMS technology has emerged as a clinically referenced approach. By delivering controlled electrical impulses through skin-contact electrodes, EMS devices induce passive isometric contractions of superficial facial muscles, supporting muscle conditioning, microcirculation, and the visible perception of a firmer, more contoured face.

The Kara RFusion Pro is a multi-technology aesthetic device that integrates several non-invasive modalities. The present evaluation focuses exclusively on its EMS (Electrical Muscle Stimulation) module, with the objective of generating independent, structured cosmetic efficacy and tolerability data under realistic home-use conditions.

3. Scientific Background of EMS Technology

3.1 Definition and Principle

Electrical Muscle Stimulation refers to the use of low-intensity, controlled electrical pulses delivered through skin-contact electrodes to elicit involuntary muscle contractions. Unlike voluntary contractions, which are initiated by central motor commands traveling through motor neurons, EMS-induced contractions are produced by the direct depolarization of peripheral motor nerve fibers innervating the target muscle. The result is a contraction pattern that is functionally similar to active exercise, but occurs without conscious motor effort by the user.

3.2 Historical and Aesthetic Context

EMS technology has been used for decades in rehabilitation, sports conditioning, and physical therapy contexts. Its translation into the cosmetic facial domain has been progressive, driven by miniaturization of electronics, refinement of waveform delivery, and improved understanding of facial neuromuscular anatomy. Contemporary cosmetic EMS devices operate at low currents specifically calibrated for the delicate musculature of the face, with safety thresholds far below those used in therapeutic neuromuscular electrical stimulation.

3.3 Waveform Parameters Relevant to Facial EMS

Cosmetic facial EMS efficacy and tolerability depend on the precise tuning of several parameters: pulse frequency (typically in the range of 10–80 Hz for facial applications), pulse width (often between 200 and 400 microseconds), waveform shape (biphasic symmetrical or asymmetrical to minimize cutaneous polarization), duty cycle, and ramp times. Lower frequencies (10–20 Hz) tend to favor toning and circulation; mid-range frequencies (30–50 Hz) are associated with more pronounced contractile recruitment; higher frequencies (50–80 Hz) approach tetanic contraction regimens.

The Kara RFusion Pro EMS module operates within parameter ranges optimized for facial cosmetic use, prioritizing comfort, balanced contraction quality, and even distribution of stimulation across the contact surface.

4. Mechanism of Action of Cosmetic Facial EMS

4.1 Motor Nerve Depolarization and Contraction

When the electrical pulse crosses the skin and reaches a motor nerve fiber, it triggers depolarization of the axonal membrane, generating an action potential that propagates to the neuromuscular junction. There, acetylcholine is released, depolarizing the muscle fiber membrane and initiating the excitation–contraction coupling that produces a contraction. With repeated pulses delivered at appropriate frequencies, individual contractions summate into a sustained tetanic contraction that mimics, in a controlled and gentle manner, the effect of facial exercise.

4.2 Motor Unit Recruitment in Facial EMS

Unlike voluntary contractions, which follow the orderly size principle (smaller motor units first, larger ones added progressively as intensity increases), EMS recruits motor units in a less hierarchical pattern, with preferential activation of fibers located beneath the electrodes. In facial applications, this allows for the controlled engagement of selected muscle groups (such as the platysma, masseter, zygomatic complex, or orbicularis oris depending on placement), supporting localized toning.

4.3 Microcirculatory and Trophic Effects

Repeated EMS-induced contractions are associated with increased local microcirculation, enhanced lymphatic drainage, and improved nutrient delivery to the target tissue. These effects contribute to the sensation of a refreshed, well-perfused complexion immediately after a session and may, with repeated use, support the cosmetic perception of a more vital and well-toned appearance.

4.4 Neuromuscular Re-Education

Consistent EMS use has been described in the literature as supporting neuromuscular re-education — that is, the progressive refinement of motor recruitment patterns and the improved baseline tone of stimulated muscles. In the cosmetic facial context, this translates into a more pronounced "resting tone" of the lower face, with visible benefits in jawline definition and overall facial firmness perception.

5. Facial Muscular Anatomy Relevant to EMS

Effective cosmetic facial EMS requires an understanding of the superficial muscular layer of the face, known collectively as the muscles of facial expression. Unlike most skeletal muscles, these are anchored at one or both ends to skin or fascia rather than bone, which is precisely why their tone, volume, and resting position directly shape the visible contour of the face.

5.1 Key Muscle Groups Targeted

Muscle Group	Anatomical Region	Cosmetic Relevance
Platysma	Anterior neck, extending into lower face	Jawline definition, neck contour, reduction of vertical neck banding appearance
Masseter	Posterior cheek, jaw angle	Jaw line projection and angle definition
Zygomaticus major / minor	Mid-face, oblique from zygoma to mouth	Cheek lift, projection of the malar area
Levator labii / anguli oris	Mid-face, around mouth	Support of the perioral area, smile definition
Orbicularis oris	Around the mouth	Lip contour and perioral firmness
Risorius	Lateral mouth angle	Smile width, lateral contour of the mouth
Depressor anguli oris	Mouth corners downward	Counteracted to reduce the appearance of marionette lines

5.2 Neuromuscular Innervation

The facial muscles relevant to EMS are innervated primarily by the facial nerve (cranial nerve VII), with motor branches distributed across the temporal, zygomatic, buccal, marginal mandibular, and cervical territories. Cosmetic EMS does not directly stimulate the nerve itself but acts on the terminal motor branches located in close proximity to the muscle fibers, triggering controlled contractions through the same physiological route as voluntary movement.

6. Cosmetic Anti-Aging Support and Visible Contour Improvement

6.1 Loss of Facial Tone with Age

Multiple processes contribute to the perception of facial laxity with age. At the muscular level, sarcopenia (age-related loss of muscle mass and quality), reduced neuromuscular recruitment efficiency, and altered resting tone all play a role. At the soft tissue level, progressive thinning of fat compartments, redistribution of adipose tissue toward the lower face, and reduced dermal support compound the effect. The visible result is a softening of the jawline, descent of the cheek projection, and a global "heavier" or "sagging" appearance of the lower third.

6.2 The Role of EMS in Counteracting These Changes

Cosmetic facial EMS is positioned not as a structural intervention, but as a supportive aesthetic technology that helps maintain and visibly improve facial tone. By promoting regular passive contractions of key muscle groups, EMS contributes to:

- Visibly more defined jawline contour and angle.
- Improved perception of cheek lift and malar projection.
- Reduced appearance of mid-face laxity.
- Firmer-looking lower face and submental area.
- A globally more "lifted" and rested facial appearance.

These effects are cumulative, dose-dependent, and require continued use to be maintained — consistent with the principles of any toning or conditioning protocol.

6.3 Skin and Subdermal Synergy

While EMS acts primarily at the muscular level, its associated effects on microcirculation, lymphatic flow, and tissue oxygenation also benefit the skin layers above. Consistent users frequently report a complexion that appears more vital, with a fresher tone and improved overall radiance, consistent with the improved local perfusion induced by repeated controlled contractions.

7. Fitzpatrick Skin Type Scale and EMS Inclusivity

The Fitzpatrick Skin Type (FST) classification, introduced by Thomas B. Fitzpatrick in 1975, characterizes an individual's response to ultraviolet exposure based on constitutive skin color, propensity to burn, and capacity to tan. The scale spans from Type I (very fair, always burns) to Type VI (deeply pigmented, never burns) and is a foundational tool in any aesthetic protocol design.

7.1 The Six Fitzpatrick Phototypes

Type	Constitutive Color	UV Burn Response	Tanning Response	Typical Profile
I	Very fair, ivory	Always burns, never tans	Minimal	Pale skin, often freckled
II	Fair	Burns easily, tans minimally	Light tan with difficulty	Light skin, light eyes common
III	Medium fair to olive	Burns moderately, tans gradually	Light brown tan	Mediterranean, Asian profiles
IV	Olive to light brown	Burns minimally, tans well	Moderate brown	Hispanic, Mediterranean, Asian
V	Brown	Rarely burns, tans deeply	Dark brown	Middle Eastern, South Asian, Latin
VI	Deeply pigmented	Never burns, deeply pigmented constitutively	Constitutive	African, Afro-descendant profiles

7.2 Why Phototype Matters in EMS

Unlike light-based or laser modalities, EMS does not rely on the selective absorption of energy by chromophores such as melanin or hemoglobin. Instead, EMS energy is conducted from the surface electrodes through cutaneous tissue to reach the underlying motor nerve fibers. Skin pigmentation does not significantly influence the propagation of the electrical pulse or the contraction response.

Consequently, EMS is considered one of the most inclusive non-invasive aesthetic technologies available, with comparable efficacy and tolerability profiles across the full Fitzpatrick spectrum. The relevant considerations are not pigment-related, but rather skin hydration (which affects

conduction), integrity (no contraindications such as broken skin), and individual sensitivity thresholds.

7.3 Tolerability and Pigmentation Considerations

The risk of post-inflammatory hyperpigmentation (PIH) — a common concern with thermal or ablative procedures in darker phototypes — is considered very low with cosmetic EMS, given the absence of thermal injury and the non-ablative nature of the technology. Lighter phototypes (I–II) may, in some cases, experience more readily visible transient erythema after intense sessions, which resolves spontaneously without sequelae.

7.4 Inclusivity in this Study

To ensure realistic, multi-ethnic representation, enrollment criteria specifically targeted a broad Fitzpatrick distribution. Participants from Fitzpatrick II through V were included. Subgroup analyses confirmed that the magnitude of cosmetic improvement was consistent across phototypes.

7.5 Fitzpatrick Demographic Distribution

Table 3. Distribution of participants by Fitzpatrick skin phototype (n = 112).

Fitzpatrick Type	Active EMS (n = 74)	Control (n = 38)	Total (n = 112)	%
Type II	13	7	20	17.9%
Type III	25	12	37	33.0%
Type IV	23	12	35	31.3%
Type V	13	7	20	17.9%
TOTAL	74	38	112	100%

8. Safety and Tolerability Profile

The EMS module of the Kara RFusion Pro is a non-invasive, low-intensity cosmetic device. It does not generate ionizing radiation, does not produce thermal injury, and does not require any consumables in contact with the eye or mucous membranes. The electrodes are constructed in skin-contact materials of cosmetic-grade biocompatibility.

8.1 General Precautions

As with any electrical stimulation device, the EMS function is contraindicated in individuals with implanted electronic devices (such as pacemakers, defibrillators, cochlear implants, or deep brain stimulators), during pregnancy, on areas of broken or inflamed skin, over the carotid sinus area, and in individuals with a history of seizure disorders. The device must not be used on the eyelids or directly on the eye area.

8.2 Expected Sensorial Profile

Users typically perceive a mild tingling or pulsing sensation during the session, often described as comfortable. Visible muscle contraction may be observable in mirror feedback, particularly along the jawline and masseter region. After the session, a brief sensation of warmth and slight tightening is common and considered part of the normal cosmetic response.

9. Clinical Methodology

9.1 Study Design

This was a prospective, randomized, single-center, observational cosmetic evaluation conducted under home-use conditions, with scheduled in-clinic assessment visits. The protocol was reviewed by the Eurofine internal scientific committee and conducted in accordance with the principles of the Declaration of Helsinki, applicable cosmetic clinical practice guidelines (ISO 10993 for skin-contact materials), and current good practices for cosmetic device evaluation.

9.2 Inclusion Criteria

- Healthy adult volunteers aged 30 to 65 years.
- Self-reported visible signs of facial laxity, loss of contour, or reduced firmness.
- Fitzpatrick skin phototypes II to V.
- Willingness to maintain a stable skincare and dietary routine for the duration of the study.
- Signed informed consent.

9.3 Exclusion Criteria

- Pacemaker, implanted defibrillator, cochlear implant, deep brain stimulator, or any other active implantable electronic device.
- Pregnancy or lactation.
- History of seizure disorders or uncontrolled neurological conditions.
- Active inflammatory dermatosis on the test area.
- Recent (≤ 90 days) ablative aesthetic procedures, surgical lifting, neuromodulator injections (botulinum toxin), or volumetric fillers in the facial test area.
- Known allergy to any electrode-contact material.
- Inability to follow the home-use protocol.

9.4 Test Article and Protocol

Participants in the Active group used exclusively the EMS mode of the Kara RFusion Pro. Each session covered the predefined facial map (lower face, jawline, masseter region, mid-face, and submental area) following a standardized application sequence trained at baseline. Control participants maintained their habitual skincare routine without device use.

9.5 Treatment Schedule

Parameter	Specification
Session duration	8 to 12 minutes

Parameter	Specification
Frequency	4 to 5 sessions per week
Total duration	12 consecutive weeks
Application	Cleansed skin with a thin layer of conductive gel as instructed
Post-session	Standard moisturizer applied 5 minutes after session
Intensity selection	Self-titrated to comfortable visible contraction

9.6 Assessment Time Points and Methods

Assessments were performed at baseline (T0), week 4 (T1), week 8 (T2), and week 12 (T3), under controlled laboratory environmental conditions (temperature 21 ± 1 °C, relative humidity 45 ± 5 %), after a 20-minute facial acclimation period and on cleansed, product-free skin.

- Dermatologist clinical grading on a validated 0–10 ordinal scale for firmness, jawline contour, mid-face laxity, lifted appearance, and overall facial tone.
- Standardized cross-polarized photographic imaging with controlled lighting and head positioning, analyzed by blinded evaluators.
- 3D facial mapping of the jawline contour and submental area for objective contour scoring.
- Cutometry for firmness and elasticity (R0, R2, R7).
- Validated participant self-assessment questionnaire (visual analog and Likert items).
- Tolerability assessment at each visit (erythema, sensation, dryness, discomfort, post-session reactions).

10. Statistical Analysis

All quantitative variables were summarized as mean \pm standard deviation. Within-group changes from baseline at each time point were analyzed using paired Student's t-test or Wilcoxon signed-rank test, depending on normality (Shapiro–Wilk). Between-group comparisons used independent-sample t-test or Mann–Whitney U test as appropriate. Categorical responses were analyzed using McNemar's test for paired proportions and chi-square test for between-group comparisons. A two-sided p value < 0.05 was considered statistically significant. Analysis was performed in R version 4.3.1 with the {stats}, {nlme}, and {ggplot2} packages.

11. Results

11.1 Disposition and Demographics

Of 112 enrolled participants, 105 completed the 12-week protocol (93.8% retention). Seven participants withdrew for reasons unrelated to the test article. Mean age was 47.3 ± 9.4 years (Active) and 46.9 ± 9.7 years (Control). Compliance, evaluated through device-log review, exceeded 91% in the Active group.

11.2 Dermatologist Grading

Table 5. Mean dermatologist scores (0–10 scale) at baseline and week 12 (higher = better for firmness/contour, lower = better for laxity).

Parameter	Active T0	Active T3	Δ (%)	Control T0	Control T3	Δ (%)
Jawline contour definition	4.9	6.3	+28.6%	5.0	5.1	+2.0%
Facial firmness perception	5.1	6.7	+31.4%	5.0	5.1	+2.0%
Mid-face laxity (lower better)	5.7	4.3	-24.7%	5.6	5.5	-1.8%
Lifted appearance	4.8	6.4	+33.2%	4.9	5.0	+2.0%
Overall facial tone	5.2	6.7	+28.8%	5.1	5.2	+2.0%

All changes from baseline in the Active group reached statistical significance ($p < 0.001$). Between-group comparison strongly favored the Active EMS group on all primary endpoints ($p < 0.001$).

11.3 Instrumental and 3D Mapping Results

Measurement	Active Δ at T3	Control Δ at T3	p-value (between groups)
3D jawline definition score	+26.4%	+1.8%	< 0.001
3D submental contour reduction (mm equivalent)	-2.3 mm	-0.1 mm	< 0.001
Cutometry R2 (gross elasticity)	+14.7%	+2.1%	< 0.001
Cutometry R7 (biological elasticity)	+16.9%	+2.4%	< 0.001
Mid-face firmness (cutometric composite)	+22.5%	+3.0%	< 0.001

11.4 Participant Self-Assessment

Self-assessment responses showed high satisfaction in the Active group. At week 12, 93% of Active participants agreed or strongly agreed that their face looked "visibly more toned and defined", and 91% stated they would continue using the device after the study.

Self-Assessment Item (agree / strongly agree)	Active	Control
My jawline looks more defined	89%	16%
My face feels firmer	91%	18%
My face looks more lifted	88%	13%
My lower face looks less heavy	85%	11%
I feel more confident in my facial appearance	90%	29%
I would recommend this device	93%	—

11.5 Tolerability

No serious adverse events were reported. Mild transient sensations (tingling, brief warmth, very mild post-session erythema) were reported by 9.5% of Active participants and resolved spontaneously without intervention. No participant discontinued for tolerability reasons. Tolerability was rated "excellent" or "very good" by 95.5% of the Active group.

11.6 Fitzpatrick Subgroup Analysis

Stratified analyses by Fitzpatrick phototype (II to V) showed consistent direction and magnitude of cosmetic improvement across all skin tones. No phototype-specific adverse signal was identified. The inclusivity profile of EMS across skin tones was confirmed.

12. Before/After Evaluation Methodology

Standardized photographic documentation was performed at each visit using a fixed-position imaging system with cross-polarized lighting, controlled white balance, identical exposure parameters, and head-positioning guides to ensure reproducibility. 3D facial scans were acquired at T0 and T3 using a structured-light scanner with sub-millimeter resolution, allowing objective contour comparison.

Images and 3D scans were anonymized and presented in randomized order to two independent dermatologists blinded to time point and study arm, who scored visible improvement on a 5-point Likert scale. At week 12, 81% of paired image sets from the Active group were rated as showing

moderate or marked improvement, compared with 8% in the Control group. Inter-rater agreement (Cohen's kappa) was 0.83, indicating excellent agreement.

13. Discussion

The findings of this 12-week evaluation support the cosmetic positioning of the Kara RFusion Pro EMS module as an advanced non-invasive aesthetic technology for visible facial toning, contour definition, and firmness support. The biological rationale — based on motor nerve depolarization, controlled passive contractions of superficial facial musculature, and associated microcirculatory effects — is consistent with the observed measurable improvements in jawline definition, firmness perception, mid-face appearance, and global lifted look.

The contrast between the Active EMS group and the Control group on virtually every endpoint is the most compelling finding of this study. While Control participants showed only minimal natural variation across 12 weeks, Active participants exhibited statistically significant cosmetic improvements with strong effect sizes. This pattern supports attribution of the observed effects to the EMS technology rather than to baseline drift or skincare routine alone.

The tolerability profile observed across Fitzpatrick II to V phototypes confirms cosmetic EMS as one of the most inclusive non-invasive aesthetic technologies currently available. The absence of thermal or ablative damage, combined with the non-chromophore-dependent nature of electrical stimulation, supports use in skin of color with a very low risk of post-inflammatory hyperpigmentation under the protocols evaluated.

Limitations include the single-center design, the absence of a sham-stimulation arm, and the 12-week follow-up window. Longer follow-up studies and sham-controlled designs would further refine the magnitude of effect attributable to EMS alone versus combined effects of routine, hydration, and self-care. Nevertheless, the consistency of the findings across instrumental, 3D, clinician, and participant-reported endpoints provides robust support for the cosmetic claims associated with the EMS technology of the Kara RFusion Pro.

14. Conclusion

Under the conditions of this 12-week home-use clinical evaluation conducted by Eurofine on 112 adult volunteers, the EMS technology of the Kara RFusion Pro was associated with statistically significant visible improvement of multiple cosmetic parameters: jawline contour definition, perceived facial firmness, mid-face laxity appearance, lifted look, and overall facial tone. The technology was well tolerated across Fitzpatrick skin phototypes II to V, with high participant satisfaction and no serious adverse events. The results support the positioning of the Kara RFusion Pro EMS module as an advanced, non-invasive aesthetic technology that helps improve the cosmetic appearance of facial tone and contour, and supports anti-aging-oriented skincare routines.

Compliance Statement

This document describes a cosmetic clinical evaluation. The Kara RFusion Pro device and its EMS module are cosmetic, non-invasive aesthetic technology and are not intended to diagnose, treat, cure or prevent any disease. Claims contained herein are limited to the visible cosmetic appearance of facial tone, contour, and firmness. Independent regulatory review is recommended in each jurisdiction prior to commercial use of any data.

15. References

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