Evolution of Home-Use Focused Ultrasound Stimulation Technology

From Thermal Tissue Destruction to Precision Non-Thermal Biological Stimulation

For those 40–70, appearance isn't defined by skin alone. It's defined by firmness — around the eyes, jawline, neckline, and shoulders. That firmness lives in the fascia, often 4.5–10 mm or deeper beneath the skin.

These are also the most sensitive areas of the body. Reaching them safely has never been possible through a one-time clinical procedure — or through daily use at home. Until now.

The answer isn't more intensity. It's continuous, optimal-pressure stimulation — precisely sequenced across multiple depths, gentle enough for daily use, even in sensitive areas.

That's what builds real, cumulative change — not overnight, but week over week, in a way people can feel and trust.

Objective

To establish a safe, non-thermal ultrasound platform optimized for cumulative clinical benefit — enabling effective, repeatable stimulation even in anatomically sensitive regions where thermal (HIFU-based) devices cannot be used.

Core Technology Framework

The ten capabilities below build on one another rather than standing independently. A non-thermal operating principle (foundation) is what first makes it possible to hold pressure and duration together (1–2) — the specific combination that thermal designs cannot sustain. That stable, continuous operation is what then makes focusing accuracy and precision reproducible (3–4), which in turn support multi-depth, wide-coverage beamforming (5–6), verified safety and output consistency (7), and ultimately cumulative, superior, and site-inclusive clinical outcomes (8–10).

1. **Optimized Acoustic Pressure:** Deliver a safe and effective non-thermal stimulation level suitable for repeated daily use.
2. **Continuous Human Tissue Stimulation:** Sustain stimulation at that pressure long enough to induce cumulative biological response, rather than the brief, high-intensity pulses characteristic of thermal effects.
3. **Focusing Accuracy:** Achieve reliable focal placement at the intended tissue depth.
4. **Focusing Precision:** Maintain sub-millimeter focal consistency for reproducible stimulation.
5. **Sequential Multi-Focus Beamforming:** Electronically scan multiple focal depths to maximize tissue coverage.
6. **Extended Scanning Coverage:** Expand the effective treatment area while maintaining focal quality.
7. **Device Performance Verification:** Verify acoustic output and focusing performance for every production device.
8. **Weekly Cumulative Clinical Response:** Target progressive improvement over repeated daily treatments.
9. **Superior Clinical Performance:** Demonstrate clinically meaningful improvement versus conventional home-care devices.

10. **Targeted Benefits for Sensitive Regions:** Support lifting and wellness care of the eye area, jawline, neck, and other anatomically sensitive regions that thermal devices are restricted from treating.

Engineering Specifications and Supporting Evidence

Non-thermal operation is listed as a foundational reference point (SD-01); items 2–10 correspond directly to the numbered capabilities above.

Engineering Specification	Supporting Evidence	Ref.
Non-thermal acoustic stimulation (foundation)	KRISS acoustic measurement; FDA thermal-safety rationale	SD-01
Optimized acoustic pressure with continuous stimulation (0.5–3 s)	Biological response literature; production QC pressure-stability data	SD-02
≤1 mm depth resolution (focusing accuracy)	Beam simulation + KRISS measurement	SD-03
≤200 µm focusing precision	Hydrophone focus mapping	SD-04
≥4 sequential focal depths	Beamforming algorithm validation	SD-05
>500 µm lateral scanning coverage	Scan mapping	SD-06
<10% pressure variation across production units	Production QC report	SD-07
Progressive weekly clinical improvement	Clinical Study #1 & #2	SD-08
>2× clinical performance vs. conventional home-care devices	Comparative clinical data	SD-09
Sensitive-area (eye, jawline, neck) lifting benefit	Clinical report & before/after imaging	SD-10

Foundational Rationale: Why This Technology Is Necessary

This section lays out the reasoning chain behind the product, from the biological premise to the specific engineering choices it required. It is provided for technical and regulatory reviewers; supporting data referenced here is detailed in the Engineering Specifications and Evidence tables above.

1. Why Now: The Fascia Layer

The clinical relevance of the fascia layer to visible lifting and firmness outcomes has only recently become widely recognized. Fascia typically sits deeper than 4.5 mm, and focused ultrasound is effectively the only energy modality capable of reaching that depth with a controlled, safe dose. Because both the clinical interest in fascia and the use of focused ultrasound for this purpose are recent developments, established performance and safety standards for continuous, non-thermal fascia stimulation do not yet exist.

Prior research: the underlying principle — that low-intensity, non-thermal focused ultrasound can produce a measurable, reproducible physiological response comparable to acupuncture — was already established in the peer-reviewed literature over a decade ago [1]. That work also identified the limiting factor: existing transducer designs (single-depth focus, complex acoustic matching) could not be commercialized into a practical device. MUTi's program began from that gap — translating a validated biological principle into a manufacturable, reproducible semiconductor platform.

2. Why It Matters: The Hospital-to-Home Transition

Thermal coagulation-based fascia stimulation (HIFU) is tolerated in clinical settings because a trained provider manages the risk in real time. Moving the same principle into unsupervised, general-population home use removes that management layer, and creates four requirements that do not arise in a supervised clinical context:

11. **Safety at low, stable output:** The device itself — not a provider — must keep pressure within a safe, effective range at all times.
12. **Adaptability across users:** A clinician exchanges applicator tips (often 7 or more depth options) to match each patient's anatomy; an unsupervised home device must instead scan multiple focal depths electronically to reach the same range of users.
13. **Reproducible, cumulative feedback:** Without a clinician to interpret results, users must be able to observe consistent, predictable improvement over time to trust the treatment.
14. **Coverage of sensitive regions:** Regions with the greatest visible aging effect (eye area, jawline, neck) are also the regions thermal devices are labeled against; a home platform must be able to treat them safely.

3. Why It Hasn't Been Solved: The Thermal Trade-off

PZT (HIFU) and CMUT transducers require high drive voltage and present high electrical impedance, which generates heat under sustained operation. This forces an operating trade-off: output can be held low enough to avoid heat buildup, or it can be run continuously — but not both. As a result, these technologies are structurally limited to brief, high-intensity, intermittent pulses rather than continuous low-pressure stimulation, regardless of drive voltage. Simply lowering the drive voltage on such a device does not resolve this: at lower voltage, spatial, temporal, and pressure variation across elements and over time increases relative to the (now smaller) signal, producing inconsistent, unrepeatable stimulation rather than a safe continuous dose. MUTi's low-voltage (35V) pMUT architecture removes the impedance mismatch that causes this heat buildup in the first place, making continuous, low-variation operation possible by design rather than by turning power down on a high-voltage platform.

4. Why It Was Never Validated: Gaps in Clinical Testing Practice

Existing clinical testing conventions are not set up to demonstrate this kind of outcome. Cohorts large enough for standard statistical power are frequently restricted, by internal protocol, to a single instrument (e.g.,

Cutometer elasticity only); cohorts small enough to support multi-instrument, multi-site measurement (Cutometer, F-ray, Antera 3D) do not pool across studies. Industry practice otherwise splits into two tracks — cosmetic-grade efficacy claims (elasticity, brightening) or medical-grade safety review (e.g., 510(k), which is safety- rather than efficacy-focused) — with no established category for a cumulative, reproducible, multi-site lifting outcome. MUTi's clinical program was therefore designed from the ground up: repeated multi-instrument measurement across independent clinics and seasons, evaluating both quantitative (Cutometer, F-ray, Antera 3D) and qualitative (structured user-reported outcome) results together.

5. Why the Regulatory Landscape Hasn't Caught Up

Current regulation, measurement convention, and advertising practice are built around a binary: professional clinical treatment versus consumer cosmetic use. That binary predates a period in which precision, semiconductor-grade instruments are used daily, unsupervised, in the home. Home-use HIFU entered this gap not through a dedicated regulatory category built for it, but through manufacturing and distribution scale — reaching consumers faster than a new standard could be written for it. MUTi's position is the reverse: to propose the category and standard that this gap requires, rather than to scale into the gap ahead of one.

Evidence Summary

KRISS (Korea Research Institute of Standards and Science) verification: focusing pressure of ~944 kPa (~1 MPa) at 6 mm nominal depth (5.3 mm in tissue, after correcting for 0.7 mm gel thickness — close to average fascia depth), repeatable across measurement runs. Peak spatial-pulse-average intensity (Isppa) of 4 W/cm²; at a 20% duty cycle, spatial-peak temporal-average intensity (Ispta) of approximately 1 W/cm² — within the <3 W/cm² Ispta threshold referenced for continuous therapeutic ultrasound.

P&K Skin Research Center clinical results (2025 H2, two independent studies): linear, reproducible improvement across Week 0 / Week 2 / Week 4 measurement points, up to ~2× control (gel-only) across elasticity, lifting, and neck-firmness endpoints, replicated across separate clinics and seasons (390 data points total across the full clinical program). User-reported outcome scores averaged 4.2+ out of 5.0 with no response below 3.0, and no adverse skin reactions were reported during the study period.

Conclusion: *In a field this new, populated only by devices and testing conventions that do not produce reproducible, cumulative clinical data, that data could not previously be generated — not because no one attempted it, but because the underlying hardware and testing methodology required to produce it did not yet exist.*

PZT HIFU vs. cMUT Therapy vs. MUTi pMUT

cMUT narrows HIFU's focal precision through a MEMS process, but remains electrically constrained to high-voltage, high-impedance drive — which produces the same heat build-up that limits PZT HIFU to brief, high-intensity pulses. MUTi's low-voltage pMUT architecture removes that constraint, making continuous non-thermal operation and sensitive-area use possible.

Item	PZT HIFU	cMUT Therapy	MUTi pMUT
Technology Position	Thermal HIFU	HIFU-replacement research	Continuous non-thermal therapy platform
Operating Principle	High-intensity, intermittent pulses (thermal)	High-voltage MEMS transducer; research stage	Low-voltage, continuous, programmable stimulation
Beam Control	Fixed / limited	MEMS-based, still thermally constrained	Multi-depth digital beamforming
Sensitive-Area Use	Prohibited by device labeling (eye, jawline)	Prohibited — inherits HIFU's thermal constraint	Enabled — non-thermal, no labeling restriction
Home Use	Limited	Research stage	Designed for daily home use

Manufacturing Readiness

MUTi's pMUT chips are produced on SilTerra's 8-inch MEMS wafer line, a foundry with an established track record in high-volume pMUT manufacturing (fingerprint sensors). Across multiple production runs since 2022, yield has matured from early-stage instability to a stable, high-yield commercial process, without changes to the core design — refinements were limited to non-functional packaging elements. This distinguishes design risk (resolved from the outset) from manufacturing risk (matured through iterative production), and supports MUTi's cost structure at consumer-product scale, unlike research-oriented pMUT foundries.

References

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[2] KRISS (Korea Research Institute of Standards and Science). Water tank acoustic pressure verification of MUTi pMUT chip, 35V excitation.

[3] P&K Skin Research Center. Clinical efficacy studies of MUTi device (Studies 1 & 2, 2025), 390 data points, Cutometer/F-ray/Antera 3D measurements.

[4] Cho K, Kim B, Kim Y, Lee S, Song J. "cMUT Probe Cooling Design by Thermal Network." Samsung Advanced Institute of Technology. IEEE International Ultrasonics Symposium (IUS) 2012. doi:10.1109/ULTSYM.2012.0157

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[7] Kim B, Song J, Lee S, Cho K, Kim Y, Jeon T. "Volumetric Ultrasound Image-Forming Using Fully Controllable 2-D CMUT-on-ASIC Arrays." Samsung Advanced Institute of Technology, Medical System Lab.

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[10] Kim Y, Cho K, Kim B, Lee S, Jeon T, Song J. "2D Capacitive Micromachined Ultrasound Transducer Using Novel Tiling Based on Silicon Frame." Samsung Advanced Institute of Technology. Proc. SPIE 8675, 86750E (2013). doi:10.1117/12.2006140

Patents (inventor: Kyungil Cho, Samsung Electronics):

[11] US Patent 8,974,393 B2, "Ultrasonic Probe" (filed 2013, granted 2015) — heat spreader and dissipation module for an IC bonded to a cMUT.

[12] US Patent 10,660,612 B2, "Ultrasound Probe and Ultrasound Imaging Device" — cMUT tile configurations and 4x4 matrix array structures.

[13] US Patent 9,071,893 B2, "Multi-Array Ultrasonic Probe Apparatus and Method" — cMUT arrays bonded to the upper surface of application-specific integrated circuits.

[14] US Patent 10,292,680 B2, "Ultrasonic Probe and Manufacturing Method Thereof" (with Samsung Electronics and Kyungpook National University) — cMUT arrays bonded to ICs with flexible PCB integration.

[15] US Patent Application 2013/0341303 A1, "Jig, Manufacturing Method Thereof, and Flip Chip Bonding Method for cMUT" — structural manufacturing technique for thin cMUT films during flip-chip bonding.