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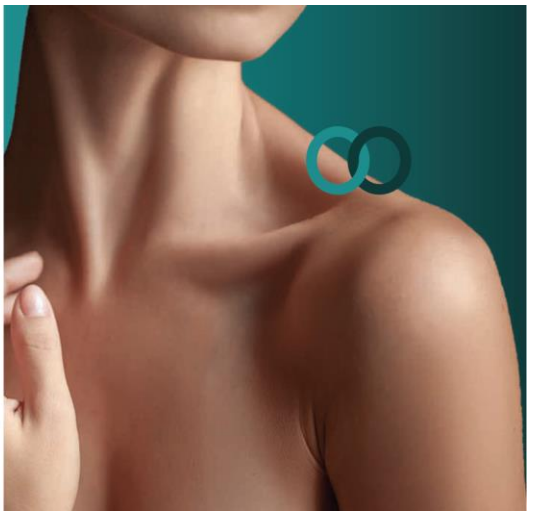
TOOsonix System ONE-M



Dermatology HIFU

The new modality in non-invasive skin treatment

Fact sheet

CE 0123

TOOsonix A/S
Agern Allé 1
DK-2970
Hoersholm
Denmark

info@toosonix.com
www.toosonix.com

TOOsonix System ONE-M is a medical device for healthcare professionals.
TOOsonix System ONE-M is currently not for sale or distribution outside the CE-regulated region.

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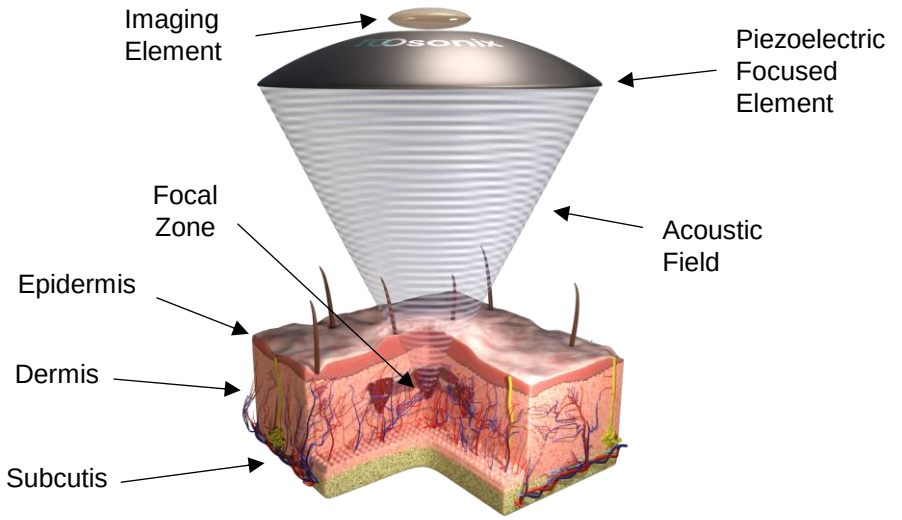
Safe skin treatment

HIFU

Non-invasive principle

Human skin therapy



System ONE-M is your new enabler for dermatologic therapy, where high-accuracy treatments with high efficacy and low pain-level are key to your treatment success.

It is a new and complementary method to, or a replacement of, lasers, PDT, cryosurgery, surgery and several topical treatments that all have high risks, low success rate and high pain levels for the patient.

How it works:

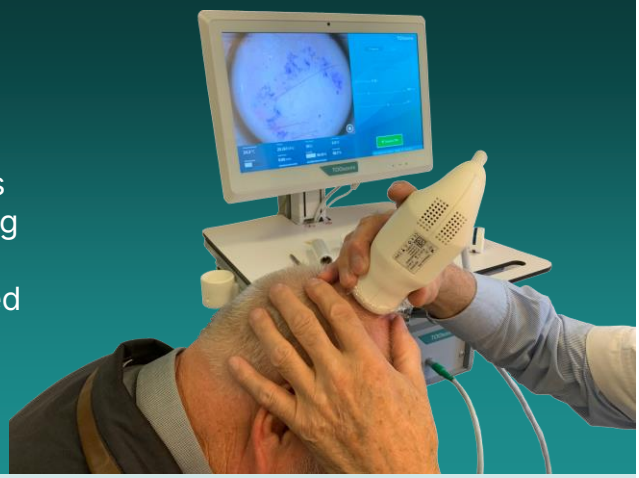
- Ultrasound is focused into a small confined point
  - A focal point is created inside the body without surgical methods
  - A momentary temperature increase forms locally within the focal point
- The local heating kills/activates cells
  - The body's immune system is activated
  - A process of cell-repair and renewal of affected cells is started
- The method is non-invasive and low pain-level
  - No need for anesthesia
  - No pre-treatment
  - No post-treatment

System ONE-M is operated with accurate real-time guidance of the area under treatment.
Activation of HIFU is done from a footswitch to secure maximum freedom and control for the operator.

Versatile skin treatment

Intended purpose

System ONE-M is intended for treatment of the human epidermis and dermis layers by administering high-intensity focused ultrasound (HIFU) doses to small and confined volumes in the human skin.



Intended conditions (Indication for use)

System ONE-M is indicated for medical and aesthetic dermatological therapy including, but not limited to, the following general categories:

Medical indications

- Basal cell carcinoma
- Actinic keratosis
- Vascular hemangiomas and tumors of the skin
- Cutaneous NF1 fibromas (cNF)
- Verruca vulgaris (common warts)
- Condylomata acuminata (genital warts)
- Cystic acne and acne comedones
- Seborrheic keratosis / Seborrheic warts
- Superficial telangiectasia (spider veins)
- Sebaceous hyperplasia
- Other benign epidermal and cutaneous neoplasms of the human skin (e.g. hidrocystoma, Fox Fordyce Disease, Birt-Hogg Dubé syndrome, epidermal inclusion cysts, etc.

Non-medical (aesthetic) conditions

- Vascular lesions (cherry spots and venous lakes)
- Small acrochordons (skin tags)
- Solar lentigines (liver spots)
- Fine-line wrinkles
- Removal of smaller tattoos and tattoos not responding to laser removal
- Other aesthetic HIFU treatments of the human skin

(see IFU for full details)

Contraindications

System ONE-M is contraindicated for ophthalmic use or any use causing the acoustic beam to pass into the bulb of the eye; use on subjects less than 18 years at the time of the start of the treatment; female patients who are pregnant, may be pregnant, or lactating; treatment of larger areas with a broken skin barrier, e.g. an open wound or similar; treatment areas located above or adjacent to (<5 cm) an implant (active or inactive); treatment of subjects with known blood coagulopathy or excessive bleeding; treatments of subjects with a known history of abnormal scar formation (e.g. keloids).

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Efficient skin treatment

Results

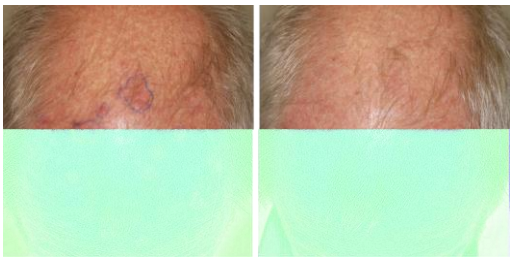
Before & After

Unique treatment efficacy

- Clinical treatments can typically be completed in a single session
- Areas of diameter 5 - 50 mm are treatable
- Skin response is mild without bruising, prolonged erythema/edema, or pain
- No pain or down-time after treatment

Basal Cell Carcinoma

Actinic Keratosis



Sebaceous Hyperplasia

Cherry Angioma

Congenital Hemangioma

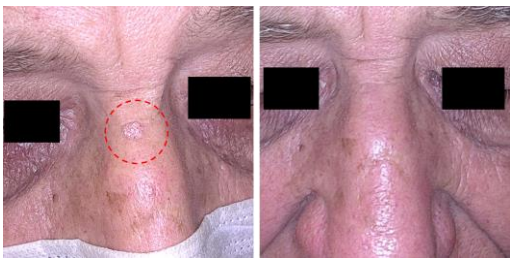
Laser-resistant Tattoos

Quick skin treatment

Results

Before & After

Verruca Vulgaris



Condylomata Acuminata

Cutaneous Neurofibroma

Fox Fordyce Disease

Seborrheic Keratosis

Apocrine Hidrocystoma

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Profitable skin treatment

Customers

Clinic revenue

Profit generation

Profit generation from day-one

Four handpieces can be chosen for System ONE-M to get you started with your regular treatments from day-one

Focal Point	Color Code	Handpiece Focal distance	Typical setting**	Key features (depending on settings and treatment type)	Treatment Examples
Superficial	Green	0.8 mm	150 ms* 0.6 - 0.9 J**	Ablative effect Quick healing	Solar Lentigines Seborrheic Keratosis Superficial Actinic Keratosis Shaded superficial tattoos
Upper dermis	Blue	1.3 mm	150 - 250 ms* 0.6 - 1.0 J**	Semi-ablative effect Wound crust formation at medium shot coverage	Cherry Angiomas Flat Verruca Vulgaris Lightly keratotic Actinic Keratosis Thin Basal Cell Carcinoma Tattoos
Middle Dermis	White	1.8 mm†	200 - 400 ms* 0.7 - 1.1 J**	Semi-ablative effect Wound crust formation at dense shot coverage	Mild Verruca Vulgaris Keratotic Actinic Keratosis Thick Basal Cell Carcinoma Deep and liner-needle tattoos
Deep Dermis	Yellow	2.3 mm†	250 - 500 ms* 0.7 - 1.2 J**	Non-ablative effect Typically no wound crust	Fine-line wrinkles Telangitasias Cutaneous fibromas Thick Basal Cell Carcinoma "Stacked treatments" for deep lesions

*Dose duration 150-200 ms gives a good initial compromise between mechanical and thermal effects. Longer dose duration time (at same energy) will produce smaller and more spherical lesion zones
**Recommended dose energy is for initial guidance only. Thicker and/or keratotic lesions require higher dose energy, while low dose energy can have sufficient clinical effect on thin soft lesions

† Non-ablative treatment without crust formation can be obtained at low dose energies, preferably using longer dose durations.
Increased risks of epidermal erosion are generated with increased dose energy and/or higher dose coverage, particularly in combination with shorter dose durations.

Note: All of the above information is for guidance only. Always make your own professional assessment of the treatment results and adjust focal depth, shot duration and shot power accordingly

"High frequency HIFU is the most versatile device for dermatology therapy brought to the market in decades.

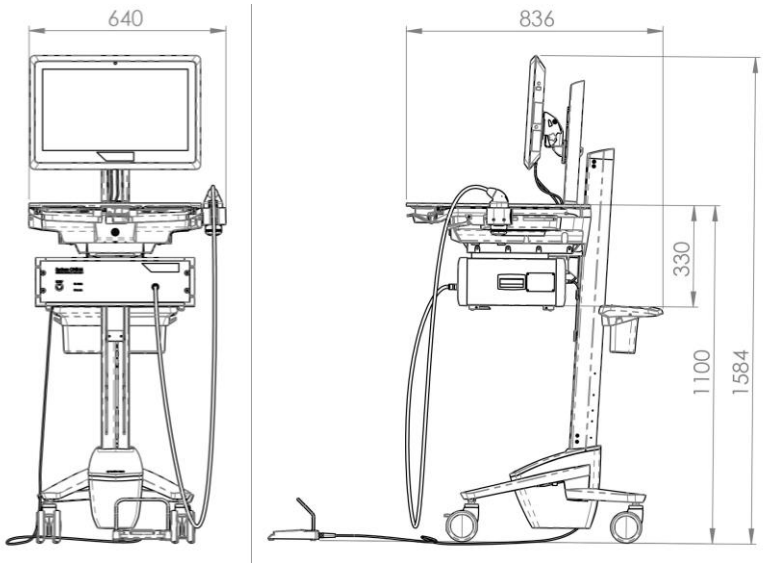
It has the potential to become the preferred modality for an extremely wide range of different treatments in almost all dermatology clinics in the world"

Professor Joergen Serup, Chief Physician
Department of Dermatology, Bispebjerg University Hospital, Denmark

The difference to other methods:

- CO_2 lasers are ablative and create open wounds
  - Long healing time
  - Post operative pain, scar formation, and dysplasia
- Switched lasers depend on energy absorption in the target content
  - Heating and treatment depth is not controllable
  - Pain level is very high
- PDT is a slow and painful method
  - Low efficacy
  - Slow, costly and painful treatment for both patients and clinics
- Cryotherapy is uncontrollable and inefficient
  - Uncontrolled and highly operator-dependent penetration depth
- Cosmetology HIFU has very large focal points
  - Method cannot treat indications isolated in dermis and epidermis

Documented skin treatment



Parameter	Description
Overall system	
Electrical appliance classification (IEC 60601-1:2006)	Class I (Protective Earthing)
EMC / EMI classitfication (IEC CISPR11:2015)	Group 1 Class A (Ultrasonic Therapeutic equipment, clinical and residential use)
Life-time of combined system	5 years
Warranty of combined system and its units	1 Year
Mains cable lenght	2 m
Mains cable type	IEC 60320 compatible
Input rating	230 V 50 Hz 1.5 A
Operating conditions	15 - 30 °C 10 - 75 %RH max 2000 m altitude Non condensing
Storage and Transport conditions	0 - 50 °C 5 - 95 %RH 500 - 1060 hPa Non condensing
Dimensions (maximum height x width x depth)	160 x 65 x 85 cm^3
Total weight of system	60 kg
Handpiece ONE-M - Applied Part	
Applied Part Classification	Type B
Cable Length	2 m
Cable jacket material	Silicone
Integrated optical feed	1280px x 960px
Shelf life (stored in empty and dry condition)	1 year
Nominal focal depth range	0.8 - 2.3 mm
HIFU operating frequency range	20 MHz ±10%
Maximum shot duration	500 ms ± 10%
Maximum acoustic power	9 W ± 15%
Maximum acoustic energy	1.3 J ±15%
Total energy credit	30 kJ
Ingress protection rating	IPX1 Transducer head IPX7
Weight	700 g
Compliance, standards and regulations	
Certification type	CE certificate
Regulation	MDR 2017 / 745 (EU)
Risk Classification	Class IIa
Basic safety and essential performance	IEC 60601-1:2005 + A1:2012 + A2:2021
EMC	IEC 60601-1-2:2015 + A1:2021
Acoustic safety	IEC 60601-2-62:2015
Software	IEC 62304:2006 + A1:2015
Usability	IEC 60601-1-6:2010 + A1:2013
Usability	IEC 62366-1:2015 + A1:2020
Country of Origin	Denmark

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About TOOsonix and System ONE-M

MISSION

Create better lives with high frequency ultrasound therapy

VISION

One TOOsonix system in every hospital and dermatology clinic

FOUNDED AND FUNDED

2017
by HIFU and business veterans

TREATMENTS

25+
Relevant indications identified

LOCATION

DTU Science Park
Copenhagen
Denmark

CUSTOMER BASE

Private Dermatology Clinics and Public Hospitals

TOOsonix has been ISO13485:2016 certified since 2018

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