

TOOsonix System ONE-R

Datasheet

A new HIFU Modality for Dermatology, Cosmetology and Small-Animal Research



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TOOsonix System ONE-R

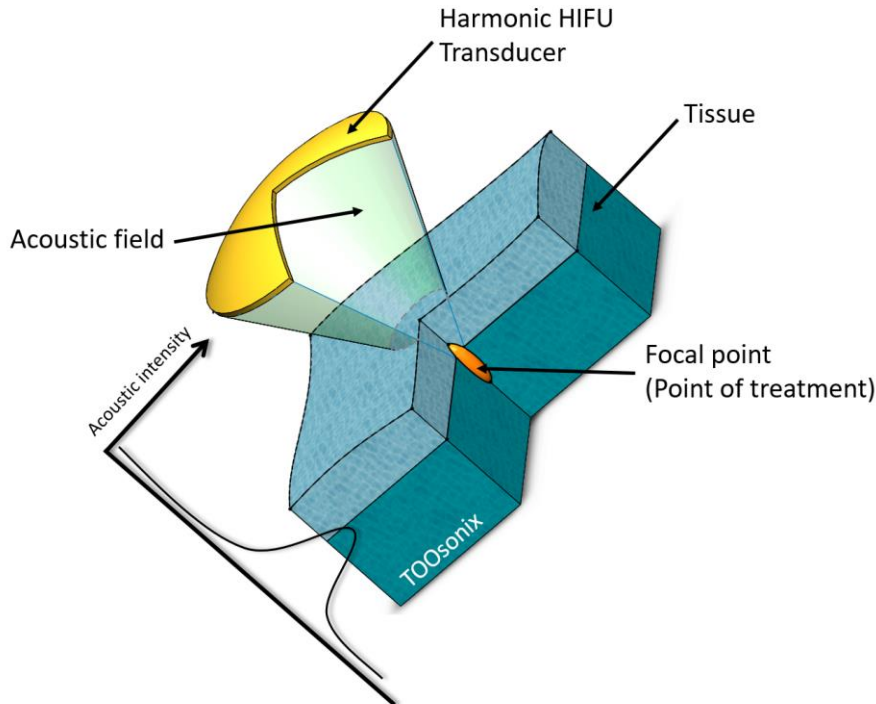
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HIFU

Principle

Applications

Opportunities



Unprecedented high frequency for unprecedented HIFU accuracy

System ONE-R is the new enabler for HIFU treatments in areas, where small and accurate HIFU focal points are key to your research success.

This extends the highly successful HIFU functionally to new and exiting areas:

- General dermatology
- Small-animal model research
- Dermato-oncology
- Cosmetology
- Ultrasound mediated drug delivery
- Cell manipulation
- Fundamental HIFU Research
- Sonochemistry Research
- etc.

Please Note: TOOsonix System ONE-R and its parts is a laboratory equipment meant for research-use only. It should be operated by qualified and trained professionals only.

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Handpiece

Session control



High frequency HIFU handpieces with visible advantages

Two H01 handpieces are included with each System ONE-R.

The handpieces integrates HIFU treatment and a high-quality optical video-feed to provide unprecedented accuracy of treatments.

The handpieces offer the following key features:

- 20 MHz operating frequency
- -3 dB ellipsoid acoustic intensity focal zone with a diameter around 100 μm and length around 500 μm
- Accurate control of focal point location via real-time integrated optical microscope
- Light-weight to secure ergonomic operation during treatment
- Secure communication protocol for automatic authorization of valid and functional handpieces only

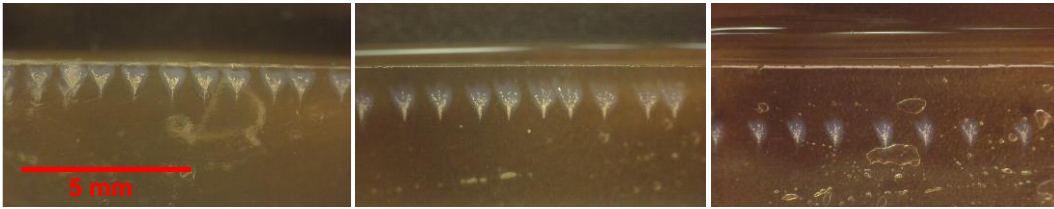
Handpieces with other frequencies and/or focal depths are available on request

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HIFU

Performance

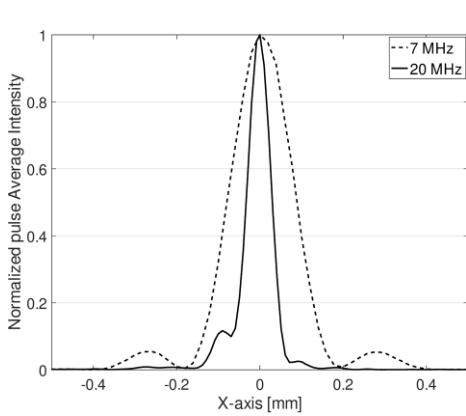


A

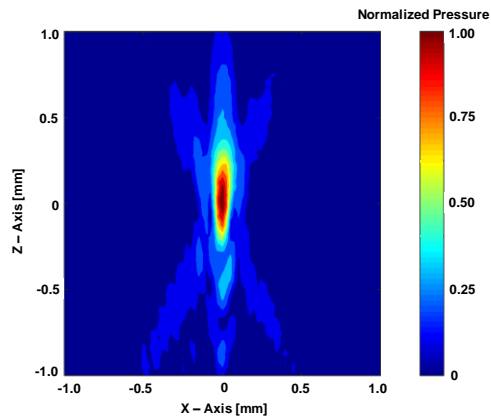
B

C

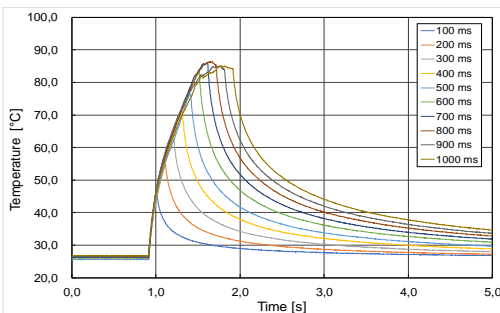
Cross sections of HIFU lesions made in Tissue Mimicking Phantom Gel at 20 MHz. A: Nom. Focal Depth 1.7 mm. B: Nom. Focal Depth 2.2 mm. C: Nom. Focal Depth 2.7 mm



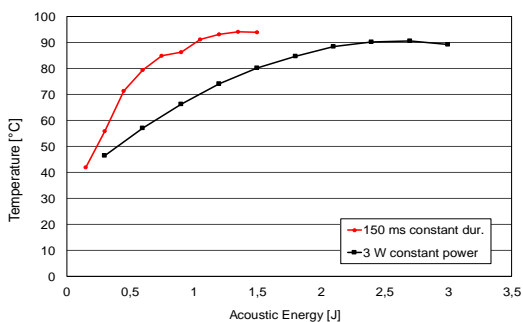
Normalized pulse average intensity (measured) from TOOsonix H01 transducers operating at 20 MHz and 7 MHz. The 20 MHz transducer offers a significantly smaller and well-defined focal zone



Compressional pressure field from a TOOsonix 20 MHz H01 transducer. The ellipsoidal -3 dB acoustic intensity focal zone is 110 μ m in diameter and 549 μ m in length



Temperature dynamics in focal point by HIFU treatment at 3W



Example of peak temperatures in a TMP gel in HIFU treatment. The temperature can be accurately controlled by energy and pulse duration settings

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Software

Optics

Session control



Real-time control of your treatment session

System ONE-R comes with a pre-installed and ready-to-use software, which can be easily operated from the highly responsive touchscreen PC.

The software displays a large-size optical video-feed of the area under HIFU treatment, as well as intuitive controls for the session settings. The software furthermore displays a range of key health statistics, indicators and data.

The software offers the following key features:

- Intuitive keyboard-free operation
- Easy setting of pulse mode (single shot or repeated shot mode)
- Easy setting of acoustic power
- Easy setting of shot duration
- On-screen indication of shot energy and duty cycle
- User-friendly navigation and activation of settings and sub-menus
- Possibility to save data and video directly to an external USB drive

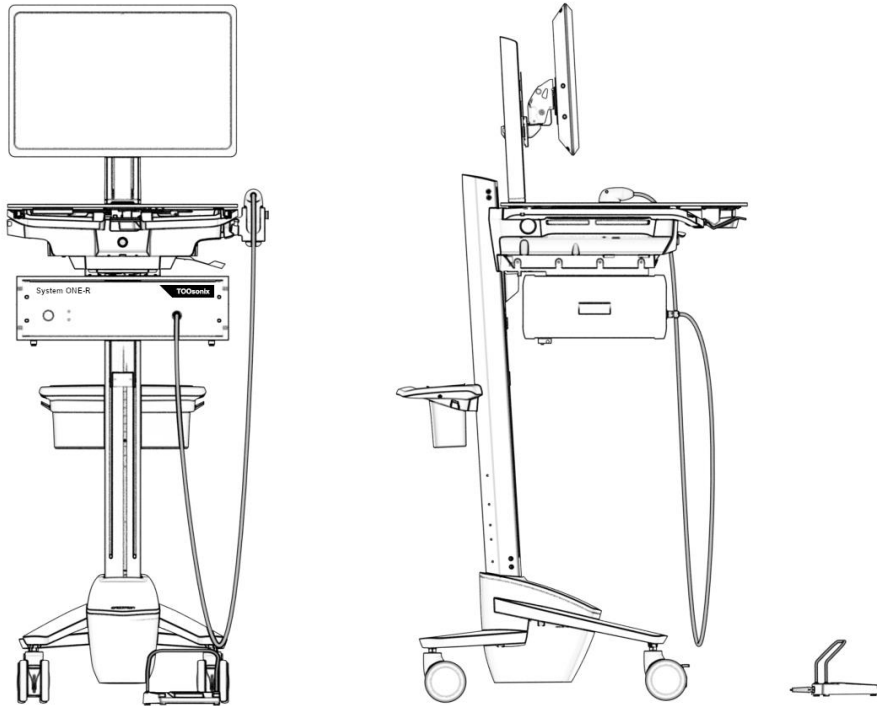
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Usability

Adjustments

Environments



Ultimate mobility. Ultimate flexibility

System ONE-R offers a flexible and mobile solution.

The system is designed to operate and fit equally well into a clinical setting as well as research laboratory environment.

The system offers the following key features:

- Height-adjustable to accommodate both standing and sitting operation
- Footswitch-activation of HIFU transmission to allow maximum attention and control of the subject under treatment
- Ample storage room for consumables in integrated shelf under the work-table and utility basket on the backside of the system
- Easy cleaning of all surfaces with regular detergents or ethanol
- Easy and stable transport of the system due to its high-quality castors and stable architecture

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Specification

System

	Parameter	Description
System		
	Inteded use	Research Only Equipment
	Electrical Appliance Classification (IEC 61140)	Class I
	Electromagnetic Environm. Classification (EN 55011)	Class A
	EMC Classification (EN 55011)	Group 2
	Overvoltage category	CAT II
	Max. Dimensions (W x D x H)	600 x 800 x 1800 mm ³
	Input Power cable	IEC 60320 compatible, 2 m
	Input power supply	230 VAC, 50 Hz
	Total System Maximum Power	520 W
	Total weight of system	53 kg
	Additional Load Capacity	max 5 kg
	Life-time of combined system	5 years
	Warranty of combined system and its units	1 Year
	Operating conditions	15 - 35 °C, 10 - 75 % RH (non condensing)
	Transport and storage conditions	0 - 50 °C, 5 - 95 % RH (non condensing)
	Modes of operation	Single Shot Mode , Repeated Shot Mode
UPU – Ultrasonic Power Unit		
	Maximal input power	400 W
	Output RF frequency	5 – 25 MHz
	Maximum RF output power (into 50 Ohm)	90 W
	IP Rating	IP30
Panel PC		
	PC type	Cybernet NB22 / S22
	Monitor	22". Capacitive, Multitouch
	Certification level	IEC 60601-1
	CPU	Intel i-5
	RAM	8 GB
	Hard drive	SSD 128 GB
	Operating System	Microsoft Win10 Enterprise LTSB
	Software	TOOsonix System ONE-R ver. 1 or above
	Interfaces	4 x USB
	IP Rating	IP 65
Footswitch		
	Type	Steute KF-MED GF11
	Certification level	IEC 60601-1
	IP Rating	IP X8
	Number of activations	> 1 million
	Weight	0.8 kg
Mobile Cart		
	Type	Ergotron Styleview SV41-6320-0
	Workspace height adjustment	80-110 cm, Manual adjustment
	Worksurface size	55.6 x 59.6 cm
	PC / monitor mount	VESA Mis D
	IP Rating	IP X8
Compliance		
	Certification type	CE mark Directive 2014/35/EU Directive 2014/30/EU
	Electric safety standard	EN 61010-1 : 2010
	EMC standard	EN 61326-1 : 2013



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Specification

Handpiece

Parameter	NFD 1.7 mm	NFD 2.7 mm
Handpiece General		
Cable Length	2 m ± 10%	
Cable jacket material	Polyurethane (PU)	
Handpiece Material	Medical Grade Polyamide	
Acoustic Window Material	LDPE film Thickness ~10 µm	
Connector type	Aluminium hybrid multipole	
Shelf life (stored in empty and dry condition)	1 year	
Weight	300 g	
Integrated HIFU Transducer		
Nominal Focal Depth	1.7 mm	2.7 mm
Typical maximum focal depth in soft tissue (tested in TMP gel)	0.5 to 0.9 mm	1.5 to 2.0 mm
HIFU Operating Frequency	20 MHz ± 5 %	
Maximum shot duration	1000 ms	
Acoustic power	0.5 - 9 W ± 10%	
Acoustic energy	0.05 - 6.0 J	
Total energy credit	30 kJ	
-3 dB (acoustic intensity) Focal Diameter perp. to acoustic axis (ellipsoid shape)	80 µm ± 20%	
-3 dB (acoustic intensity) Depth of Focus in the acoustic axis (ellipsoid shape)	400 µm ± 20%	
Transducer chamber filling volume	6.2 ml	6.0 ml
Integrated Optical Microscope		
Live video capability	1280p x 960p	
CMOS image sensor resolution	2.0 M Pixels	
Compliance		
Certification type	CE mark Directive 2014/35/EU Directive 2014/30/EU	
Electric safety standard	EN 61010-1 : 2010	
EMC standard	EN 61326-1 : 2013	



About TOOsonix

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TOOsonix is a Danish registered company founded in 2017 on the foundations of strong technical knowledge in ultrasound and medical device technology.

Our mission is to help people by use of high frequency ultrasonic therapy.

We are located in the DTU Science Park approximately 25 km north of Copenhagen, Denmark, a campus hosting a wide range of international companies within the medical device- biotechnology- and pharmaceutical industries.

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