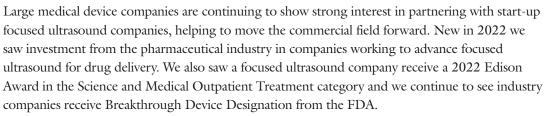
FUS Industry

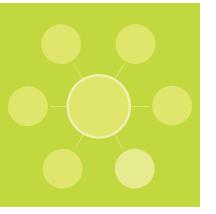




Overview



During 2022, 17 new focused ultrasound companies entered the ecosystem—ten manufacturers, five OEMs and two microbubble companies. From publicly available sources and industry reporting, we estimate the field employs nearly 3,000 individuals spread around the world. Just under half of the worldwide employee count is concentrated in the United States, Israel, and France. The median company size is 12 employees and 66 percent of companies have 20 or fewer employees. There are over 1,000 focused ultrasound devices in use for commercial treatment around the world; these are fairly evenly distributed between North America, Europe, and Asia.



VIII. FUS Industry

VIII. 2 Overview

Company Types, Employees, and Locations

VIII. 3 Geographic Distribution

VIII. 4 Companies

VIII. 5 Employees

VIII. 6 Employee Distribution

VIII. 7 Employee Locations by Country

Companies by Region

VIII. 8 North America

VIII. 8 Timelines of Companies

VIII. 9 Companies

VIII.11 Europe

VIII.11 Timelines of Companies

VIII.12 Companies

VIII.14 Asia

VIII.14 Timelines of Companies

VIII.15 Companies

Devices

VIII.18 In Use

VIII.19 In Use by Region

VIII.20 Distributors by Region

VIII.24 With Treatment and Planning Guidance

VIII.24 North America

VIII.26 Europe

VIII.28 Asia



Geographic Distribution of Companies

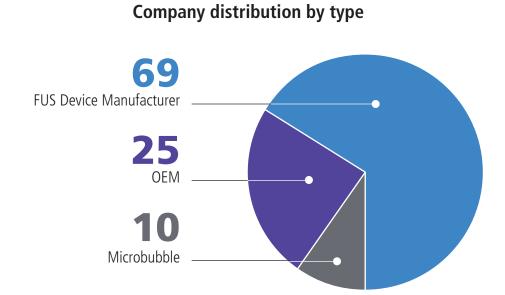
2022

| 104 | North America | Europe 26 | Asia |
|---|---------------|-----------|------|
| FUS companies 69 FUS device manufacturers | 31 | 16 | 22 |
| Companies with approvals | 3 | 4 | 9 |

Companies

FUS companies*





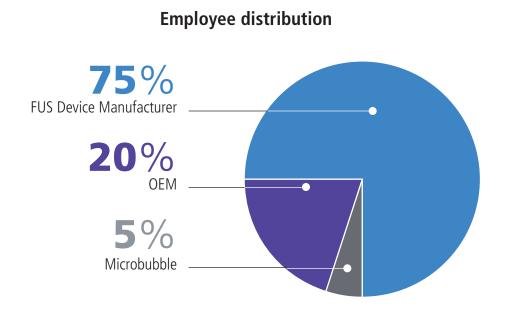
^{*} This analysis includes all FUS industry companies where employee information was available, including FUS device manufacturers, OEM, and microbubble companies.

Just as a reminder, the company timelines include the year the company became involved in the focused ultrasound industry instead of the date of incorporation. For many early-stage focused ultrasound manufacturing companies, this date is one and the same; however, for the OEM and/or microbubble companies, it is often different.

Employees







^{*} Number of employees estimated from publicly available sources and directly reported by companies on our annual survey.

Most of the focused ultrasound industry employment is by focused ultrasound device manufacturers. Despite these companies being early stage and having small workforces, they are more numerous than OEM and microbubble companies. The largest geographic location of focused ultrasound employment is the United States, followed by Israel and France. These three countries comprise 50 percent of the labor pool with the remainder of the employees broadly distributed around the globe.

Employee Distribution*

employees

is the median company size

66%

of companies have

20 or fewer employees

10%

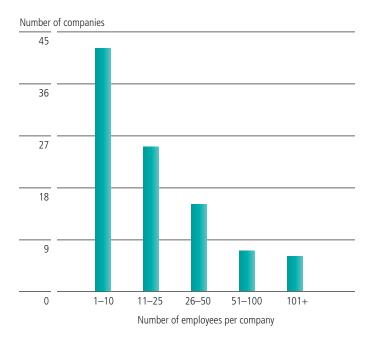
of the total workforce is employed by the

52 smallest companies

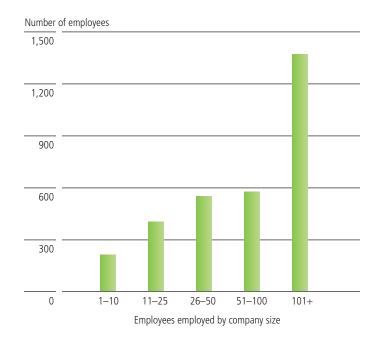
of the total workforce is employed by the

8 largest companies

Number of Companies

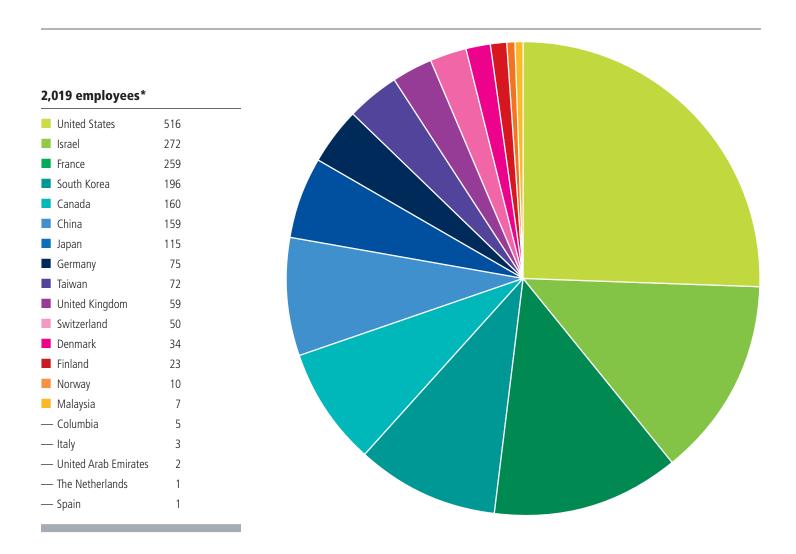


Number of Employees



^{*} This analysis includes device manufacturers, OEM, and microbubble companies.

FUS Employee Locations



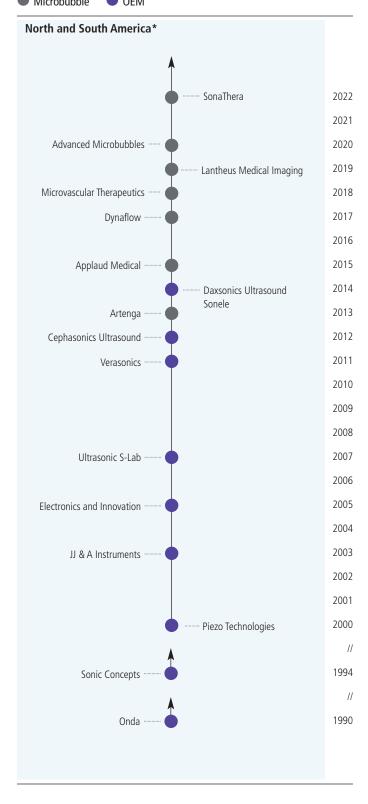
^{*}Number of employees directly reported by companies on our annual survey.

North America—Timelines of Companies

Clinical Device Manufacturers



Other FUS Companies Microbubble OEM



North America—Companies

North America

CLINICAL DEVICE MANUFACTURERS

Acoustic MedSystems INC | Savoy, Illinois, United States, acousticmed.com

Acoustiic INC | Seattle, Washington, United States, acoustiic.com

Alpheus Medical INC | North Oakdale, Minnesota, United States, alpheusmedical.com

Arrayus Technologies INC² | Burlington, Ontario, Canada, arrayus.ca

AthenaCare LLC | Salt Lake City, Utah, United States

BrainSonix CORP | Sherman Oaks, California, United States, brainsonix.com

Cerevast Medical INC | Bothell, Washington, United States, cerevast.com

Cordance Medical INC | Mountain View, California, United States, cordancemedical.com

Delsona Therapeutics INC¹ New York, New York, United States

Discogen | Weston, Florida, United States, discogen.com

Exo Imaging INC | Redwood City, California, United States, exo-imaging.com

EyeSonix | Long Beach, California, United Sates, eyesonix.com

FUS Instruments INC | Toronto, Ontario, Canada, fusinstruments.com

FUSMobile INC | Alpharetta, Georgia, United States, fusmobile.com

Grey Matter Neurosciences | Toronto, Ontario, Canada

HistoSonics INC | Ann Arbor, Michigan, United States, histosonics.com

INIA Biosciences INC | Boston, Massachusetts, United States, iniabiosciences.com

International Cardio CORP LLC | Edina, Minnesota, United States, hifu-rx.com

MR Instruments INC | Hopkins, Minnesota, United States, mrinstruments.com

NeuroSonics Medical INC | Baltimore, Maryland, United States, neurosonicsmedical.com

NeuSound Bio | California, United States

NovusTX Devices INC | Calgary, Alberta, Canada, novustx-devices.com

Openwater | San Francisco, California, United States, openwater.cc

Orchard Ultrasound Innovation | Sunnyvale, California, United States, orchardultrasound.com

Profound Medical CORP | Mississauga, Ontario, Canada, profoundmedical.com

[🛨] Manufacturers with regulatory approvals. To see a detailed breakdown of regional and country approvals, see charts starting on p. IX.5.

¹ Manufacturer was formerly known as TheraWave Bio INC.

² Manufacturer was formerly known as Harmonic Medical INC.

North America—Companies continued

North America continued

CLINICAL DEVICE MANUFACTURERS continued

Sonablate CORP | Charlotte, North Carolina, United States, sonablate.com

SonoVascular INC | Chapel Hill, North Carolina, United States, sonovascular.com

SonoVol INC | Durham, North Carolina, United States, sonovol.com

Sonus Microsystems | Vancouver, British Columbia, Canada, sonusmicrosystems.com

UltraNeuro | Cambridge, Massachusetts, United States, www.pivottheworld.com

Zeta Surgical INC | Boston, Massachusetts, United States, zetasurgical.com

MICROBUBBLE

Advanced Microbubbles INC | Newark, California, United States, advancedmicrobubbles.com
Applaud Medical INC | San Francisco, California, United States, applaudmedical.com
Artenga INC | Ottawa, Ontario, Canada, artenga.com

Dynaflow INC | Jessup, Maryland, United States, dynaflow-inc.com

Lantheus Medical Imaging INC | North Billerica, Massachusetts, United States, lantheus.com
Microvascular Therapeutics LLC | Tucson, Arizona, United States, mvtpharma.com

SonoThera INC | San Francisco, California, United States, sonothera.com

OEM

Cephasonics Ultrasound | San Jose, California, United States, www.cephasonics.com

Daxsonics Ultrasound INC | Halifax, Nova Scotia, Canada, daxsonics.com

Electronics and Innovation LTD | Rochester, New York, United States, eandiltd.com

JJ & A Instruments LLC | Rathdrum, Idaho, United States, jja-instruments.com

Onda CORP | Sunnyvale, California, United States, ondacorp.com

Piezo Technologies | Indianapolis, Indiana, United States, piezotechnologies.com

Sonele INC | Markham, Ontario, Canada, sonele.com

Sonic Concepts INC | Bothell, Washington, United States, sonicconcepts.com

Ultrasonic S-Lab LLC | Concord, California, United States, ultrasonic-s-lab.com

Verasonics INC | Kirkland, Washington, United States, verasonics.com

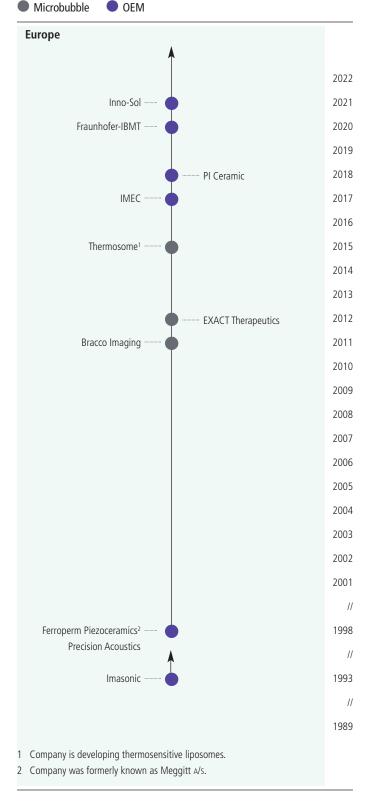
[🛨] Manufacturers with regulatory approvals. To see a detailed breakdown of regional and country approvals, see charts starting on p. IX.5.

Europe—Timelines of Companies

Clinical Device Manufacturers



Other FUS Companies



Europe—Companies

Europe

25

CLINICAL DEVICE MANUFACTURERS

Cardiawave SA | Paris, France, cardiawave.com Carthera SA | Paris, France, carthera.eu

- + EDAP TMS SA | Vaulx-en-Velin, France, edap-tms.com
- EyeTechCare SA | Lyon, France, eyetechcare.com Image Guided Therapy SA | Pessac, France, imageguidedtherapy.com Medsonic LTD | Limassol, Cyprus, medsonic.com.cy OrthoSon LTD | Oxford, England, United Kingdom, orthoson.com OxSonics LTD | Oxford, England, United Kingdom, oxsonics.com Qwanteus | France, qwanteus.com Synced GmbH | Hamburg, Germany
- ◆ Theraclion SA | Malakoff, France, theraclion.fr
 Therason | France
- TOOsonix A/S | Hørsholm, Denmark, toosonix.com
 TRANS-FUSIMO | Bremen, Germany, trans-fusimo.eu
 Ultralab LTD | Çankaya/Ankara, Turkey, ultralabltd.com
 VeinSound SAS | Lyon, France, veinsound.com

⁺ Manufacturers with regulatory approvals. To see a detailed breakdown of regional and country approvals, see charts starting on p. IX.5.

Europe—Companies continued

Europe continued

MICROBUBBLE*

Bracco Imaging SPA | Milano, Italy, braccoimaging.com

EXACT Therapeutics AS | Oslo, Norway, exact-tx.com

Thermosome GMBH¹ | Planegg/Martinsried, Germany, thermosome.com

OEM

Ferroperm Piezoceramics² | Kvistgaard, Denmark, meggittferroperm.com
Fraunhofer-Institut für Biomedizinische Technik | Sulzbach, Germany, ibmt.fraunhofer.de
Imasonic sa | Voray-sur-l'Ognon, France, imasonic.com
imec | Leuven, Belgium, imec-int.com
PI Ceramic GmbH | Lederhose, Germany, piceramic.com
Precision Acoustics LTD | Dorchester, England, United Kingdom, acoustics.co.uk

^{*} Also includes thermosensitive liposomes.

¹ Company is developing thermosensitive liposomes

² Company was formerly known as Meggitt A/s.

Asia—Timelines of Companies

Clinical Device Manufacturers



Other FUS Companies Microbubble Asia YoungTek Electronics Medad Technology S-Sharp Corp. Tamura Dong II Technology **EofE Ultrasonics** Humanscan Nepa Gene

Asia—Companies

Asia

30

CLINICAL DEVICE MANUFACTURERS

- + Alpinion Medical Systems co LTD | Seoul, South Korea, alpinion.com
- 🛨 Changjiangyuan Technology Development со LTD | Beijing, China, cjykj.com
- + Chongqing Haifu Medical Technology co LTD | Chongqing, China, haifumedical.com
- + EpiSonica CORP | Hsinchu, Taiwan, episonica.com IMGT co LTD | Seongnam, South Korea, nanoimgt.com
- ♣ Insightec LTD | Tirat Carmel, Israel, insightec.com

Korust CO LTD | Anyang, South Korea, korust.com

MBInsight Systems INC | Taiwan

Mianyang Sonic Electronic LTD | Mianyang City, China, ultrasound.cn

NaviFUS CORP | New Taipei City, Taiwan, navi-fus.com

Neurosona co LTD | Seoul, South Korea, neurosona.com

NINA Medical LTD | Nazareth, Israel, ninamed.com

- 🛨 Shanghai A&S Science Technology Development со LTD | Shanghai, China, aishen.com.cn
- + Shende Medical Equipment Technology CO LTD | Shanghai, China, shendehc.com Shenzhen Huikang Medical Apparatus CO LTD | Shenzhen, China, eswl.cn
- ♣ Shenzhen PRO-HITU Medical Technology CO LTD | Shenzhen, China, pro-hifu.com

SONIRE Therapeutics INC | Tokyo, Japan, sonire-therapeutics.com

Sound Wave Innovation CO LTD | Tokyo, Japan, sw-innovation.com

Suntec Industries co LTD | Shanghai, China

Vensica Therapeutics² | Misgav, Israel, vensica.com

 Wuxi Haiying Electronic Medical Systems co ltd | Wuxi, China, haiyingmedical.com.cn

 Zhonghui Medical Technology co ltd¹ | Shanghai, China, zhonghuimt.com

[🕂] Manufacturers with regulatory approvals. To see a detailed breakdown of regional and country approvals, see charts starting on 🏿 p. IX.5.

¹ Commonly known as Sinoways.

² Manufacturer was formerly known as Vensica Therapeutic.

Asia—Companies continued

Asia continued



Dong Il Technology LTD | Hwaseong, South Korea, dongiltech.co.kr EofE Ultrasonics co LTD | Seoul, South Korea, ultrasonics.co.kr

Humanscan co LTD | Ansan, South Korea, humanscan.co.kr

Medad Technology | Dubai, United Arab Emirates, medadtechnology.com

Nepa Gene co | Chiba, Japan, nepagene.jp

S-Sharp corp | New Taipei City, Taiwan, s-sharp.com

Tamura CORP | Tokyo, Japan, tamuracorp.com

YoungTek Electronics | Hsinchu City, Taiwan, ytec.com.tw

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FUS Devices in Use

Number and Growth

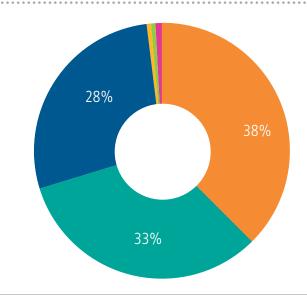
2022

1,265
FUS Devices

110/0 Growth 2021 over 2020

Worldwide Distribution

2022



■ North America 28%
■ Europe 33%
■ Asia 38%
■ South America >1%
■ Oceania >1%
■ Africa >1%

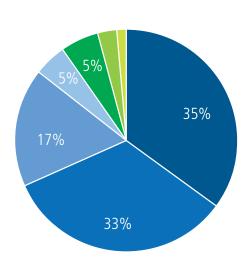


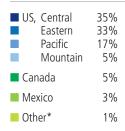
FUS Device Use by Region



314

Devices



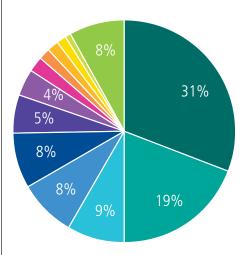


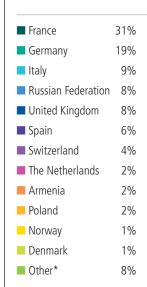
^{*} Cayman Islands, Cuba, Dominica, and Dominican Republic

Europe

372

Devices



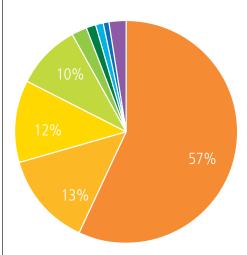


^{*} Austria, Belgium, Bulgaria, Czech Republic, Finland, Georgia, Greece, Latvia, Monaco, Portugal, Romania, Serbia, Sweden, Turkey, and Ukraine

Asia

430

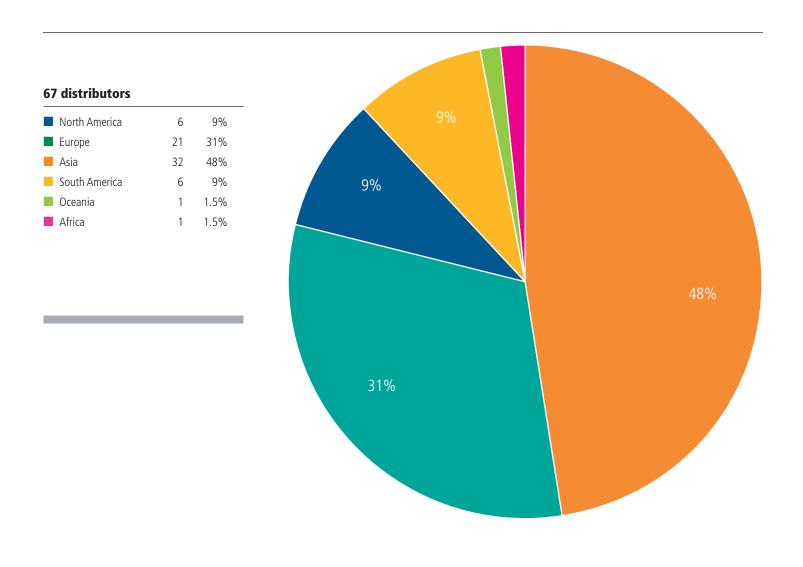
Devices





^{*}Iran, Kazakhstan, Lebanon, Malaysia, Myanmar, Philippines, Uzbekistan, and Vietnam

Distributors by Region



Distributors by Region continued

North America

Agiliti Health INC

American HIFU LLC

Cyber Robotic Solutions SA de CV

HIFU Prostate Services LLC

Soluciones Medicas Avanzadas sas

Vituro Health LLC

Europe

ab medica SPA

ADS Elektronik Tıbbi Cihazlar AS

Andromed Tıbbi Cihazlar ve Sağlık Hizmetleri

Brainbox LTD

Consultronix sa

InnoMedicus AG

Kungshusen Medicinska AB

Levi Danismanlik ve Ticaret As

Medicina Analítica Consumibles SA

Medistim Danmark APS

Medkonsult sno

Palex Medical sa

Promedica Bioelectronics SRL

ProMedical oy

Sigmacon UK LTD

SofMedica

Synektik Group

Tema Sinergie SPA

Timko sp zoo

Vingmed AS

VIVAX Pharmaceuticals SRO

Distributors by Region continued

Asia

Allmed Solutions

Amed co LTD

AMI Technologies LTD

Amos Gazit LTD

Beijing Beike Digital Medical Technology co LTD

Beijing Ren De Sheng Technology

Best Digital со LTD

Bravotac CORP LTD

CanAm Scientific

Century Scientific and Equipment co WLL

Demakai со цтр

Demed Solutions SDN BHD

Double Success co LTD

DSS Imagetech PVT LTD

ECHO Healthcare INC

Ekpac China LTD

Hanyoung Trading co LTD

Huons Medical

imedtac со LTD

Medfocus co LTD

Medical Imaging System PTE LTD

Nanomedix PVT LTD

Pro Chime Enterprise CORP

Rad Medical CORP

Sumo Corporations LTD

Takai Hospital Supply со LTD

Tasly SonaCare Medical Engineering Technology CO LTD

Theraclion China LTD

Transmedic PTE LTD

Valor Health co LTD

Varitron

Yangde Instrument co LTD

South America

Cencomex sa

Imemed Bolivia

Medicinelaser sa

Protrauma sa

Sirex Médica sa

Strattner & Cia LTDA

Oceania

Getz Healthcare Australia

Africa

SARL Medimatec

Currently, 16 focused ultrasound device manufacturers have commercial products available. Please see Chapter 10 for further details on these companies and their products.

However, with an ecosystem of 70 manufacturers, that means 83 percent are in the R&D stage. The field is still very early stage.

What follows is a table with high-level information about the various devices around the world and what type of imaging is utilized for treatment and planning guidance.



| Manufacturer | Device | Treatment guidance | Planning guidance | Approval |
|-----------------------------------|---|---|-------------------|----------|
| North America | | | | |
| Research & Development | | | | |
| Acoustic MedSystems | ACOUSTx TheraVision | Ultrasound, CT-fluoroscopy, MRI, and 3D targeting | _ | |
| Acoustiic | AgilitUS | MR guidance | MR guidance | • |
| Alpheus Medical | CV01 | _ | _ | |
| Arrayus ² | Symphony | US & MR guidance | _ | |
| AthenaCare | Muse MRgFUS System | MR guidance | MR guidance | |
| BrainSonix | BXPulsar 1001 LIFUP | MR guidance | MR guidance | |
| | BXPulsar 1002 LIFUP | MR guidance | MR guidance | |
| Cerevast Medical | Aureva Pulse | US guidance | _ | |
| | Reflow RVO | US guidance | _ | |
| Delsona Therapeutics ¹ | Ultranav (prototype) | Image fusion | Neuronavigation | |
| Exo Imaging | Performance Ultrasound Platform | _ | _ | |
| EyeSonix | TUG - Therapeutic Ultrasound for Glaucoma | Unguided | Visual guidance | |
| FUS Instruments | DS-50 | _ | _ | |
| | LP-100 | MR guidance | _ | |
| | RK-100 | _ | _ | |
| | RK-20 | Other guidance | _ | |
| | RK-300 | MR guidance | _ | |
| | RK-50 | Other guidance | _ | |
| FUSMobile | Neurolyser | Other guidance | Not used | |
| HistoSonics | Edison | US guidance | US guidance | |
| International Cardio | HIFU Synthesizer | US guidance | US guidance | |
| MR Instruments | DuoFLEX ACCESS Coil | MR guidance | MR guidance | |
| | MR-guided TRUST | MR guidance | MR guidance | |
| | (Transcranial Ultrasound Stimulation) | | | |
| NeuroSonics Medical | NeuroSonics (prototype) | US guidance | MR guidance | |
| Sonosa Medical | Sonosa Therapeutic | US guidance | Not used | |

¹ Manufacturer was formerly known as TheraWave.

² Manufacturer was formerly known as Harmonic Medical INC.



| Manufacturer | Device | Treatment guidance | Planning guidance | Approval |
|------------------|-----------|--------------------|-------------------|----------|
| North America | | | | |
| Commercial | | | | |
| Profound Medical | Sonalleve | MR guidance | MR guidance | + |
| | TULSA-PRO | MR guidance | MR guidance | + |
| Sonablate Corp. | Sonablate | US guidance | MR/US fusion | + |
| | Sonatherm | US guidance | US guidance | + |



| Manufacturer | Device | Treatment guidance | Planning guidance | Approval |
|------------------------|---------------------------------|--------------------|-------------------|----------|
| Europe | | | | |
| Research & Development | | | | |
| Cardiawave | Valvosoft | US guidance | US guidance | |
| CarThera | SonoCloud 1 | Unguided | Not used | |
| | SonoCloud 9 | Unguided | Not used | |
| EDAP TMS | EDAP (prototype) | US guidance | US guidance | |
| Image Guided Therapy | ЗВор | Stereotactic frame | _ | |
| | LabFUS | MR guidance | MR guidance | |
| | Rodent FUS System | MR guidance | MR guidance | |
| | TargetedFUS | MR guidance | MR guidance | |
| | UFOGUIDE | MR guidance | MR guidance | |
| Medsonic | Bone phantoms - Medsonic | MR guidance | _ | |
| | MR-Compatible Transducers | MR guidance | _ | |
| | Robotic Systems | MR guidance | _ | |
| | Shinsei motor electronic system | MR guidance | _ | |
| | Skull phantoms - Medsonic | MR guidance | _ | |
| OxSonics | SonoTran System | US guidance | US guidance | |
| TOOsonix | System ONE-R | Image fusion | Visual guidance | |
| TRANS-FUSIMO | TransFUSIMO Treatment System | MR guidance | MR guidance | |
| VeinSound, SAS | PHEA1 | US guidance | US guidance | |



| Manufacturer | Device | Treatment guidance | Planning guidance | Approval |
|--------------|------------------------|----------------------------|--|----------|
| Europe | | | | |
| Commercial | | | | |
| EDAP TMS | Ablatherm Focal One | Image fusion Image fusion | US guidance MR & US guidance, Biopsies | + |
| EyeTechCare | EyeOP1 | Unguided | - | + |
| Theraclion | Echopulse SONOVEIN | US guidance US guidance | US guidance Not used | : |
| TOOsonix | System ONE-M | Image fusion | Visual guidance | + |



| Manufacturer | Device | Treatment guidance | Planning guidance | Approval |
|------------------------------------|------------------------------|--------------------|-------------------|----------|
| Asia | | | | |
| Research & Development | | | | |
| Alpinion Medical Systems | VIFU2000 | US guidance | _ | |
| Chongqing Haifu Medical Technology | CZG300 | US guidance | _ | |
| | JC200D | US guidance | _ | |
| | JC300 | US guidance | _ | |
| | LCA200 | Unguided | Not used | |
| IMGT | IMD10 | US guidance | US guidance | |
| Korust co LTD | Le Mette | Unguided | Not used | |
| | RHINOS | Other guidance | Other | |
| | UTIMS | Unguided | Not used | |
| Mianyang Sonic Electronic | CZ901 | US guidance | _ | |
| NaviFUS | NaviFUS System (Model 001) | Neuronavigation | MR/CT fusion | |
| | NaviFUS System (Model 101) | Other guidance | MR/CT fusion | |
| | NaviFUS System (Model 101-K) | Other guidance | MR/CT fusion | |
| Neurosona | NS-US100 | Other guidance | MR/CT fusion | |
| | NS-US200 | Other guidance | MR/CT fusion | |
| NINA Medical | LOTUS-1 | US guidance | US guidance | |
| Shenzhen Huikang Medical Apparatus | HIFU 2001 | US guidance | _ | |
| Shenzhen PRO-HITU Medical | PRO3008 | US guidance | US guidance | |
| | UT1000 | Unguided | Not used | |
| Sonire Therapeutics | Suizenji | US guidance | CT guidance | |
| Suntec Industries | Suntec System | US guidance | - | |
| Vensica Medical ¹ | The Vibe | _ | _ | |
| | Vensica (prototype) | US guidance | _ | |
| Zhonghui Medical | SUA-I | US guidance | US guidance | |
| | SUV-I | US guidance | US guidance | |

¹ Manufacturer was formerly known as Vensica Therapeutics.



| Manufacturer | Device | Treatment guidance | Planning guidance | Approval |
|---------------------------------------|---|--------------------|-------------------|----------|
| Asia | | | | |
| Commercial | | | | |
| Alpinion Medical Systems | Alpius 900 | US guidance | _ | + |
| Changjiangyuan Technology Development | NUTAS — Non-invasive Ultrasound Tumor | | | |
| | Ablation System | US guidance | US guidance | + |
| | SUPER Knife-Focused Beam Therapy System | MR & US guidance | _ | + |
| Chongqing Haifu Medical Technology | CZB | US guidance | _ | + |
| | CZF | US guidance | _ | + |
| | JC | US guidance | _ | + |
| | JC200 | US guidance | _ | + |
| EpiSonica | ArcBLATE (ARC-100M) | MR guidance | MR guidance | + |
| Insightec | Exablate Body ¹ | MR guidance | MR guidance | + |
| | Exablate Neuro | MR guidance | MR/CT fusion | + |
| | Exablate Prostate | MR guidance | MR guidance | + |
| Shanghai A&S | HIFUNIT9000 | US guidance | MR guidance | + |
| Shende Medical Equipment Technology | Aceso | MR guidance | _ | + |
| Shenzhen PRO-HITU Medical | PRO2008 | US guidance | US guidance | + |
| | PRO300 | US guidance | US guidance | + |
| | PRO5G | Other guidance | Visual guidance | + |
| Wuxi Haiying Electronic Medical | HY2900 | US guidance | _ | + |

¹ Device was formerly known as Exablate MrgFUS.