FEP-BY
HIGH INTENSITY FOCUSED ULTRASOUND THERAPY SYSTEM
China Medical Technologies, Inc. (CMT) is a high-tech enterprise, trading on Nasdaq with the ticker—CMED. We currently conduct our operations principally through our wholly-owned subsidiary—Beijing Yuande Bio-Medical Engineering Co., Ltd. in China. Established in 1999, the headquarters and manufacturing facilities of Yuande are located in the Beijing Economic-Technological Development Area. The company was awarded ISO9001 certification in 2001 and ISO13485:2003 in 2006. CMT’s main products are the High Intensity Focused Ultrasound therapy system (FEP-BY Series) and the Enhanced Chemiluminescence Immunoassay system (ECLIA).

With more than ten years of development by scientists and physicians, our High Intensity Focused Ultrasound (HIFU) therapy system was approved by the State Food and Drug Administration (SFDA) of China in 1999. The innovated FEP-BY02 Series HIFU therapy system allows for a broader range of treatment indications and more comfortable treatment positions for patients.
The CMT FEP-BY Series High Intensity Focused Ultrasound therapy system has the ability to deliver high intensity focused ultrasound from an external source deep into tissues with a large convergence angle. The focus is oval in shape and is approximately 3 mm in diameter and 10 mm in length. The combination of thermal and mechanical (cavitation) bioeffects can result in cell death and tissue necrosis. The device is clinically used to treat both benign and malignant solid tumors.
Transmitted from outside, focusing inside the body

Accumulating treatment model
Transmission of ultrasound is delivered in a pulsed fashion with transmission and intermission times determined by the operator.
Each ceramic piezoelectric unit is selected from tens of thousands of units. In order to achieve high focusing accuracy and stability, each transducer is made of hundreds of elements with the same frequency.

The wide angle of convergence (80 °) of the high intensity ultrasound beam keeps the acoustic intensity at the skin surface below the threshold for pain and skin burns. (Patented technology)
Pathological Changes caused by HIFU

Coagulative Necrosis

Cell Destruction

Degeneration or Apoptosis

Fibrosis
FEP-BY02 Clinical Indications

Our HIFU therapy system has been used to treat both malignant and benign solid tumors. It has been approved by the SFDA of China to treat the following types of tumors:

- Pancreatic tumors
- Liver tumors
- Solid tumors in pelvis cavity
- Kidney tumors
- Breast tumors
- Tumors in limbs or superficial tissue
- Solid tumors on bone
- Uterine fibroids

Our HIFU therapy system can be used as monotherapy or as an adjunct to surgery, radiotherapy and/or chemotherapy. Potential benefits of HIFU therapy include extending survival times, alleviating pain and improving the quality of life for patients. In addition, HIFU therapy may enhance tumor-specific immunity and sensitize tumors to improve treatment response to radiotherapy and chemotherapy. HIFU monotherapy has been demonstrated to be beneficial in the treatment of uterine fibroids and benign prostatic hyperplasia.
A non-invasive procedure

Our HIFU therapy system offers patients a non-invasive treatment alternative. Treatments performed with our HIFU therapy system do not require incisions or needle injections. As a result, this minimizes the risk and complications associated with invasive procedures. Due to the invasive nature of surgery and the significant side effects associated with chemotherapy and radiotherapy, it is often not possible
Minimal side effects

Treatments performed with our HIFU therapy system have minimal side effects and relatively few complications. Compared to other HIFU tumor therapy systems that are commercially available in China, our HIFU therapy system produces less intense ultrasound waves at the skin surface due to the large convergence angle of the ultrasound beam, which significantly reduces the likelihood of skin burns and collateral damage.
High degree of safety

Treatments using our HIFU therapy system can be performed without anesthesia since it does not cause significant discomfort or skin-burns. This allows patients to give immediate feedback to the physician if they are experiencing any discomfort during treatment. In addition, since HIFU therapy is non-invasive, there is essentially no risk of hemorrhage.
Flexible treatment control model

Physicians have the option to perform the treatment automatically or manually using a computer based treatment program. The software allows physicians to interrupt treatments at any time during HIFU therapy to adjust treatment parameters.

Dual transducers, broader range of treatment indications, more comfortable treatment positions

Real time positioning and monitoring; short recovery time; low treatment cost
Clinical Cases

At present, our FEP-BY Series HIFU therapy system has been used in more than 200 hospitals in China with treating more than 40,000 patients.

Pancreatic cancer, case 1

64 year old male with pancreatic cancer involving the neck of the pancreas. CT-scan demonstrates tumor involving the pancreatic neck and reduction in tumor size following HIFU therapy.

Pancreatic cancer, case 2

51 year old female with pancreatic cancer involving the pancreatic body and symptoms of abdominal pain. CT-scan demonstrates partial tumor necrosis.

Pancreatic cancer, case 3

67 year old male with tumor involving the pancreatic body. There was no progression of disease for over one year following HIFU therapy. PET demonstrated decreased metabolic activity within the treated region.
- **Patient’s pain was relieved following HIFU therapy.**
- **HIFU** can effectively alleviate symptoms, ablate tumor, improve the quality of life and survival times for patients with pancreatic cancer.

**Hepatocellular carcinoma**

80 year old male with hepatocellular carcinoma
The tumor was undetectable 11 months after HIFU therapy.

**Liposarcoma**

56 year old male with a recurrence of liposarcoma
Reduction in tumor size 3 months following HIFU therapy.

**Carcinoma of the Renal Pelvis**

81 year old female with carcinoma of the right renal pelvis
Contrast enhanced-CT scan demonstrates tumor necrosis.
Lymph node metastasis

Before treatment 76 year old male with a proximal rectal cancer
Sigmoidoscopy demonstrated tumor necrosis following HIFU therapy.
Sigmoidoscopy showed no recurrence 5 years after HIFU therapy.

Rectal cancer

Before treatment after treatment 5 years after treatment

76 year old male with a proximal rectal cancer
Sigmoidoscopy demonstrated tumor necrosis following HIFU therapy.
Sigmoidoscopy showed no recurrence 5 years after HIFU therapy.

Uterine fibroids

37 year old female with a submucosal hysteromyoma
MRI demonstrated tumor necrosis and the patient regained the normal menstruation following HIFU therapy.

Before treatment after treatment

Example of excised tissue previously treated with HIFU
Pathology demonstrates tumor necrosis and fibrosis

65 year old male with colon cancer with lymph node metastasis
The lymph node was treated with HIFU. PET-CT demonstrated that the tumor had no metabolic activity after HIFU therapy.
A case of synergy between HIFU & radiation

64 year old male with a large bladder tumor that disappeared 3 months after 40GY radiation and HIFU treatment

Several studies support the clinical benefit of combining radiation with HIFU.

Patient can potentially receive lower dosage of radiation plus HIFU which can reduce the side effect caused by radiotherapy

78 year old male with a gastric tumor
Obvious reduction in tumor size and strengthened tumor echo 3 months following HIFU therapy
Technical Specification

FEP-BY Series Technical Specification

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating frequency</td>
<td>1.1MHz±15%</td>
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<tr>
<td>Focal dimensions</td>
<td>&lt;3mmx3mmx10mm</td>
</tr>
<tr>
<td>Acoustic focal maximum intensity</td>
<td>&lt;15KW/cm²</td>
</tr>
<tr>
<td>Maximum electrical power</td>
<td>2000W</td>
</tr>
<tr>
<td>Transducers</td>
<td>Upper and lower transducers</td>
</tr>
<tr>
<td>Convergence method</td>
<td>Multielement array and concave self-focusing</td>
</tr>
<tr>
<td>Convergence angle</td>
<td>80°</td>
</tr>
<tr>
<td>Maximum probe movement</td>
<td>100mm</td>
</tr>
<tr>
<td>Transmission method</td>
<td>pulse</td>
</tr>
<tr>
<td>Pretreatment preparation</td>
<td>No anesthesia needed</td>
</tr>
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FEP-BY Series Technical Data of Transducers and Treatment Bed

<table>
<thead>
<tr>
<th>Transducer</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Transducer:</td>
<td>Up and down movement: ≥280mm</td>
</tr>
<tr>
<td></td>
<td>Left and right inclination: ≥±18°</td>
</tr>
<tr>
<td></td>
<td>Front and back inclination: ≥±5°</td>
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<tr>
<td>Lower Transducer:</td>
<td>Up and down movement: ≥150mm</td>
</tr>
<tr>
<td></td>
<td>Left and right inclination: ≥±5°</td>
</tr>
<tr>
<td></td>
<td>Front and back inclination: ≥±5°</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment Bed:</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>L×W×H,mm: 1980×1650×1820</td>
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<tr>
<td>Vertical movement</td>
<td>≥120mm</td>
</tr>
<tr>
<td>Horizontal movement</td>
<td>≥120mm</td>
</tr>
<tr>
<td>Front and back inclination</td>
<td>≥±5°</td>
</tr>
</tbody>
</table>
HIFU Standard Configuration

- Control system software
- Control system
- Ultrasound imaging system
- Monitor
- Control panel
- Printer

Highly integrated control system with a user-friendly interface

Incorporates a high-quality commercial B-mode ultrasound imaging system from a leading ultrasound manufacturer customized to provide image-guided targeting and monitoring of HIFU therapy.
- Dual transducer treatment bed
- Treatment seat
- Image probes (3)
- Power supply system
- Water treatment system
We Make Life Healthier
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