

[54] **METHOD FOR EXAMINING, LOCALIZING AND TREATING WITH ULTRASOUND**

[75] **Inventor: Jacques Dory, Coupvray-Esblay, France**

[73] **Assignee: EDAP International, S.A.**

[21] **Appl. No.: 276,431**

[22] **Filed: Nov. 22, 1988**

**Related U.S. Patent Documents**

Reissue of:

[64] **Patent No.: 4,658,828**  
**Issued: Apr. 21, 1987**  
**Appl. No.: 728,905**  
**Filed: Apr. 30, 1985**

U.S. Applications:

[63] **Continuation-in-part of Ser. No. 674,889, Nov. 26, 1984, Pat. No. 4,617,931.**

[30] **Foreign Application Priority Data**

Dec. 14, 1983 [FR] France ..... 83 20041  
 May 3, 1984 [FR] France ..... 84 06877

[51] **Int. Cl.<sup>5</sup> ..... A61B 8/00; A61N 5/00**  
 [52] **U.S. Cl. .... 128/660.03; 128/399**  
 [58] **Field of Search ..... 128/660.03, 24 A, 399, 128/804, 24 AA**

[56] **References Cited**

**U.S. PATENT DOCUMENTS**

- 2,484,626 10/1949 Keller .
- 2,632,634 3/1953 Williams .
- 2,645,727 7/1953 Willard .
- 2,792,829 5/1957 Calosi .
- 3,168,659 2/1965 Bayre et al. .
- 3,237,623 3/1966 Gordon ..... 128/24 A
- 3,338,235 8/1967 Gordon .
- 3,560,913 2/1971 Copley .
- 3,735,755 5/1973 Eggleton et al. .
- 3,756,071 9/1973 Dory .
- 3,785,382 1/1974 Schmidt-Kloiber et al. .
- 3,810,174 5/1975 Heard et al. .
- 3,879,698 4/1975 Pepper .
- 3,911,730 10/1975 Niklas .
- 3,924,259 12/1975 Butler et al. .

- 3,927,557 12/1975 Viertl .
- 3,942,531 3/1976 Hoff et al. .
- 3,958,559 5/1976 Glenn et al. .... 128/24 A
- 3,974,682 8/1976 Soldner et al. .
- 4,005,258 1/1977 Dory .
- 4,046,149 9/1977 Komiya .
- 4,058,114 11/1977 Soldner .
- 4,070,905 1/1978 Kossoff .

(List continued on next page.)

**FOREIGN PATENT DOCUMENTS**

- 010000058 12/1978 European Pat. Off. .
- 0036353 9/1981 European Pat. Off. .
- 0045265 2/1982 European Pat. Off. .
- 0068961 1/1983 European Pat. Off. .

(List continued on next page.)

**OTHER PUBLICATIONS**

Deposition Transcript of Jacques Dory, Feb. 15-17, 1989, pp. 394-395, 546-549 and 597.

Trial Transcript Testimony of Dr. William Swindell, pp. 34, 36, 39, 45, 48, 50, 5190, 52, 53.

New Hospital Technologies, Auzenet et al., Proceedings from the Mar.-Oct. 1984 Training Course.

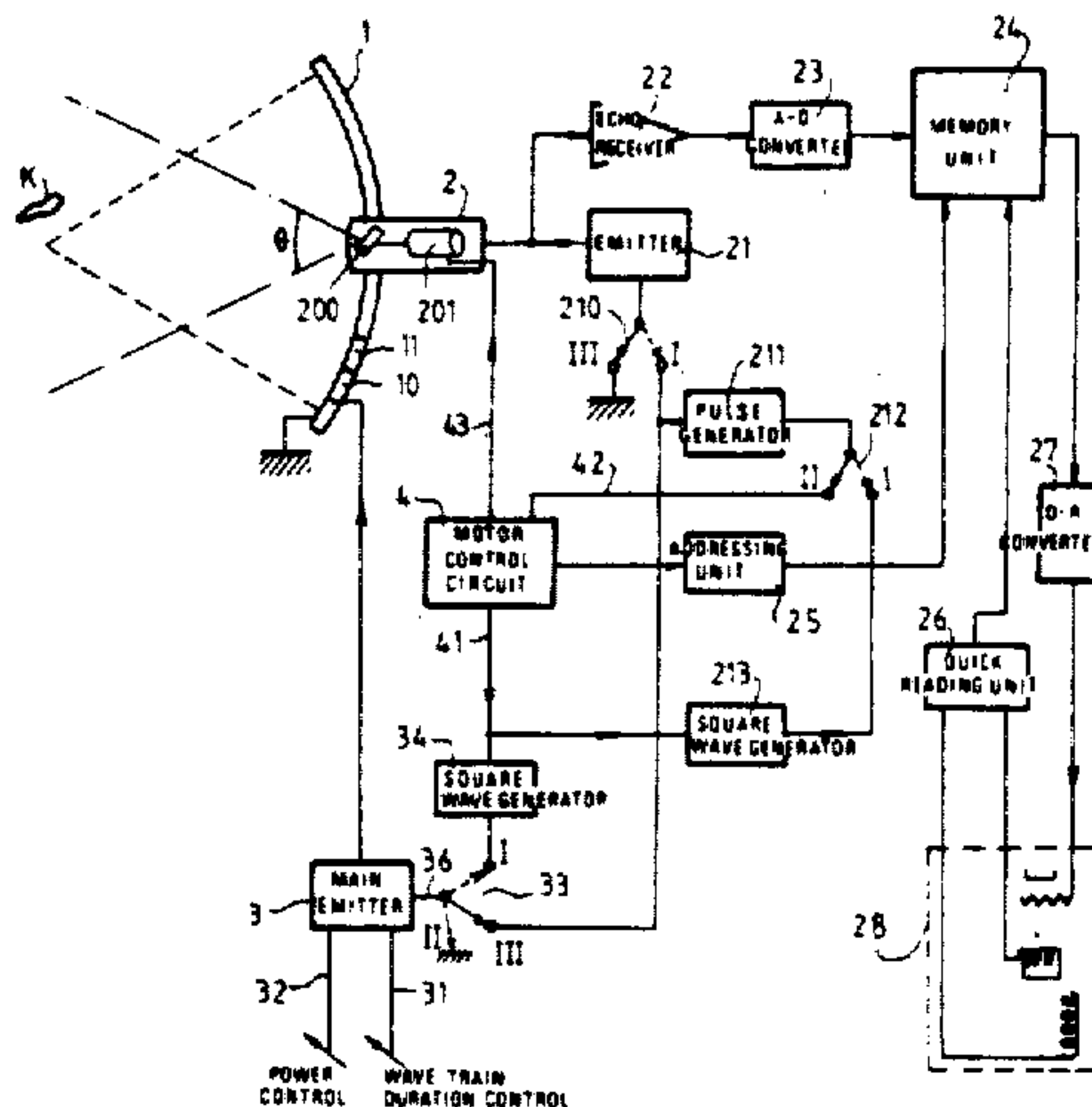
(List continued on next page.)

*Primary Examiner*—Lee S. Cohen  
*Attorney, Agent, or Firm*—William A. Drucker

[57] **ABSTRACT**

A hyperthermia applicator comprises a generator of a focused ultrasonic beam comprising a main high frequency electric wave emitter and a main piezoelectric transducer and an echography device comprising an auxiliary high frequency electric pulse generator associated with an auxiliary piezoelectric transducer which generates an ultrasonic examination beam sweeping the zone to be treated. During a main treatment and checking operating mode, the focused beam is emitted by the main transducer energized by the main emitter during periodic time intervals separated by shorter time intervals. During the shorter time intervals, the examination beam is emitted and echographic images are formed.

**4 Claims, 3 Drawing Sheets**



## U.S. PATENT DOCUMENTS

4,084,582 4/1978 Nigam .  
 4,094,306 6/1978 Kossoff .  
 4,097,835 6/1978 Green .  
 4,163,394 8/1979 Soldner .  
 4,174,634 11/1979 Dory .  
 4,181,120 1/1980 Kunii et al. .  
 4,199,246 4/1980 Muggli .  
 4,204,435 5/1980 Bridoux et al. .  
 4,205,686 6/1980 Harris et al. .  
 4,209,022 6/1980 Dory .  
 4,218,768 8/1980 Hassler .  
 4,235,111 11/1980 Hassler .  
 4,245,511 1/1981 Soldner .  
 4,274,421 6/1981 Dory .  
 4,281,550 8/1981 Erikson .  
 4,281,661 8/1981 Dory .  
 4,287,770 9/1981 Weyns .  
 4,294,119 10/1981 Soldner .  
 4,305,296 12/1981 Green et al. .  
 4,311,147 1/1982 Hausler .  
 4,315,514 2/1982 Drewes et al. .... 128/660 X  
 4,340,944 7/1982 Dory .  
 4,350,917 9/1982 Lizzi et al. .  
 4,368,410 1/1983 Hance et al. .  
 4,373,395 2/1983 Borburgh et al. .  
 4,375,818 3/1983 Suwaki et al. .  
 4,385,255 5/1983 Yamaguchi et al. .  
 4,412,316 10/1983 Diepers .  
 4,417,582 11/1983 Trimmer et al. .  
 4,434,341 2/1984 Busby .  
 4,440,025 4/1984 Hayakawa et al. .  
 4,441,486 4/1984 Pounds ..... 128/24 A .  
 4,458,533 7/1984 Borburgh .  
 4,462,092 7/1984 Kawabuchi et al. .  
 4,470,308 9/1984 Hayakawa et al. .  
 4,474,180 10/1984 Angulo .  
 4,478,083 10/1984 Hassler et al. .  
 4,484,569 11/1984 Driller et al. .  
 4,486,680 12/1984 Bonnet et al. .  
 4,501,277 2/1985 Hongo .  
 4,526,168 7/1985 Hassler et al. .... 128/303  
 4,535,771 8/1985 Takayama .  
 4,536,673 8/1985 Forster .  
 4,545,385 10/1985 Pirschel .  
 4,550,606 11/1985 Drost .  
 4,561,019 12/1985 Lizzi et al. .  
 4,564,980 1/1986 Diepers .  
 4,570,634 2/1986 Wess .  
 4,586,512 5/1986 Do-huu et al. .

4,608,983 9/1986 Müller et al. .  
 4,610,249 9/1986 Makofski et al. .  
 4,618,796 10/1986 Riedlinger .  
 4,618,887 10/1986 Birk .  
 4,620,545 11/1986 Shene et al. .  
 4,622,969 11/1986 Forssmann et al. .  
 4,622,972 11/1986 Giebeler, Jr. .  
 4,639,904 1/1987 Riedlinger .  
 4,646,756 3/1987 Watmough et al. .  
 4,671,292 6/1987 Matzak .  
 4,674,505 6/1987 Pauli et al. .  
 4,685,461 8/1987 Forssmann et al. .  
 4,721,106 1/1988 Kurtze et al. .  
 4,721,108 1/1988 Heine et al. .  
 4,858,597 8/1989 Kurtze et al. .

## FOREIGN PATENT DOCUMENTS

0072498 2/1983 European Pat. Off. .  
 0081639 6/1983 European Pat. Off. .  
 0090138 10/1983 European Pat. Off. .  
 0108190 5/1984 European Pat. Off. .  
 0124686 11/1984 European Pat. Off. .  
 0133946 3/1985 European Pat. Off. .  
 0155028 9/1985 European Pat. Off. .  
 654673 12/1937 Fed. Rep. of Germany .  
 2018468 10/1970 Fed. Rep. of Germany .  
 2053982 5/1972 Fed. Rep. of Germany .  
 2223319 12/1972 Fed. Rep. of Germany .  
 2202989 7/1973 Fed. Rep. of Germany .  
 2351247 4/1975 Fed. Rep. of Germany .  
 2538960 4/1977 Fed. Rep. of Germany .  
 2645738 4/1977 Fed. Rep. of Germany .  
 2635635 2/1978 Fed. Rep. of Germany .  
 2648908 5/1978 Fed. Rep. of Germany .  
 2712341 5/1978 Fed. Rep. of Germany .  
 2718847 11/1978 Fed. Rep. of Germany .  
 2722252 11/1978 Fed. Rep. of Germany .  
 2826828 7/1979 Fed. Rep. of Germany .  
 2925933 3/1980 Fed. Rep. of Germany .  
 2904115 8/1980 Fed. Rep. of Germany .  
 2913251 10/1980 Fed. Rep. of Germany .  
 2921444 11/1980 Fed. Rep. of Germany .  
 3119295 12/1982 Fed. Rep. of Germany .  
 3120611 12/1982 Fed. Rep. of Germany .  
 3122056 12/1982 Fed. Rep. of Germany .  
 3142639 5/1983 Fed. Rep. of Germany .  
 3146626 6/1983 Fed. Rep. of Germany .  
 3150513 6/1983 Fed. Rep. of Germany .  
 3210919 10/1983 Fed. Rep. of Germany .

(List continued on next page.)



## FOREIGN PATENT DOCUMENTS

3220751	12/1983	Fed. Rep. of Germany .
3240691	4/1984	Fed. Rep. of Germany .
3241026	5/1984	Fed. Rep. of Germany .
3316837	11/1984	Fed. Rep. of Germany .
3320998	12/1984	Fed. Rep. of Germany .
3328068	2/1985	Fed. Rep. of Germany .
3426398	3/1986	Fed. Rep. of Germany .
1215631	4/1960	France .
1334210	6/1963	France .
2222658	10/1974	France .
2247195	5/1975	France .
2275771	1/1976	France .
2298107	8/1976	France .
2410276	6/1979	France .
2477723	9/1981	France .
2487664	2/1982	France .
2487665	2/1982	France .
2546737	12/1984	France .
2589715	5/1987	France .
44-18782	8/1969	Japan .
45-26168	8/1970	Japan .
57-95795	6/1982	Japan .
8400504	9/1985	Netherlands .
7900371	6/1979	PCT Int'l Appl. .
8402350	5/1984	PCT Int'l Appl. .
8503631	8/1985	PCT Int'l Appl. .
998173	7/1965	United Kingdom .
2113099	8/1983	United Kingdom .
2126901	4/1984	United Kingdom ..... 128/399
2140693	12/1984	United Kingdom .
179076	2/1966	U.S.S.R. .
221209	7/1968	U.S.S.R. .
423033	4/1974	U.S.S.R. .
469462	5/1975	U.S.S.R. .
602180	4/1978	U.S.S.R. .
1114409	9/1984	U.S.S.R. .

## OTHER PUBLICATIONS

A Scanning, Focused Ultrasound Hyperthermia Delivery System, D. M. Cooper et al.  
 Ultrasound: Its Applications in Medicine and Biology,  
 Intense Focused Ultrasound: Its Production, Effects  
 and Utilization.  
 Ultrasonic Imaging, C. R. Hill, Journal of Physics E  
 Scientific Instruments, vol. 9, Mar. 1976.  
 Hepp, W., *Überblick über die Entwicklung der Stosswellenlithotripsie*, (Publ. Dornier Medizintechnik), Sep. 1984.

Programme & Abstract, BMUS 13th Annual Meeting, 14th-15th Dec. 1981, London.

Hausler et al., "Ultraschallverfahren Zur Ortung Von Nierensteinen", *Symposium Biophysikalische Verfahren zur Diagnose und Therapie von Steinleiden der Harnwege Wissenschaftliche Berichte*, Meersburg, Jun. 10-11, 1976, pp. 54-60.

Lauterborn, Session 3, "Cavitation: General and Basic Aspects", 3:1-General and Basic Aspects of Cavitation, pp. 195-202.

Wells, P. N. T., "Ultraschall in der Medizinischen Diagnostik", Walter de Gruyter, Berlin, 1980.

Wells, P. N. T., "Scientific Basis of Medical Imaging", Churchill Livingstone, Edinburgh, 1982.

*Symposium/Biophysikalische Verfahren zur Diagnose und Therapie von Steinleiden der Harnwege Wissenschaftliche Berichte*, Meersburg, Jun. 10-11, 1976.

Bittner, "Über Die Möglichkeiten, Nierensteine Mit Hilfe Des Ultraschall-A-Verfahrens Nachzuweisen Und Zu Lokalisieren", *Symposium/Biophysikalische Verfahren zur Diagnose und Therapie von Steinleiden der Harnwege Wissenschaftliche Berichte*, Meersburg, Jun. 10-11, 1976, pp. 61-69.

Bartels, "Zur Frage Der Nierenstein-Darstellung Mit Der B-Scan Sonographie", *Symposium/Biophysikalische Verfahren zur Diagnose und Therapie von Steinleiden der Harnwege Wissenschaftliche Berichte*, Meersburg, Jun. 10-11, 1976, pp. 70-73.

Bartels, "Intraoperative Röntgenuntersuchungen Der Niere Mit Dem Renodorgerat", *Symposium/Biophysikalische Verfahren zur Diagnose und Therapie von Steinleiden der Harnwege Wissenschaftliche Berichte*, Meersburg, Jun. 10-11, 1976, pp. 74-81.

Guilgkett, "Stobspannungen und Stobströme"(Symposium unknown), pp. 2-22.

Hausler, "Physikalische Grundlagen Der Instrumentellen Und Der Extrakorporalen Zerkleinerung Von Harnsteinen", *Symposium/Biophysikalische Verfahren zur Diagnose und Therapie von Steinleiden der Harnwege Wissenschaftliche Berichte*, Meersburg, Jun. 10-11, 1976, p. 32.

Lizzi, F., "Ultrasonic Hyperthermia for Ophthalmic Therapy", *IEEE Transactions on Sonics and Ultrasonics*, vol. SU-31, No. 5, Sep. 1984, pp. 473-481.

(List continued on next page.)



## OTHER PUBLICATIONS

- Lizzi, et al., "Thermal Model for Ultrasonic Treatment of Glaucoma", *Ultrasound in Med. & Biol.*, vol. 10, No. 3, 1984, pp. 289-298.
- Chaussy et al., "Extrakorporale Stobwellenlithotripsie-Beginn einer Umstrukturierung in der Behandlung des Harnsteinleiden?", *Urologe A*, vol. 23, 1984, pp. 25-29.
- Chaussy, et al., "Extracorporeal Shock Wave Lithotripsy for the Treatment of Urinary Tract Stones", *Hospimedica*, Sep.-Oct. 1986, pp. 21-27.
- "Ultrasonic Focusing Radiators", pp. 225-285, 306-307.
- Kurtze, "Über die Bedingungen für das Auftreten von Kavitation in Flüssigkeiten", (source unknown), pp. 1-47.
- Chaussy et al., "Shock Wave Treatment for Stones in the Upper Urinary Tract", *Urologic Clinics of North America*, vol. 10, No. 4, Nov. 1984, pp. 743-750.
- Macovski, "Medical Imaging Systems", pp. 4-6 and 173-181, 1983, Prentice-Hall, Inc.
- Brannen et al., "Ultrasonic Destruction of Kidney Stones", Original Clinical Articles, Mason Clinic, Seattle, Feb. 1984, vol. 140, No. 2, pp. 227-232.
- Duck, F. et al., "Acoustic Shock Generation by Ultrasonic Imaging Equipment", *Brit. J. Radiol.*, Mar. 1984, pp. 231-240.
- Chaussy et al., "Extracorporeal Shock Wave Lithotripsy (ESWL) for Treatment of Urolithiasis", Special Issue to *Urology*, vol. 23, No. 5, May 1984, pp. 59-66.
- Elder et al., "Ultrasonic Lithotripsy of a Large Staghorn Calculus", *J. Urol.*, vol. 131, Jun. 1984, pp. 1152-1154.
- Ultrasonics*, Jan. 1984, pp. 5-6.
- Watanabe et al., "Micro-Explosion Cystolithotripsy", *J. Urol.*, vol. 129, Jan. 1983, pp. 23-28.
- Campbell, J. et al., "Normalization of Ultrasonic Scattering Measurements to Obtain Average Differential Scattering Cross Sections for Tissues", *J. Acoust. Soc. Am.*, vol. 74, No. 2, Aug. 1984, pp. 393-399.
- Hunt et al., "Ultrasound Transducers for Pulse-Echo Medical Imaging", IEEE Transactions on Biomedical Engineering, vol. BME-30, No. 8, Aug. 1983, pp. 453-481.
- Hynynen et al., "A Clinical Hyperthermia Unit Utilizing an Array of Seven Focused Ultrasonic Transducers", 1983, Ultrasonics Symposium, IEEE, pp. 816-821.
- Ultrasonics*, May 1982, pp. 99-101.
- Chaussy, "Berührungsfreie Nierensteinzertrümmerung Durch Extrakorporal Erzeugte, Fokussierte Stobwellen", *Beitrage Zur Urologic*, vol. 2, Karger, Basel, 1980, pp. 40-41, Translation of entire source included, Chaussy et al., Extracorporeal Shock Wave Lithotripsy—New Aspects in the Treatment of Kidney Stone Disease, Karger, Basel, 1982.
- Ziegler et al., "Erfahrungen mit Hochenergetischen Stobwellen Bei der Behandlung Von Nierensteinen", Results of High Intensity Shock Wave Treatment of Renal Calculi, Program of the 7th Annual Meeting, European Intrarenal Surgery Club, Ghent, Belgium, 1982, (Translation included).
- Program of the 7th Annual Meeting, European Intrarenal Surgery Club, Ghent, Belgium, 1982.
- Riedlinger et al., "Erzeugung Hochenergetischen Ultrashallimpulse Mit Fokussierenden Piezowandlern", Generation of High Energy Ultrasound Impulses with Focusing Piezoelectric Transducers, Fortschritte der Akustik, FASA/DAGA '82, Gottingen, 1982, pp. 755-758, (Translation included).
- Coleman, et al., "Applications of Therapeutic Ultrasound in Ophthalmology", reprinted from Progress in Medical Ultrasound, vol. 2/1981, Amsterdam, Excerpta Medica, pp. 263-270.
- Hausler and Stein, "Fokussierbare Unterwasserimpuls-schallquellen", *Acustica*, vol. 49, No. 4, 1981, pp. 273-279.
- Coleman et al., "Production of Alternate Filtration Paths for Treatment of Glaucoma with High Intensity Ultrasound", Paper No. 1303, AIUM/SDMS Annual Convention, San Francisco, Calif., Aug. 17-21, 1981.
- Bulow et al., "Electrohydraulic Lithotripsy with Aspiration of the Fragments Under Vision—304 Consecutive Cases", *J. Urol.*, vol. 126, Oct. 1981, pp. 454-456.
- Chaussy et al., "First Clinical Experience with Extracorporeally Induced Destruction of Kidney Stones by Shock Waves", *J. Urol.*, vol. 127, Mar. 1982, pp. 417-420.

(List continued on next page.)



## OTHER PUBLICATIONS

- Coleman et al., "Ultrasonically Accelerated Resorption of Vitreous Membranes", *American Journal of Ophthalmology*, 89:490-499, 1980.
- Wells, P. N. T., "Diagnostic Imaging in Europe", *Ultrasonics*, Mar., 1980, pp. 91-92.
- "Echographic Ultrasonore: Un Circuit CCD Pour Simplifier L'Electronique De Commande", *Mesures Regulation Automatisation*-Fevrier 1980, pp. 25-27.
- Lizzi et al., "Experimental Treatment of Intra-Ocular Carcinoma with High Intensity Focused Ultrasound", Paper No. 1305, Proceedings of the 25th Annual Meeting of the American Institute of Ultrasound in Medicine, Sep. 15-19, 1980, New Orleans, Louisiana.
- Marshall, F. et al., "A Comparison of Ultrasonography and Radiography in the Localization of Renal Calculi: Experimental and Operative Experience", *J. Urol.*, vol. 126, Nov. 1981, pp. 576-580.
- Hynynen, K. et al., "Design of Ultrasonic Transducers for Local Hyperthermia", *Ultrasound in Med. and Biol.*, vol. 7, No. 4, 1981, pp. 397-402.
- Coleman, D. et al., "Experimental Investigations into Glaucoma Treatment Using High Intensity Focused Ultrasound", 24th Annual Meeting of the American Institute of Ultrasound in Medicine, Aug. 27-31, 1979, Paper No. 1301.
- Fraatz, V. N. et al., "Lichtoptisch Abbildung Fokussierter Ultraschallfelder", *Materialpruf.*, vol. 21 (1979), No. 10, Oct., pp. 359-363.
- Konrad et al., "Fokussierte Stobwellen zur Berührungsfreien Nierensteinertrümmerung an der Freigelegten Niere", *Urologe A* 18 (1979), pp. 289-293.
- von Klot, R., "Ausbreitung von Ultraschallimpulsen bei der Prufung von Kernreaktor-Druckbehältern mittels Schallemissionsanalyse", *Materialpruf.*, vol. 21 (1979), No. 10, Oct. pp. 353-358.
- Romer, V. M. et al., "Fresnelsche Zonenplatte zur Schallfeldfokussierung", *Materialpruf.*, vol. 21 (1979), No. 10, Oct., pp. 363-365.
- Fry, "Ultrasound: Its Applications in Medicine and Biology", Elsevier Scientific Publishing Company, Amsterdam, 1978, pp. 689-707; 724-741; and 743-745.
- Petersen, "Piezoelektrische Aktoren", *Feinwerktechnik & Messtechnik*, 86 (1978), pp. 304-308.
- Raudsz, "Pschrometrische Bestimmung", *Feinwerktechnik & Messtechnik*, 86 (1978), p. 303.
- Hausler et al., "Properties and Physiological Application of Focussed Fluid Shock Waves", ASA Meeting, Honolulu, Hawaii, Dec. 1978, pp. 2-12.
- Kossoff, G., "Analysis of Focusing Action of Spherically Curved Transducers", *Ultrasound in Med. & Biol.*, vol. 5, 1979, pp. 359-365.
- Wells, P. N. T. "Biomedical Ultrasonics", Academic Press, London, 1977, pp. 494-495.
- Ibid.*, pp. 208-213.
- Ibid.*, pp. 511-594.
- Edell, S. et al., "Ultrasonic Evaluation of Renal Calculi", *Am. J. Roentgenol.*, 130:261-263, Feb. 1978.
- Coleman et al., "Therapeutic Ultrasound in the Production of Ocular Lesions", *American Journal of Ophthalmology*, 86:185-192, 1978.
- Hill, C., "Ultra-Sonic Imaging", *J. Physics E Scientific Instruments*, vol. 9, Mar., 1976, pp. 153-162.
- Sturtevant, B. et al., "The Focusing of Weak Shock Waves", *J. Fluid Mech.*, 1976, vol. 73, Part 4, pp. 651-671.
- Wanner et al., "Problematik Einer Integrierten Ultraschallortung im Versuchsmodell Berührungsfreier Nierensteinertrümmerung", Symposium Biophysikalische Verfahren Zur Diagnose und Therapie von Steinleiden der Harnwege, Meersburg, Jun. 10 and 11, 1976, pp. 235-240.
- Brinkmeyer et al., *Beobachtung Kurzer Kavitationstosswellen mit Kohärent-Optischen Methoden*, DAGA '76, pp. 461-464.
- Portions of the 1977 Clinical Ultrasound Purchaser's Catalogue, (Publ. 1976 by McGraphics, Denver, Colo.).
- Portions of the 1978 Clinical Ultrasound Purchaser's Catalogue, (Publ. 1977 by McGraphics, Denver, Colo.).
- Howards et al., "Current Status of Mechanical Lithotripsy", *Transactions of the American Association of Genito-Urinary Surgeons*, vol. 65, 1973, pp. 123-125.
- Linke, C. et al., "Localized Tissue Destruction by High-Intensity Focused Ultrasound", *Arch. Surg.*, vol. 107, Dec. 1973, pp. 887-891.
- Gavrilov, L. et al., "Use of Focused Ultrasound to Accelerate the 'Maturing' of a Cataract", *Sov. Phys-Acoust.*, vol. 20, No. 3, Nov.-Dec., 1974, pp. 229-231.

(List continued on next page.)



## OTHER PUBLICATIONS

- Greenleaf, J. et al., "Algebraic Reconstruction of Spatial Distributions of Acoustic Velocities in Tissue from their Time-of-Flight Profiles", *Acoustic Holography*, 1975, pp. 71-90.
- Shaw, A. et al., "A Real Time 2-Dimensional Ultrasonic Scanner for Clinical Use", *Ultrasonics*, Jan., 1976, pp. 35-40.
- Rozenberg, L., (Ed.), *Sources of High-Intensity Ultrasound*, vols. 1 and 2, 1969 (translations by James S. Wood, Plenum Press, N.Y.).
- Fry, "Ultrasonic Visualization of Ultrasonically Produced Lesions in Brain," *Confinia Neurologica*, vol. 32, pp. 38-52, 1970.
- Rozenberg, L., (Ed.), *High-Intensity Ultrasonic Fields*, 1971 (translation by James S. Wood, Plenum Press, N.Y.).
- Hill, C. et al., "A Search for Chromosome Damage Following Exposure of Chinese Hamster Cells to High Intensity, Pulsed Ultrasound", *Brit. J. Radiol.*, vol. 45, May, 1972, pp. 333-334.
- IEEE Transactions on Sonics and Ultrasonics*, Jan. 1973, p. 54.
- Frunzel, F., *High Speed Pulse Technology*, vol. 1, Academic Press, 1965, New York.
- Tarnoczy, "Sound Focussing Lenses and Wave Guides", *Ultrasonics*, Jul.-Sep., 1965, pp. 115-127.
- Thurstone, F. et al., "Resolution Enhancement in Scanning of Tissue", *Ultrasonics*, Jan., 1966, pp. 25-27.
- Bulman, W., "Applications of the Hall Effect", *Solid-State Electronics*, vol. 9, 1966, pp. 361-372.
- Lele, "Production of Deep Focal Lesions by Focused Ultrasound-Current Status", *Ultrasonics*, Apr. 1967, pp. 105-112.
- Rozenberg, L. et al., "A Focusing Radiator for the Generation of Superhigh Intensity Ultrasound at 1 Mc", *Sov. Phys.-Acoust.*, vol. 9, No. 1, Jul.-Sep., 1963, pp. 47-50.
- Gekhman et al., "The Effect of Supersonic Waves upon the Kidneys and the Urinary Tract", (Russian) 1963, pp. 17-21.
- Fry et al., "Ultrasonic Visualization of Soft Tissue Structure Based on Gradients in Absorption Characteristics", *The Journal of the Acoustical Society of America*, vol. 35, No. 11, Nov. 1963, pp. 1788-1790.
- Eisenmenger, W. "Experimentelle Bestimmung der Stossfrontdicke aus dem Akustischen Frequenzspektrum Elektromagnetisch Erzeugter Stosswellen in Flussigkeiten bei einem Stossdruckbereich von 10 Atm bis 100 Atm", *Acustica*, (Publ. S. Hirzel Verlag, Stuttgart, Ger.), vol. 14, No. 4, 1964, pp. 187-204.
- El'piner, I., *Ultrasound/Physical, Chemical, and Biological Effects*, 1964, (English translation by F. L. Sinclair, Consultants Bureau, N.Y.).
- Friedland, "Present Status of Ultrasound in Medicine", *The Journal of the American Medical Association*, vol. 163, No. 10, Mar. 1957, pp. 799-803.
- Fry, "Precision High Intensity Focusing Ultrasonic Machines for Surgery", *American Journal of Physical Medicine*, vol. 37, No. 3, Jun. 1958, pp. 152-156.
- Rozenberg, L. et al., "Apparatus for the Generation of Focused Ultrasound of High-Intensity," *Sov. Phys-Acoust.*, vol. 5, 1959, pp. 206-210.
- Schlegel, J. et al., "The Use of Ultrasound for Localizing Renal Calculi", *J. Urol.*, vol. 86, No. 4, Oct., 1961, pp. 367-369.
- Rosenberg, L. D., "La Generation Et L'Etude Des Vibrations Ultra-Sonores De Tres Grande Intensite", *Acustica*, vol. 12, (1962), pp. 40-49.
- Berlinicke et al., "Uber Beeinflussung Von Gallensteinen Durch Ultraschall in vitro", *Klinische Wochenschrift*, Dec. 28, 1950, p. 390.
- Mulvaney, "Attempted Disintegration of Calculi by Ultrasonic Vibrations", *J. Urol.*, vol. 70, No. 5, Nov. 1953, pp. 704-707.
- Bergmann, "Der Ultraschall-und Seine Anwendung in Wissenschaft und Technik", S. Hirzel Verlag, Stuttgart, 1954, pp. 126-137.
- Translation of P3, 1938, pp. 1-39.
- Coats, "Application of Ultrasonic Energy to Urinary and Biliary Calculi", *J. Urol.*, vol. 75, No. 5, May 1956, pp. 865-874.

FIG. 1

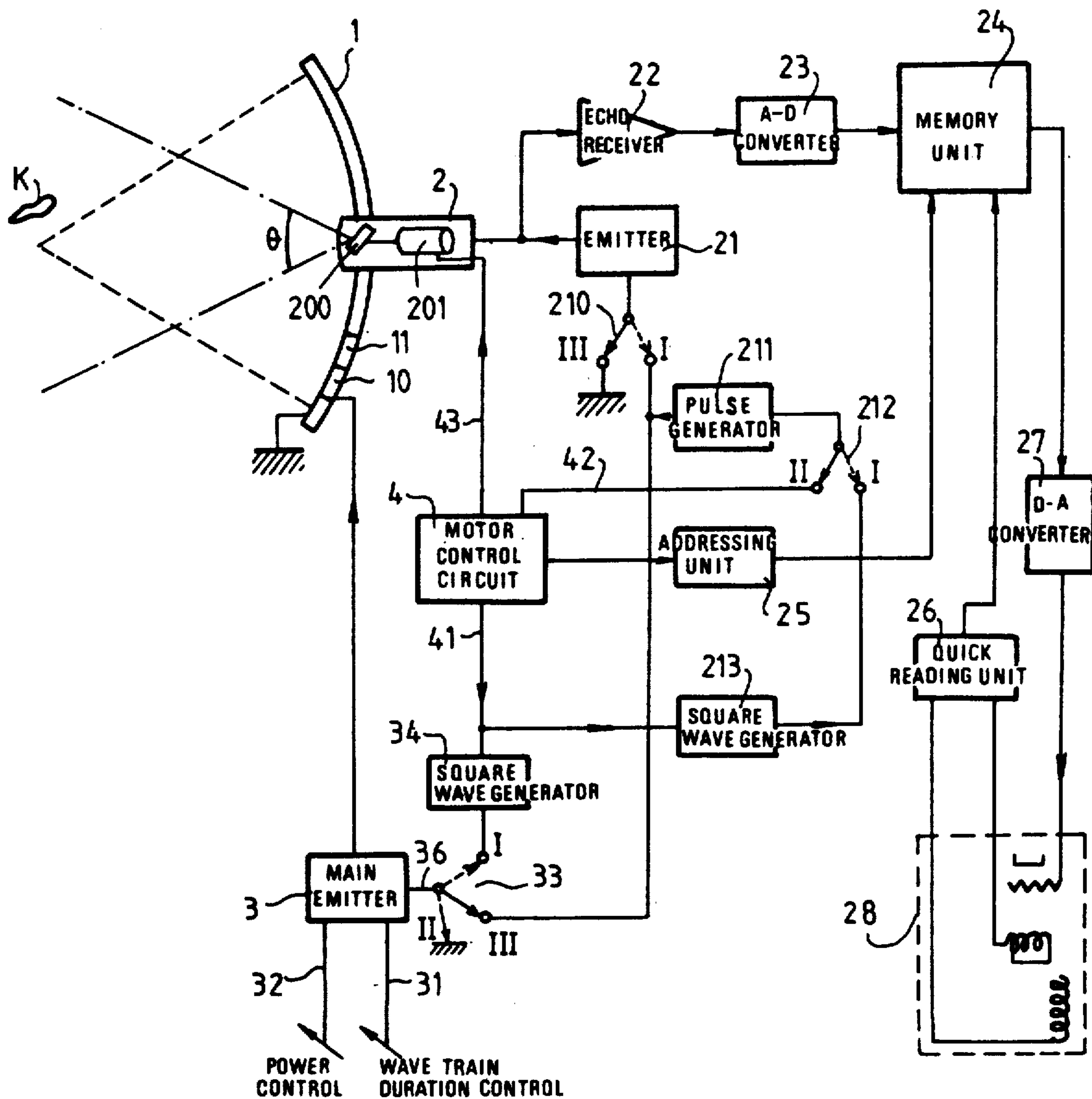


FIG. 2

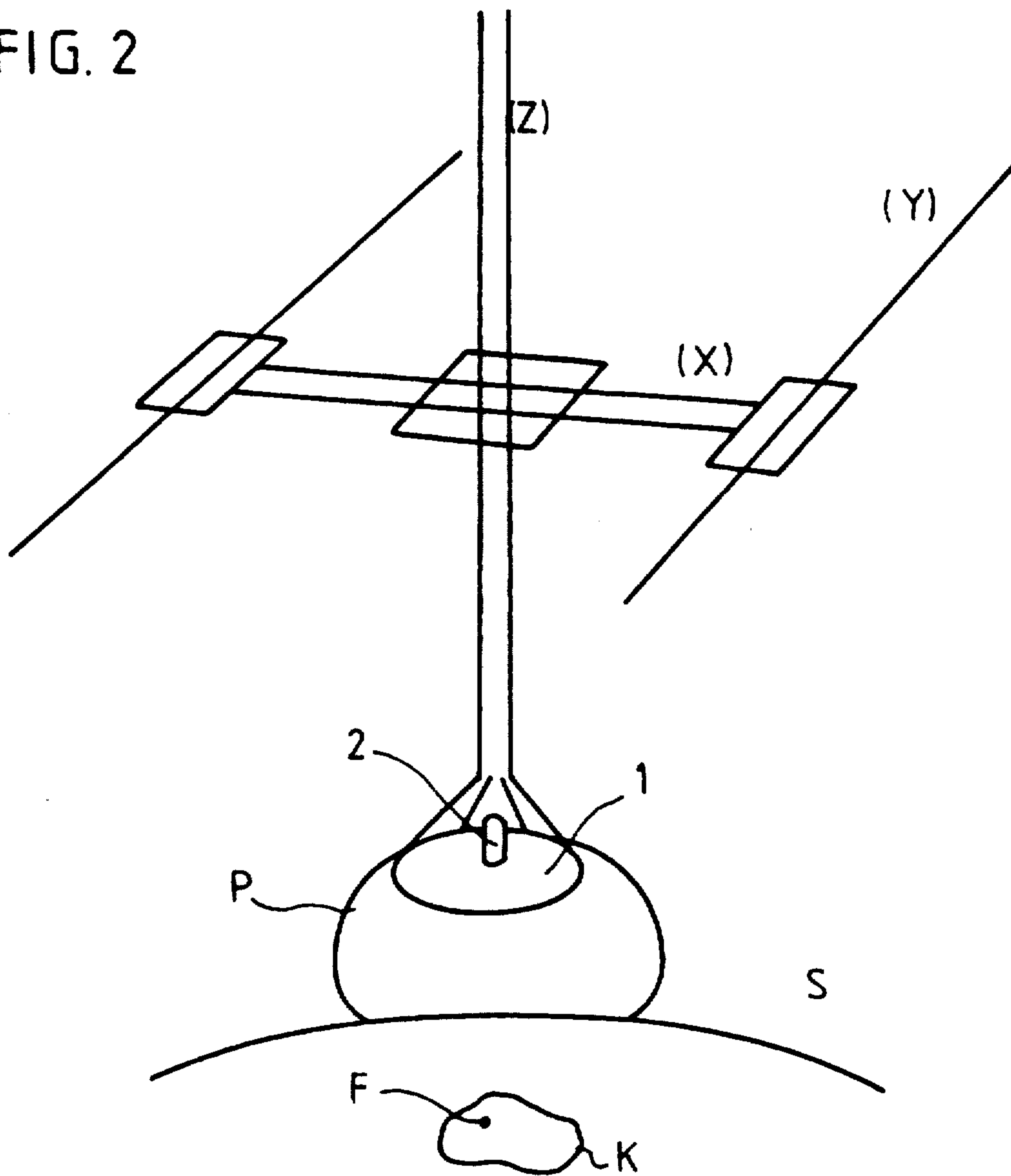


FIG. 4

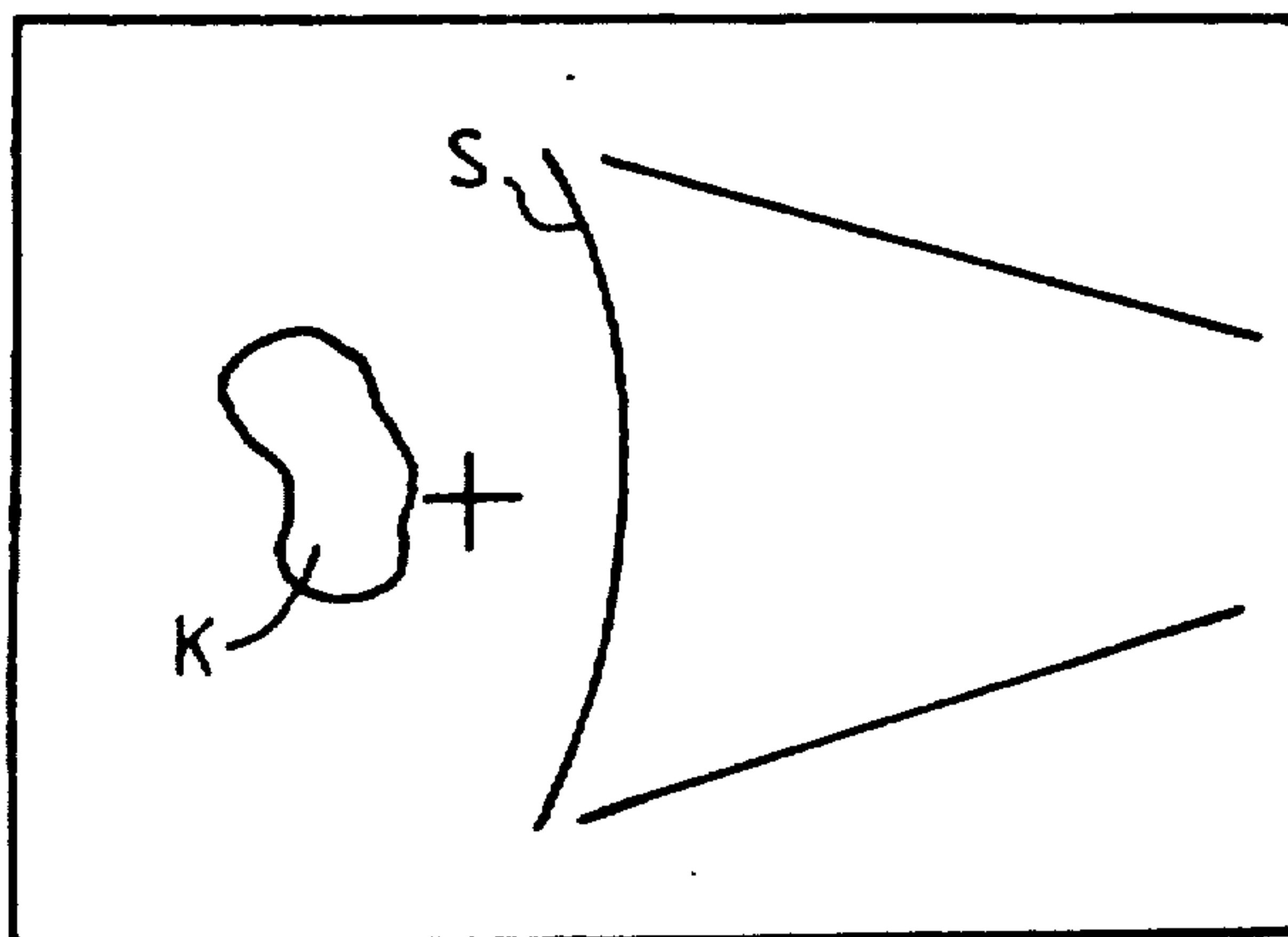
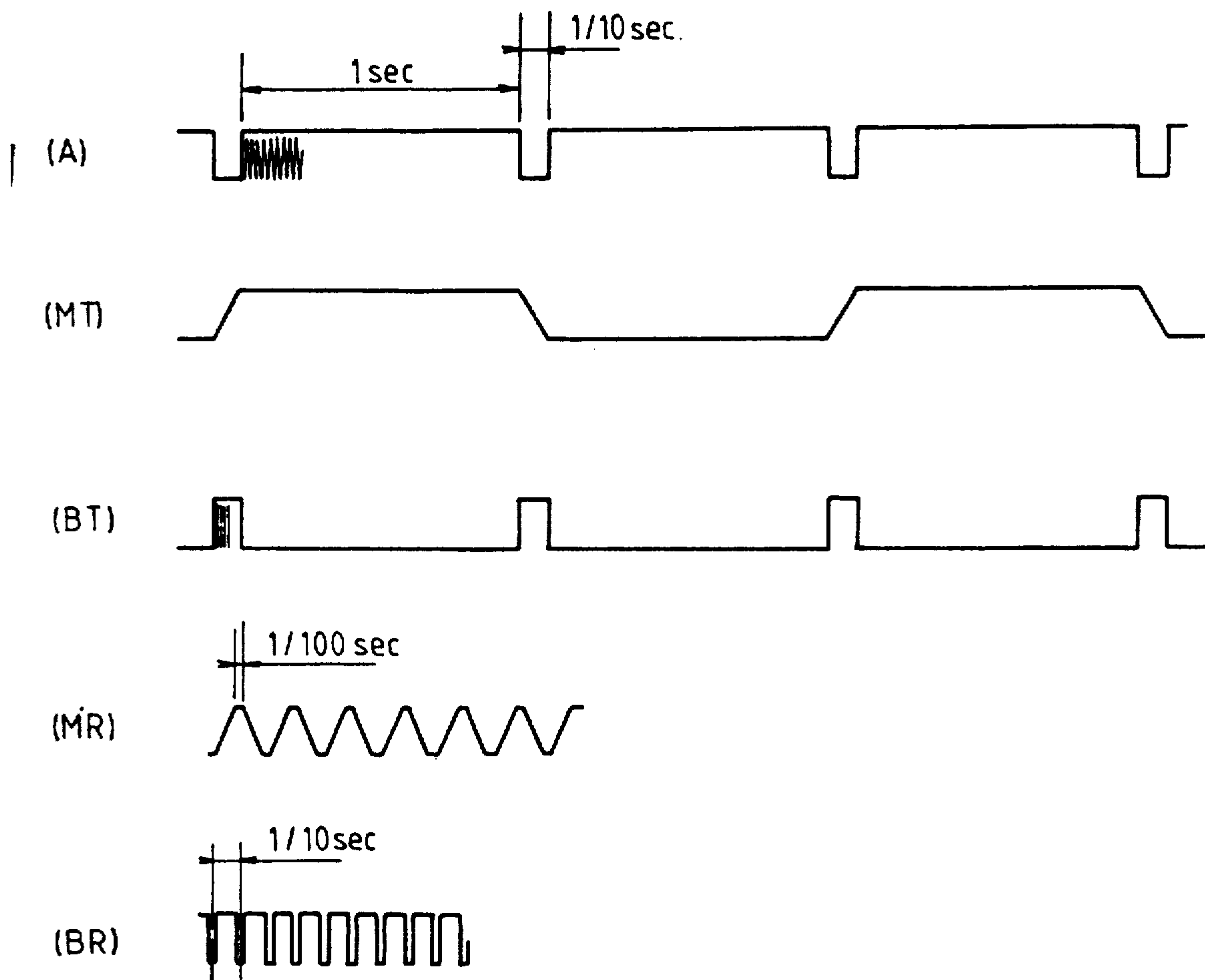




FIG. 3



## METHOD FOR EXAMINING, LOCALIZING AND TREATING WITH ULTRASOUND

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

### CROSS REFERENCE TO PRIOR APPLICATIONS

This application is a reissue of Ser. No. 06/728,405, filed 04/30/85, now U.S. Pat. No. 4,653,828 which is continuation-in-part of Ser. No. 06/674,884, filed 11/26/84, now U.S. Pat. No. 4,617,931, issued Oct. 21, 1986, on which reexamination certificate No. B1 4,617,931 issued July 12, 1988.

### BACKGROUND OF THE INVENTION

Conventional echography apparatus are obviously used for examining tumours inside the body by forming an image thereof on the screen of a cathode ray tube.

As is known, it is also possible to obtain destruction of the cells—in particular malignant cells—by subjecting them to a more or less extended temperature rise. The cells to be destroyed must for example be brought to about 45° C. in a well controlled way while avoiding reaching excessive temperatures which could cause serious burns around the lesion. The technical problem to be resolved consists then both in controlling the amount of energy and the localization thereof.

With the different prior processes (use of ultrahigh frequencies, infrared radiation, and others) superficial tumours can be treated but deeper tissues cannot be reached.

The invention proposes applying ultra sounds to the examination and hyperthermia treatment and provides an apparatus which combines the three functions of localizing the zone to be treated, of treating by raising the temperature in a well controlled way in a well defined restricted region within this zone and simultaneously checking the results of the treatment.

### SUMMARY OF THE INVENTION

The hyperthermia treatment apparatus of the invention combines a generator of a focused ultra sonic beam comprising a main high frequency electric wave emitter and a main piezoelectric transducer whose active surface is focusing, with an echography device comprising an auxiliary high frequency electric pulse generator associated with an auxiliary piezoelectric transducer and with means for causing the zone to be treated to be swept by the ultrasonic examination beam being generated by the auxiliary transducer; and with switching and adjusting means for causing, during main treatment and checking operation, the emission of said focused beam by the main transducer energized by the main emitter during periodic time intervals separated by shorter time intervals during which the emission of the examination beam and the formation of echographic images are carried out.

The apparatus advantageously comprises a first auxiliary locating operation mode during which only the periodic emission of the examination beam by the auxiliary transducer is effected and preferably a second auxiliary operating mode for checking the focal region, during which only the periodic emission of the focused beam is effected, but the main emitter is synchronized by the synchronization circuit of the auxiliary generator

for echographic operation, the time intervals which separate the successive emission periods during the two auxiliary operation modes being substantially smaller than the intervals which separate the periods of emission of the focused beam during the main mode.

It follows from the foregoing that, during the auxiliary operating modes for obtaining accurate adjustments, the quality of the echographic image, either of the zone to be treated (locating mode) or of the focal region (mode for checking the restricted region), will be substantially better than during the treatment mode, during which the successive images of the zones to be treated will follow each other for example at intervals of the order of a second, which however allow the position of the focal region to be checked satisfactorily during treatment.

In a preferred embodiment, the auxiliary transducer is fixed to the spherical surface of the main transducer and thus, during movement of this latter for bringing the focal spot into successive restricted regions of the tumour, the auxiliary transducer will at all times supply an image of the treated region and of the zone which surrounds it, thus allowing a permanent check of the treatment to be effected easily and accurately.

### BRIEF DESCRIPTION OF THE DRAWINGS

Other features and advantages of the invention will be clear from the following description.

In the accompanying drawings:

FIG. 1 is the general diagram of a hyperthermia apparatus according to a preferred embodiment of the invention;

FIG. 2 shows schematically in perspective the main transducer and its mobile support device;

FIG. 3 shows the wave forms at different points of the circuits of the apparatus; and

FIG. 4 illustrates the image obtained on the display screen which the apparatus comprises.

### DESCRIPTION OF THE PREFERRED EMBODIMENT

In FIG. 2 is shown a main transducer 1 in the form of a spherical skull cap supported by a mount which allows it to move along three orthogonal axes X, Y and Z. This mount has been shown schematically, its construction being within the scope of a man skilled in the art. Along the axis of the spherical skull cap is disposed an auxiliary transducer 2 of a generally cylindrical shape which passes through skull cap 1 and is fixed thereto. A pocket of water P is placed between the skull cap 1 and the surface S of the body of the patient, who is assumed lying flat on a horizontal plane.

The skull cap 1 has for example a diameter of 200 to 300 mm and is formed from a large number (300 or 400) of piezoelectric elements 10, 11, etc. . . . (FIG. 1) isolated from each other and juxtaposed so as to form a mosaic. These elements are metallized on both faces, one of the metallizations being connected to ground and the other to connections for energization by a main emitter 3.

This latter delivers an electric signal A (FIG. 3) formed of high frequency wave trains (500 KHz for example) of a relatively low peak power (about 10 or a 100 watts for example), but of a relatively long duration (for example of the order of a second) separated by time intervals of the order of 1/10 second, the time required for the echography device to form an image. It is then



a question of operating conditions using substantially continuous emission for the treatment. Such operating conditions may be obtained by means of emitters using power transistors. Preferably, the elements of transducer 1 will be divided up into groups each energized by a separate emitter (rectangle 3 symbolizing the assembly of these emitters), the elements of each group being spaced apart in the same circular zone of the spherical surface. By adjusting the relative phases of the emissions, it is possible to modify the energy distribution in the focusing region of the ultra sonic beam.

An input 31 to emitter 3 symbolizes an adjustment of the emitted power and an input 32 symbolizes an adjustment of the wave train duration. The focal spot formed in the center F of the sphere may, with this technique, be very small (diameter of 2 or 3 mm for example) and have a position which is strictly fixed for a given position of the transducer.

In FIG. 1 it can be seen that the auxiliary transducer 2 is itself connected both to a high frequency electric pulse emitter 21 and to a reception amplifier 22 followed by an analog-digital converter 23, itself followed by a memory 24. Emitter 21 is synchronized by a pulse generator 211 which delivers 256 pulses during each of the successive time intervals of 1/10 second. To each of these time intervals there corresponds a complete sweep of a given angular sector  $\phi$  (FIG. 1) by the beam emitted by transducer 2 so the formation, in the sweep plane, of an image of the zone observed by the echography device.

Transducer 2 is advantageously of the type described in U.S. Pat. No. 4,418,698 granted on Dec. 31, 1983, for: "Ultrasonic scanning probe with mechanical sector scanning means", that is to say that it comprises an oscillating piezoelectric element 200 controlled by a motor 201, itself controlled by an electronic circuit which is shown symbolically by a rectangle 4. This electronic circuit provides control signals for the motor 201 housed inside the case of the transducer 2 and is adapted so that a complete oscillation of the motor corresponds to the above defined duration for forming an image (1/10 sec.).

In a first operating mode (treatment and checking) switch 210 is in position I as well as switches 212 and 33.

In position I of switches 33 and 212, generator 211 is synchronized by a first output 41 of circuit 4, and this latter is then adjusted, by means not shown, for generating at its output 43 connected to motor 201 signals having the wave form (MT) shown in FIG. 3. An image is swept then in 1/10 sec. and is followed by a time interval of 1 sec. during which the oscillating element 200 remains immobile, so that transducer 2 receives no echos.

During the intervals between the sweep periods, a circuit 34 generates square waves of 1 sec. which serve for synchronizing emitter 3 whereas, during the sweep periods, a circuit 213 generates square waves of 1/10 sec. which serve for synchronizing the generator 211.

Thus, in this operating mode, transducer 1 generates an ultra-sonic beam under substantially continuous operating conditions whereas the echography device forms an image every second in the intervals between the wave trains. At (BT) has been shown the wave forms of the signals then emitted by generator 211.

In a second operating mode (locating) with switch 210 in position I, switch 33 is in position II, so that emitter 3 is not synchronized and the focused ultrasonic beam is not emitted. Switch 212 is also in position II so

that generator 211 is synchronized by a second output 42 of circuit 4 and this latter is adjusted so as to generate at its output 43 signals having the wave forms (MR) shown in FIG. 3. The 1/10 sec. sweeps are then separated by time intervals of 1/100 sec. only and the images are formed from echos coming from the reflection of the pulses generated by transducer 2. Generator 211 delivers the signals (BR).

In a third operating mode (checking the focal region), switch 210 is in position III, so that the emitter 21 and transducer 2 do not emit. Switch 212 is again in position II so that generator 211 is synchronized by the output 42 of circuit 4 and this latter is adjusted as in the second operating mode so that the 1/10 sec. sweeps are again separated by intervals of 1/100 sec. Switch 33 is in position III and consequently emitter 3 is now synchronized by the generator 211 which then delivers the signals (BR).

In this operating mode, the echographic device is therefor formed by emitter 3, transducer 1 operating for emission and transducer 2 operating for reception. The result is that an image of the zone of concentration in the focal region of the energy emitted by the transducer 1 is obtained.

The echographic signals received at 22 in the first or third operating modes are, after analog-digital conversion at 23, stored line by line in memory 24, a writing addressing device 25, controlled by circuit 4, causing the respective deflection angles of the beam emitted and/or received by transducer 2 to correspond with the respective lines of the memory. A device 26 for rapid reading of the memory energizes the X and Y deflection coils of a cathode ray tube 28, so the brightness control electrode receives the corresponding contents from memory 24, transformed into an analog signal by a digital-analog converter 27.

The practical construction of all the circuits described and shown is within the scope of a man skilled in the art. The control circuit 4 may for example comprise a one shot multivibrator delivering square waves of a duration adjustable to 1/100 s or is depending on the operating mode and circuits for generating increasing and decreasing voltages of a 1/10 s duration, triggered off by said square waves.

The apparatus which has just been described operates as follows:

In the locating operating mode, the operator searches for and localizes the zone to be treated. The display device is adapted, in a way known per se, so as to materialize on the screen of the cathode ray tube (for example by means of a cross) the theoretical position of the focal spot in the sectional plane shown, which plane passes through the axis of symmetry of transducer 1. (It is a question of B type echography). The operator begins by moving transducer 1 along X, until the tumour appears clearly on the screen, then he moves it along Y and Z, until the cross coincides with the central region of the image of the tumour (K, FIG. 4). At this moment, the switches may be placed in position for checking the focal region: only this latter is then made visible on the screen, with a luminosity proportional to the corresponding energy concentration. Thus a representation is obtained of what the distribution of the energy of the treatment wave will be, which allows the adjustments to be checked and perfected.

During treatment, the apparatus only supplies one image per second, but this rate is sufficient for substan-



tially permanently checking the position of the focal spot.

It is clear that the apparatus described allows the evolution of the tumour to be checked after each treatment sequence. It is evident that different modifications may be made thereto and even according to other embodiments, without departing from the scope and spirit of the invention.

What is claimed is:

1. Apparatus for ultrasonically heating a subject volume comprising:

- (i) a first transducer having a curved transmitting surface for generating a single first ultrasound beam focused in a restricted focal zone and drive means for exciting ultrasonic vibrations within the first transducer;
- (ii) means for displacing the first transducer with respect to predetermined axes of coordinates successively to irradiate subject volume with said ultrasound beam focal zone;
- (iii) a second transducer for generating a second ultrasound beam, said second transducer having an active surface which is substantially smaller than that of the transmitting surface of the first transducer, said second transducer having a point which is fixed with the first transducer during the displacement of the first transducer, and
- (iv) an echography device comprising said second transducer, electric pulse generator means coupled to said second transducer, means for effecting a scanning of an examination volume with the second ultrasound beam, receiver means coupled to said second transducer for receiving the echoes formed through reflection of the second ultrasound beam on reflecting surfaces within the examination volume and image forming means coupled to the receiver means for displaying images of the examination volume, said focal zone being located in a predetermined relative position within the examination volume, and said image forming means further displaying a mark which materializes said predetermined position of the focal zone.

2. Apparatus as claimed in claim 1, wherein said first transducer is formed by a mosaic of piezoelectric elements isolated from each other and forming a spherical skill cap supported by said displacing means, said skill cap having a top, said displacing means being adapted for controlling the displacement of the first transducer along three orthogonal axes, whereas the second transducer is fixed to the top of said skill cap and said means for effecting a scanning of the second ultrasound beam provide a sectorial sweep of said second beam in a plane which passes through the axis of symmetry of said skill cap.

3. Apparatus for ultrasonically heating a subject volume comprising:

- (i) a first transducer having a curved transmitting surface for generating a single first ultrasound beam focused in a restricted focal zone and drive means for exciting ultrasonic vibrations within the first transducer;
- (ii) means for displacing the first transducer with respect to predetermined axes of coordinates successively to irradiate subject volume with said ultrasound beam focal zone;
- (iii) a second transducer for generating a second ultrasound beam, said second transducer having an active surface which is substantially smaller than

that of the transmitting surface of the first transducer, said second transducer having a point which is fixed with the first transducer during the displacement of the first transducer;

- (v) an echography device comprising said second transducer, electric pulse generator means coupled to said second transducer, means for effecting a scanning of an examination volume with the second ultrasound beam, receiver means coupled to said second transducer for receiving the echoes formed through reflection of the second ultrasound beam on reflecting surfaces within the examination volume and image forming means coupled to the receiver means for displaying images of the examination volume, said focal zone being located in a predetermined relative position within the examination volume, and said image forming means further displaying a mark which materializes said predetermined position of the focal zone;
  - (v) said drive means exciting ultrasonic vibrations within the first transducer during periodic time intervals which are separated by first blanks of substantially smaller duration;
  - (vi) said echography device further comprising means for controlling the generation of electric pulses by said generator means during second periodic time intervals having the same duration as said first blanks and separated by second blanks, and
  - (vii) switchable synchronization means having first and second operating modes for effecting coincidence of each of said second blanks with said first time intervals and setting the drive means into operation during the first mode and for effecting coincidence of a plurality of said second time intervals and the associated second blanks with each of the first time intervals and setting the drive means out of operation during the second mode.
4. Apparatus for ultrasonically heating a subject volume comprising:
- (i) a first transducer having a curved transmitting surface for generating a single first ultrasound beam focused in a restricted focal zone and drive means for exciting ultrasonic vibrations within the first transducer;
  - (ii) means for displacing the first transducer with respect to predetermined axes of coordinates successively to irradiate subject volume with said ultrasound beam focal zone;
  - (iii) a second transducer for generating a second ultrasound beam, said second transducer having an active surface which is substantially smaller than that of the transmitting surface of the first transducer, said second transducer having a point which is fixed with the first transducer during the displacement of the first transducer;
  - (iv) an echography device comprising said first and second transducers, electric pulse generator means coupled to said second transducer, means for effecting a scanning of an examination volume with the second ultrasound beam, receiver means coupled to said second transducer for receiving the echoes formed through reflexion of an examination ultrasound beam on reflecting surfaces within the examination volume and image forming means coupled to the receiver means for displaying images of the examination volume, said focal zone being located in a predetermined relative position within the examination volume, and said image



7

forming means further displaying a mark which materializes said predetermined position of the focal zone;

(v) switchable synchronization means having first, second and third operating modes;

(vi) during said first and second operating modes, said drive means exciting ultrasonic vibrations within the first transducer during first periodic time intervals which are separated by first blanks of substantially smaller duration;

(vii) said echography device further comprising means for controlling the generation of electric pulses by said generator means during second periodic time intervals having the same duration as said first blanks and separated by second blanks;

(viii) said synchronization means effecting coincidence of each of said second blanks with said first

8

time intervals and setting the drive means into operation during the first mode and effecting coincidence of a plurality of said second time intervals and the associated second blanks with each of the time intervals and setting the drive means out of operation during the second mode; and

(ix) said synchronization means decoupling said electric pulse generator means from the second transducer during said third operating mode and coupling said electric pulse generator means to the first transducer, whereas said electric pulse generator means is synchronized for effecting coincidence of a plurality of said second time intervals and the associated second blanks with each of the first time intervals.

\* \* \* \* \*

20

25

30

35

40

45

50

55

60

65