PRODUCT TECHNICAL REPORT

EDAP LT-01

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Nephrolithiasis (kidney stones) and cholelithiasis (gallstones) are common diseases with a morbidity rate of approximately 3% for kidney stones and 10% for gallstones of the total U.S. population. Patients with stones which are too large to be naturally eliminated by the human body generally must have extensive surgical procedures with lengthy stays in the hospital.

Extracorporeal shock wave lithotripsy (ESWL) is a noninvasive technique that enables the remote fragmentation of renal and biliary calculi. ESWL uses extracorporeally generated shock waves that are focused on the calculi and causes its fragmentation.

This paper includes a description of the EDAP LT-01 (EDAP International, Boston, MA, USA) piezoelectric extracorporeal shock wave lithotripter and the principles of its operation.

The EDAP LT-01 extracorporeal shock wave lithotripter is a compact system that uses 320 piezoelectric transducers activated by electronic generators to produce the shock wave. This is a monofocal system, i.e., the energy produced by the piezoelectric elements is not reflected before its convergence on the focal point and the renal stone. The piezoelectric elements are dispersed across the surface of a spherical cup that has a single focal point. All of the piezoelectric elements generate pulses simultaneously and in phase (coherent source). The energy waves produced by the piezoelectric elements are concentrated onto the focal point by the spherical shape of the cup. The spherical cup is part of a maneuverable treatment head that can be positioned so that the focal point of the spherical cup coincides with a target calculus. The converging pressure waves produced by the piezoelectric elements causes the destruction of the stone.

In addition to generating the shock waves, the EDAP LT-01 uses ultrasound imaging for stone localization instead of x-ray imaging. A 3.5 MHz sectorial ultrasound imaging probe is an integral part of the EDAP LT-01 treatment head. Its imaging field includes the focus of the treatment head. The operator is able to use the ultrasound image to locate the calculus and maneuver the treatment head so that its focus precisely coincides with the target stone. In addition, the destruction of the stone can be monitored continuously, in real time, on the screen of the ultrasound scanner.

The shock waves and the imaging acoustic waves are transmitted through an adjustable level water pocket covered by an elastic membrane above the spherical cup. The membrane is placed in contact with the patient and efficient coupling is assured by using conducting gel between the membrane and the patient's skin.

Generation of shock waves with the EDAP LT-01 can be precisely adjusted so that the treatment can be individualized for each patient. The shock wave generation system of the EDAP LT-01 allows the shock wave energy per pulse and the frequency of the pulses to be easily adjusted by the operator.

Functional Description

The EDAP LT-01 lithotripter, pictured in Figure 1, consists of the following major components:

—Treatment head and support
—Electronic generator
—Ultrasound scanner
—Control console
—Treatment table
—Power supply
—Optional peripheral equipment

Treatment Head and Support

The treatment head, illustrated in Figure 2, is a major element of the EDAP LT-01 system and

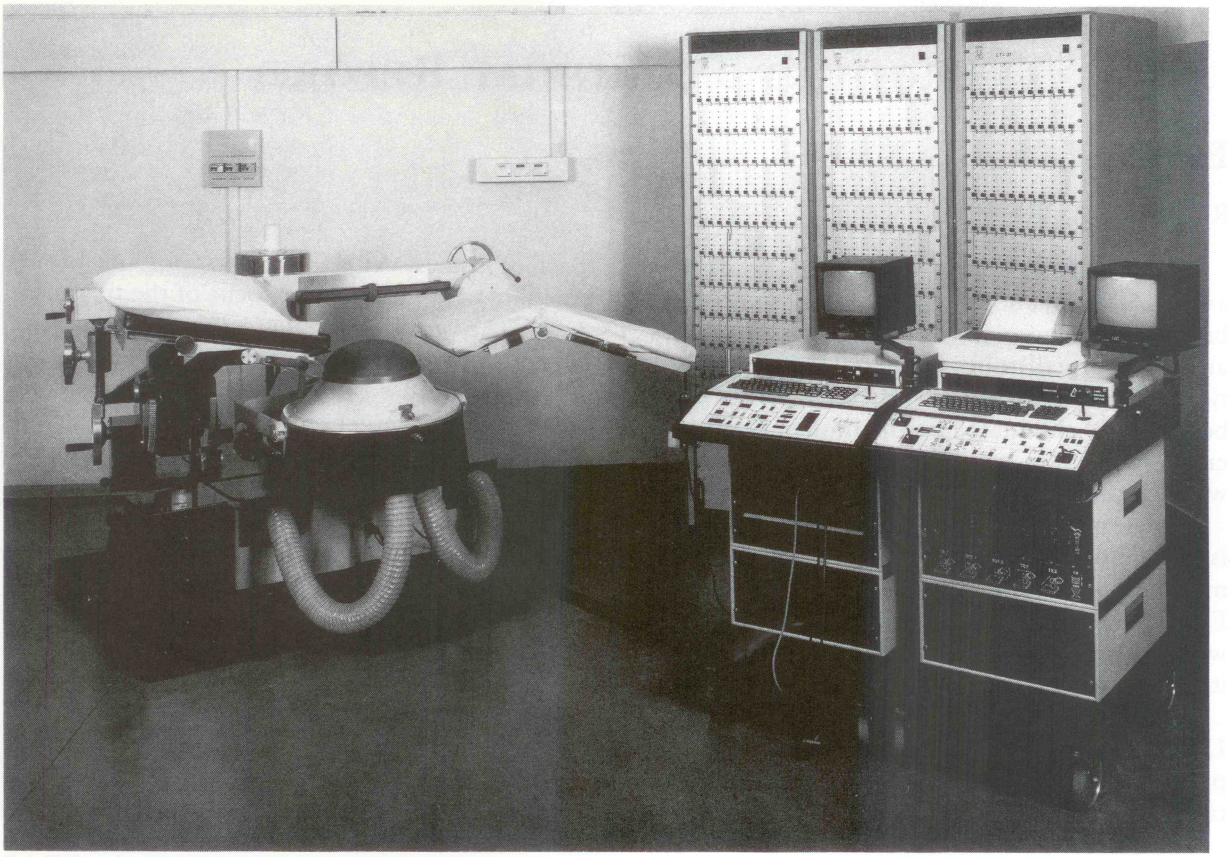


Figure 1.

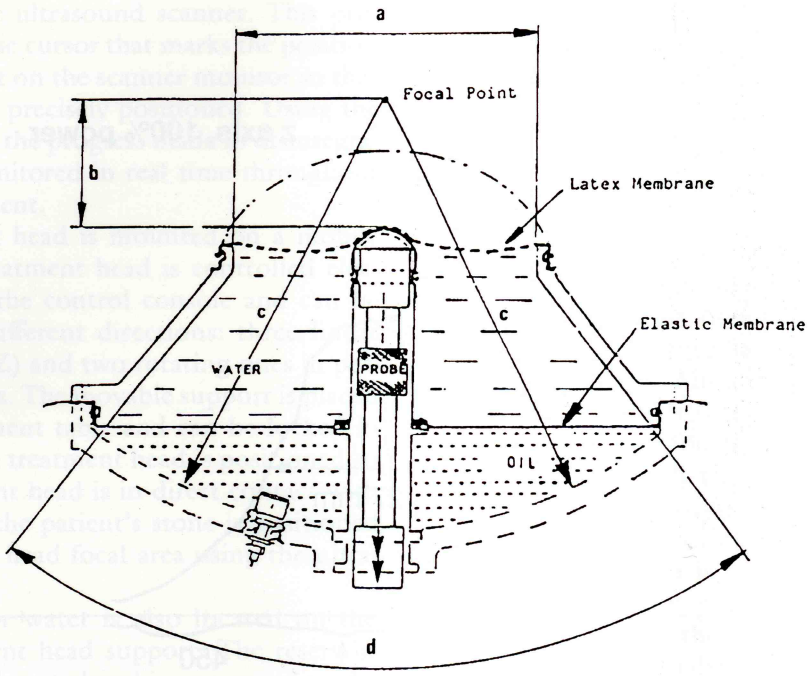
serves two purposes: it combines an ultrasound imaging probe for localization of the stone and a piezoelectric system for the destruction of the stone, both of which are housed in a fluid-filled container.

The stone destruction system is based on the convergence on a single focal point of a series of ultra-short (less than 1 microsecond) shock wave pulses generated by 320 ceramic piezoelectric elements. The piezoelectric elements are uniformly distributed across the surface of a segment of a spherical cup and around the ultrasound imaging transducer. In this way they are all focused on the same point located at the center of the sphere. Each piezoelectric element is excited by a separate emitter module in the electronic generator. A shock wave is produced when all 320 piezoelectric elements are pulsed in synchrony and the resulting individual pressure waves are focused exactly at the center of the sphere which constitutes the focal point.

There are 320 piezoelectric elements mounted on the surface of the spherical cup. Each of the piezoelectric elements has a surface area of 3.15 cm^2. Thus, the total transmitting surface area is approximately 1005 cm^2 spread out over the area of the spherical cup.

The spherical segment of the cup with the piezoelectric elements is covered with insulating oil. An elastomer membrane separates the oil from the water chamber.

The water chamber is made of a light alloy cone placed over the spherical cup and closed at its upper part with a flexible latex membrane. The chamber has variable height that is adjusted by adding or removing water. The latex membrane is placed in contact with the skin of the patient, therefore eliminating any water immersion. An ultrasound conducting gel is placed on the membrane to ensure good contact between the membrane and the patient's skin. By inflating or deflating the water chamber, the distance between



a = Diameter of Treatment Head = 306 mm

b = Distance to Focal Point (Fully Inflated) = 146 mm

c = Radius of Spherical Cup = 446 mm

d = Angle of Emitting Surface = 76 degrees

Figure 2.

the focus and the surface of the membrane can be varied from 0 to about 14.6 cm. The pulse produced by the piezoelectric elements is very brief (Fig. 3). The rise time is 44 ns and the pulse width is 76 ns. This briefness reduces the risk of damage to biological tissues.

Average maximum peak pressure is 1031 atm, using a calibration for the hydrophone of 5.87 mV/atm. The pressure pulse falls as rapidly as it rises and does not possess any significant negative components. The size of the focal point is approximately 2.3 mm by 23 mm (Fig. 4).

The distribution of peak pressures, both positive and negative, are shown on Figure 5 for Z axis at 100% power.

A real-time 3.5 MHz sectorial ultrasound probe is fitted through a cylindrical sleeve at the center of the treatment head. The probe is connected to the ultrasound scanner. The probe is a rotating transducer and provides longitudinal and transverse images and all oblique views.

The ultrasound probe provides an image of the area around the focal point of shock waves that is

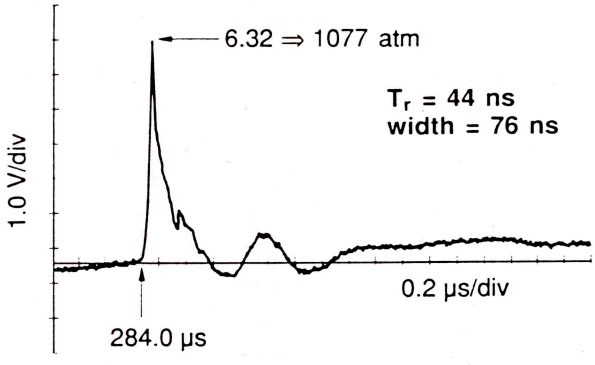


Figure 3.

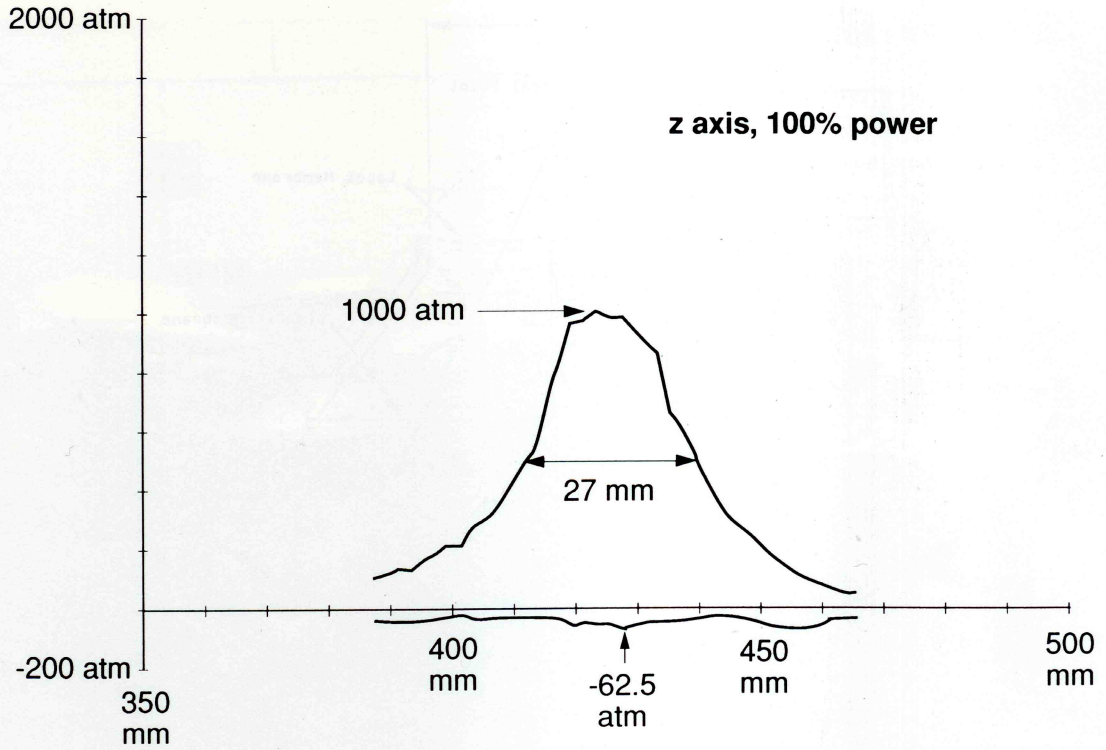


Figure 4.

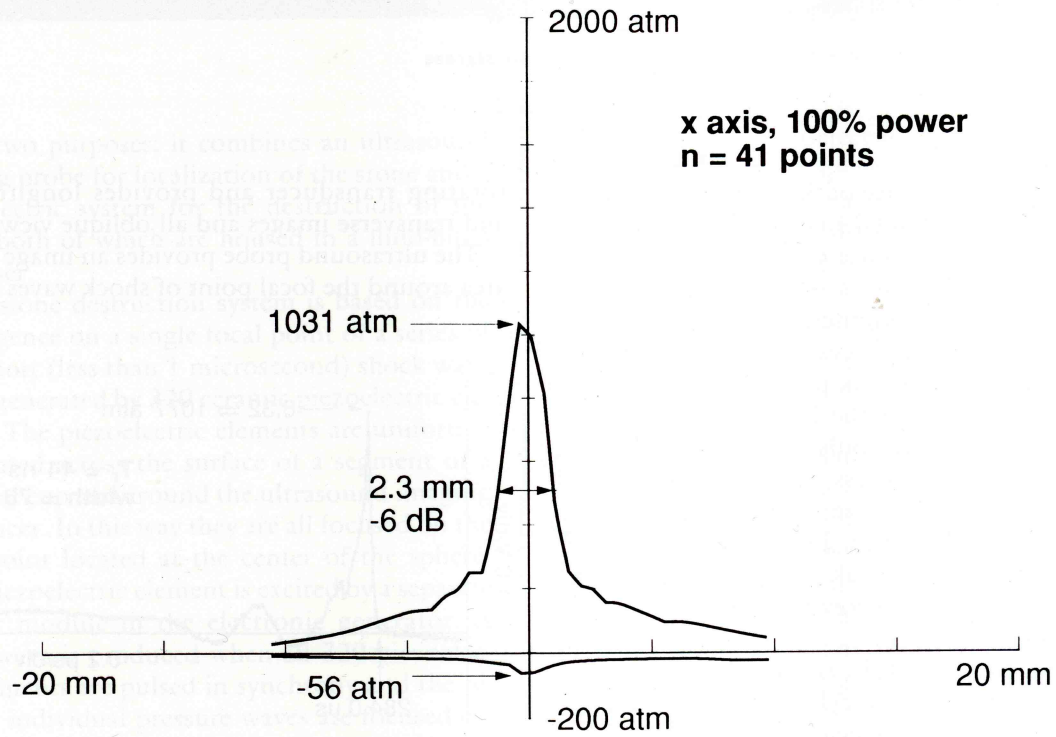


Figure 5.

displayed on the ultrasound scanner. This provides an electronic cursor that marks the position of the focal point on the scanner monitor so that the stone can be precisely positioned. Using the displayed image, the progress made in disintegration may be monitored in real time throughout the entire treatment.

The treatment head is mounted on a mobile support. The treatment head is controlled electronically from the control console and can be moved in five different directions: three linear ones (X, Y, and Z) and two rotating ones in perpendicular planes. The movable support is placed under the treatment table and can be locked in place. In use, the treatment head is positioned so that the treatment head is in direct contact with the patient and the patient's stone is positioned in the treatment head focal area using the ultrasound scanner.

A reservoir for water is also located on the movable treatment head support. The reservoir can be raised or lowered and is connected to the treatment head with a flexible tube. It supplies water to fill the treatment head. Since the treatment head can be oriented in all directions, the best firing axis can be selected. The energy delivered can be adjusted by means of a potentiometer on the control console. The rate of firing can be varied from 1.2 to 160 shots per second. In most applications, firing rates below 5 or 10 shots per second are used to reduce the pain level and avoid the use of anesthetics.

Electronic Generator

The electronic generator is the powering unit for the piezoelectric elements on the treatment head. The generator contains 320 emitter modules mounted in 32 racks and distributed in three cabinets (two cabinets have 11 emitter module racks and one cabinet has 10). The 320 emitter modules contain high-power semiconductors which excite the corresponding piezoelectric elements arranged in the spherical segment of the treatment head.

The frequency of firing is controlled from the electronic generator central rack. Firing frequencies can be selected from a front panel control and can have the following values: 1.25, 2.5, 5, 10, 20, 40, 80, or 160 Hz.

Ultrasound Scanner

The ultrasound scanner is composed of four major parts:

a. Localization controls: The controls used for localization of the stone are found on the front of the scanner.
b. Computerized localization system and monitor: This system generates and manages graphic functions, onscreen comments, calculations concerning images, and parameters of use. An Acorn Microcomputer Model BBC Master, which is integral to the ultrasound scanner, is used for these functions. The computer is used only to display information and make calculations, and does not control the lithotripter. When the scanner is started, the computer system is turned on automatically and the operator is guided by the program. The position of the focal point of the treatment head is visualized on the monitor.
c. The ultrasound scanner is equipped with a circuit which detects the presence of the stone in the fact point and controls discharges according to this presence. This feature is used especially if the stone makes large movements due to the patient's breathing. When used, the circuit automatically fires the lithotripter only when an echo is detected in an area corresponding to the focus. The detection level is adjustable so that the echo presented by the stone can be selected from other echoes. This is called real-time targeting.
d. Probes: The EDAP LT-01 system is equipped with two probes which are wide in diameter so as to obtain optimal focalization. In both probes, the focusing is achieved through acoustic lenses mounted directly in the crystals. One of these probes is operated manually and the other one is an integral part of the treatment head.

The "hand-operated probe" is a standard mechanical sector probe operating at 4.8 MHz. The crystal diameter is 20 mm, the focus is in the range of 7 to 10 cm, and the maximum sweep angle is 90°. The probe is used to verify the position of the calculus and the possibility of access prior to the installation of the patient on the treatment table. This prior localization serves for

piloting the movement of the treatment head later. The "localization probe" is a 5 MHz or 3.5 MHz mechanical sector probe mounted in the center of the treatment head. It is coupled to the water bath through a water membrane to avoid any leakage of water. The treatment head, and therefore the localization probe, is movable in all directions by a remote control. The crystal diameter of the probe is 30 mm and the focus is in the range of 120–150 mm. This long focus is necessary to take into account the water path between the probe and the patient's skin. The localization probe is used for the precise, real-time imaging of the calculus prior to and during the treatment.

Control Console

The control console consolidates all system controls except those for the ultrasound scanner. The frame of the console is identical to that of the scanner and is placed to the right of it.

The control console is composed of three major parts:

a. Control panel: The control panel comprises all the controls. Significant controls include those for the selection of the motion of the treatment head and the different treatment modes.
   All displacements of the treatment head are controlled by joysticks and the coordinates of the position are displayed on the monitor of the control console. The treatment mode is determined by operator-adjustable controls which define the rate of shots and the amplitude of the shock waves. All necessary information concerning the treatment is displayed on the monitor; for example, the maximum power, the mean power, the total energy produced, the number of shots, etc. Either manual or automatic firing modes can be selected. In automatic firing mode, the lithotripter fires only when the echo of the stone is detected within the focal point.
b. Computerized control system and monitor: An Acorn Microcomputer Model BBC Master is integrated into the control console and is used to display information relative to the position of the treatment head, record the patient's file, and drive a printer for reports. When the control is turned on, the program is automatically loaded and ready to operate.
c. Manual control switches: These switches are located on the lower front of the control console and may be used to manually position the treatment head.

Treatment Table

The treatment table is a multiposition table that allows the placement of patients in various positions useful in urology. The table allows a plain X ray or fluoroscopic image to be performed by horizontal rotations. The table is also fitted with two leg pieces which are useful for endoscopic manipulations concomitant with extracorporeal lithotripsy; for example, flushing of ureteric stones.

Power Supply (Isolation Transformer)

The power supply acts as an interface between the user and the lithotripter and permits:

—Connection with the user's power system through its isolating switch which may be padlocked.
—Visual display of the "on" position switch and the lithotripter by the "on" indicator.
—Turning on of the lithotripter using its key switch.
—Protection of the user network by means of a built-in circuit breaker and its reset push-button.

Optional Peripheral Equipment

The EDAP LT-01 can also be connected to optional systems including:

—Any standard printer
—A disk drive
—Video recorder input and output
—Multi-image monitor
—A video output (625 line)

All in all, the EDAP LT-01 is an elegantly simple technical solution to lithotripsy. It is simple and low cost to operate, highly reliable, and offers a less traumatic patient lithotripsy procedure.