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United States Patent [19]

Montecalvo et al.

[11] **Patent Number:** 5,522,878[45] **Date of Patent:** Jun. 4, 1996[54] **SOLID MULTIPURPOSE ULTRASONIC BIOMEDICAL COUPLANT GEL IN SHEET FORM AND METHOD**[75] Inventors: **David A. Montecalvo**, Plymouth;
David Rolf, Minneapolis, both of Minn.[73] Assignee: **LecTec Corporation**, Minnetonka, Minn.[21] Appl. No.: **54,745**[22] Filed: **Apr. 26, 1993****Related U.S. Application Data**

[63] Continuation-in-part of Ser. No. 344,698, Apr. 28, 1989, Pat. No. 5,205,297, which is a continuation-in-part of Ser. No. 173,589, Mar. 25, 1988, abandoned.

[51] **Int. Cl.⁶** **A61B 8/00**[52] **U.S. Cl.** **607/152; 73/644**[58] **Field of Search** 128/24 AA, 639-641,
128/662.03, 663.01; 607/152, 97; 604/20;
73/644; 252/500; 601/2[56] **References Cited****U.S. PATENT DOCUMENTS**

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Primary Examiner—Krista M. Zele*Assistant Examiner*—Brian L. Casler*Attorney, Agent, or Firm*—James V. Harmon[57] **ABSTRACT**

A solid, multipurpose, flexible, ultrasonic biomedical couplant hydrogel in sheet form is applied to the skin of a patient to facilitate the transfer of ultrasound energy between a standard ultrasound instrument and the body. The couplant sheet has broad upper and lower surfaces and a narrow peripheral edge which is usually circular, square or rectangular but can have other shapes such as the shape of the part of the body being monitored. During use, the lower surface of the sheet is applied to the skin of a patient and remain in place throughout use. The ultrasound instrument is then passed back and forth, usually in contact with the exposed upper surface of the hydrogel sheet while ultrasound energy is transmitted through the hydrogel which serves as a transmission path for the sonic energy passing to and from the body of the patient. The hydrogel sheet of the present invention is a flexible, self-supporting solid sheet which holds its form during storage and when placed on the body. The sheet contains water and a humectant such as triethylene glycol or glycerin and a network of long hydrophilic polymer molecules that hold the liquid in place and give solidity to the hydrogel sheet. The polymer can comprise polyacrylamide, karaya gum or a modified starch.

23 Claims, 4 Drawing Sheets