



US005913309A

# United States Patent [19]

Sheehan et al.

[11] Patent Number: **5,913,309**

[45] Date of Patent: **Jun. 22, 1999**

- [54] **DISPOSABLE ELEMENT FOR USE WITH A HEARING SCREENER**
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- [73] Assignee: **Natus Medical Inc.**, San Carlos, Calif.
- [21] Appl. No.: **08/861,725**
- [22] Filed: **May 22, 1997**
- [51] Int. Cl.<sup>6</sup> ..... **A61F 5/37**
- [52] U.S. Cl. .... **128/846; 128/864; 2/209**
- [58] Field of Search ..... **128/846, 864-868; 2/209, 423, 455; 181/129**

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Primary Examiner—Michael A. Brown  
 Attorney, Agent, or Firm—Orrick, Herrington & Sutcliffe LLP

## [57] ABSTRACT

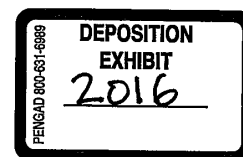
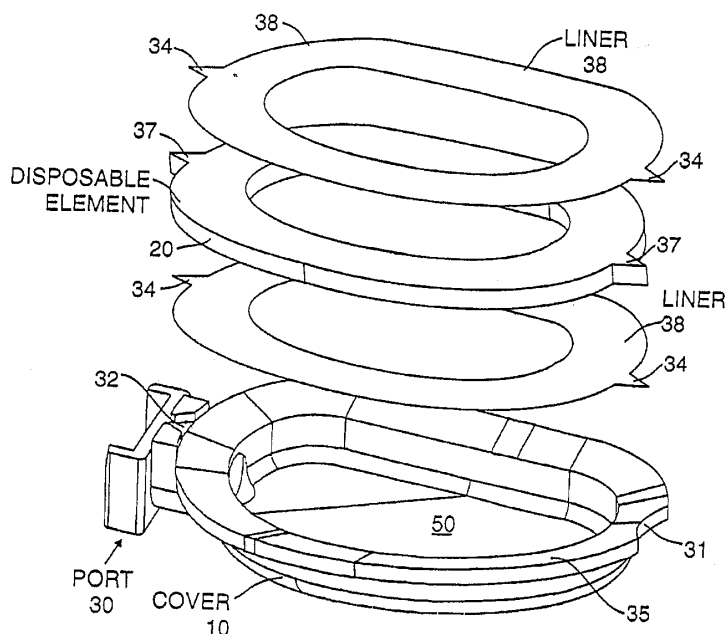
A disposable element for ear phone assembly is provided for use with a hearing screening instrument to test infants for hearing impairments. The ear phone assembly includes a generally D-shaped reusable cover including a back wall having a perimeter, a side wall extending from the perimeter to define a cavity for receiving an infant's ear, a port in the cover to receive and support a transducer, and a generally D-shaped disposable element that is adhesive coated on two sides to be secured to the cover and to the patient's head. The cover may have a notch located along the perimeter of the re-usable body for removing the disposable element. A liner is used to cover the disposable element adhesive sides to protect them from contamination during packaging and prior to use. The disposable element may have a die cut so that a portion of it can be removed to make the ear phone adjustable for infants with large ears. The ear phone is low in cost and capable of being used with any conventional hearing screening equipment.

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30 Claims, 3 Drawing Sheets



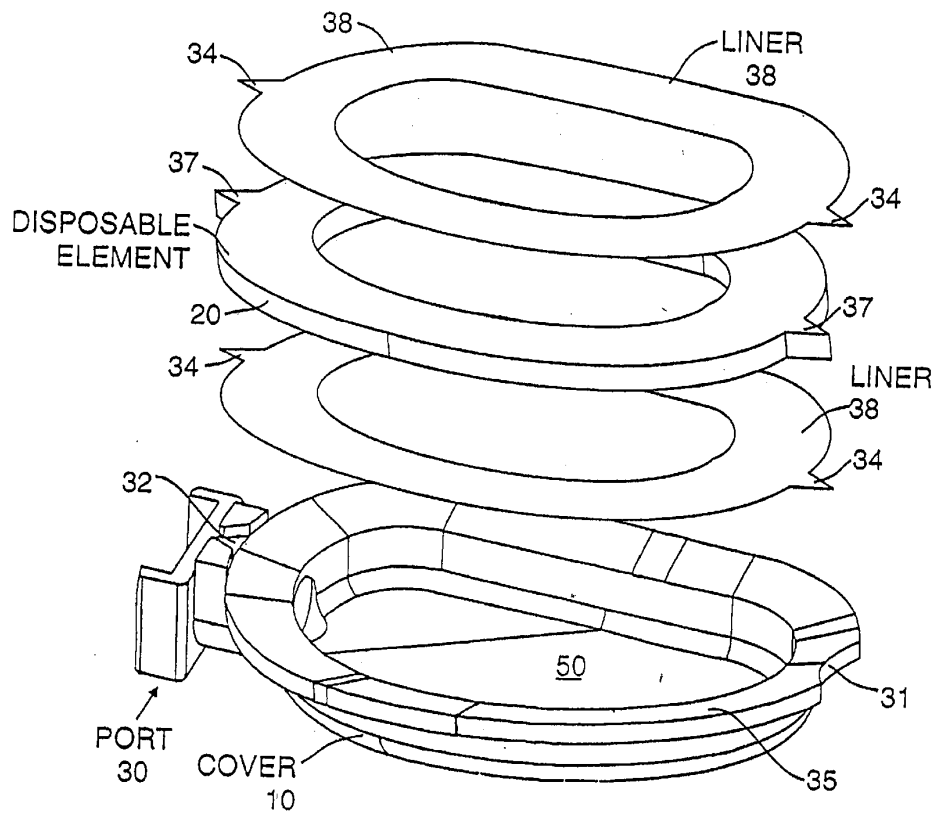


FIG. 1

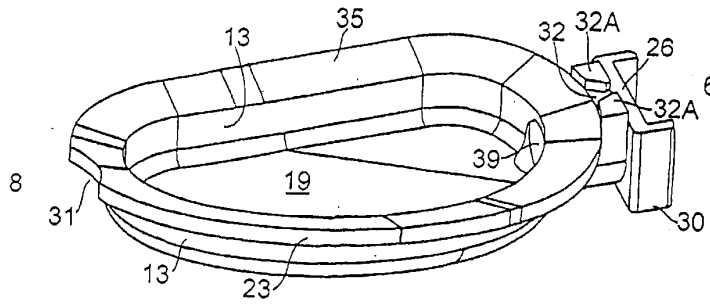


FIG. 2

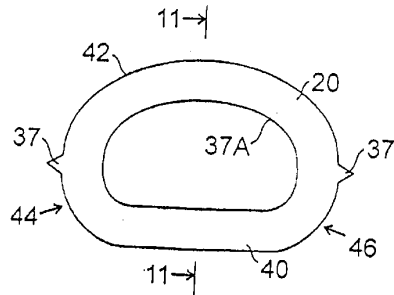


FIG. 9

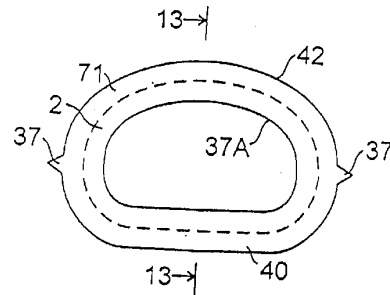


FIG. 11

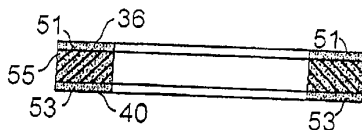


FIG. 10

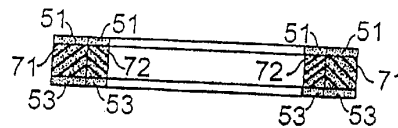


FIG. 12

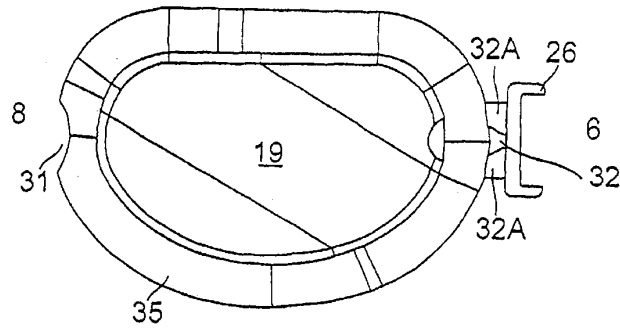


FIG. 3

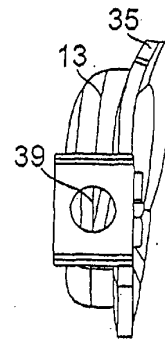


FIG. 6

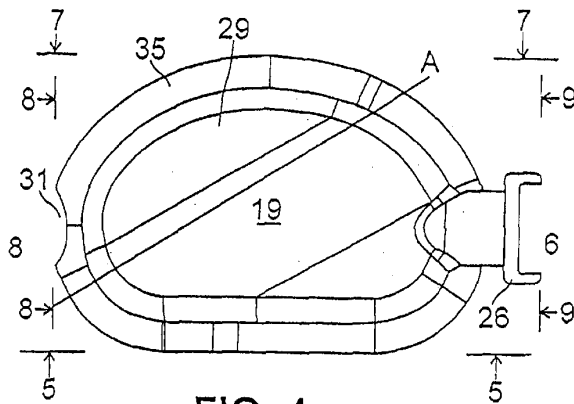


FIG. 4

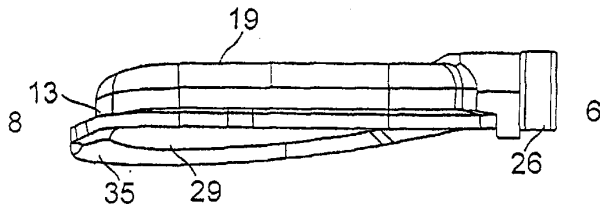


FIG. 5

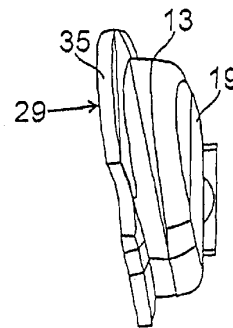


FIG. 8

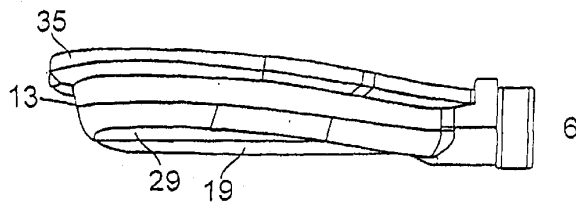


FIG. 7

## DISPOSABLE ELEMENT FOR USE WITH A HEARING SCREENER

### FIELD OF THE INVENTION

The present invention generally relates to ear phones which cover the ear, and more particularly to ear phones for infants for use in hearing screening tests.

### BACKGROUND OF THE INVENTION

It is known to conduct tests to identify hearing impairments in humans (also known as "hearing screening"). It is critical and advantageous to determine whether or not any hearing impairments exist at an early age, such as in newborns and infants. This is because the earlier a problem is diagnosed and therapy undertaken, the more likely the therapy or other intervention will minimize the potential problems and costs associated with the identified hearing impairments or loss.

Over the years, hearing screening techniques have been developed which inject a sound input into the ear and detect a response to that input. The response is related to the characteristics of the sound input and the conditions inside the ear, the neural connections, and the vibration transmission mechanism of the ear. The response can be analyzed to assess the hearing of the patient.

In many cases, and in particular in the case of infants, hearing screening is performed by using an ear phone having a cavity that fits closely about the ear. Auditory tones or "clicks" are fed into the ear phone cavity, and the response generated by the patient's ear and the neural conduction system in response to the auditory tones is sensed by a transducer. The transducer may be, for example, a microphone, suitable electrodes, piezo electric materials and like devices that generate signals representative of the response to the auditory input. These signals are then processed and the result (as well as the detected signals, if desired) can be displayed on a monitor or other viewing device for analysis of the patient's hearing.

A common problem using this method is that ambient noises, internal or external to the cavity, are capable of interfering with the stimulus or the response signals, and, thus, the result. In most cases, the monitoring equipment has mechanisms, such as microphones, for detecting and compensating for ambient background noise. However, compensating for noise inside the cavity is difficult.

U.S. Pat. No. 4,930,520 to Liverani provides a disposable ear phone for testing the hearing in infants which includes a toroidal baffle of anechoic, insulative foam, a clear planar window plastic sheet adhered to one side of the baffle defining a cavity, and an adhesive coating on the other side of the baffle for bonding the disposable ear phone to the region surrounding the infant's ear. The ear phone is capable of being used with transducers for transferring acoustical energy through a pneumatic tube to the infant's ear for testing. The Liverani device has been commercialized and is sold under the trademark EAR COUPLERS® disposable earphones by Natus Medical Incorporated, the assignee of this invention.

One of the problems with the Liverani device is that the ear phone is somewhat cost-ineffective in that the entire ear phone is not re-usable and must be disposed of after each use, and one device is used per ear. In particular, the construction and use of the device requires, according to accepted general medical practices, that after use it be disposed of as medical waste. Another problem of the

Liverani ear phone is that its construction is not capable of adjustment for infants with different size ears. As a result, it is necessary to manufacture different size ear phones and maintain an inventory of the different sizes to obtain acceptable test performance for patients having different sized ears.

Thus, there remains a need for an improved ear phone that overcomes the problems of the known device and, further, provides advances that improves the attenuation of ambient and external noise inside the cavity of the ear phone.

### OBJECTS AND SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a disposable element for an ear phone, particularly for screening the hearing of infants, which ear phone which has an improved cost effectiveness in that it comprises a durable, reusable cover and which disposable element is a low-cost, smaller disposable element that is easily attached to the durable part for use and easily removed therefrom after use.

It is another object to provide a disposable element that is capable of being used with ears of different sizes.

It is another object of the invention to provide a disposable element and an ear phone assembly that is generally free from external noise.

It is yet another object of the invention to provide a disposable element that is interchangeable in that it can be used with either a left ear cover or a right ear cover for use with testing of the left ear or the right ear.

Broadly, the present invention is directed to a disposable element for a durable ear phone assembly, which is useful for measuring auditory signals in infants. The disposable element has a thickness and an adhesive on each side of the thickness such that one side of the disposable element becomes adhered to the cover and the other side is pressed in contact with the patient's skin around the ear. Thus assembled, the ear phone assembly is secured to the patient's head about the ear, and forms a chamber which acoustically isolates the ear from the ambient environment.

In a preferred embodiment, the cover includes a port through which a transducer is inserted to conduct hearing screening tests. This permits the use of a highly durable transducer, which may be more durable than the cover and needs only to be cleaned after use.

After the hearing screening tests are completed, the ear phone assembly can be removed from the patient, the disposable element separated from the cover and disposed of, the transducer removed from the port, and the reusable durable cover can be cleaned and/or sterilized for the next use.

The disposable elements are pre-formed with a toroidal shape corresponding to the perimeter of the cover, and the adhesives are pre-coated on the disposable element sides and, prior to use, are protectively covered with removable liners.

In a preferred embodiment, the cover comprises a cavity and a flange to which the disposable element is adhered. The cavity provides a generally flat surface which extends over the ear when the ear phone assembly is in place. The cover may, however, be contoured so as to conform generally to the shape of the patient's head about the ear. As is well known, the area around the ear is not flat. Rather, the area is curved in three dimensions. The cover and in particular, the flange, may thus be provided with a shape that conforms to such a surface. For example, the cover may be formed in a

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