K963418 MAY - 2 1997 **Attachment C**

TransMedica Incorporated Model 100 Digital Electronic Stethoscope
Summary of Safety and Effectiveness

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Safety

There are no known adverse effects associated with the use of a passive electro-mechanical transducer for capturing and recording heart sounds. The TransMedica Model 100 Digital Electronic Stethoscope is non-invasive and inherently safe in both construction and use. It imparts no electrical, mechanical, or radiation energy to the patient. It is analogous to a very sensitive audio microphone which is mechanically coupled to the patient's chest by a latex foam pad which is not electrically conductive. The transducer is held place by the physician, by gravity, or with the supplied adjustable elastic strap.

Acoustic vibrations present on the patient's chest wall are conducted through the foam pad and cause micro voltage signals to be generated by the transducer. These signals are amplified, filtered, and digitized using low-voltage, battery-operated circuitry. The digital signals are isolated from line voltages in the computer data collection, storage, and retrieval system.

Effectiveness

Since 1816, when Rene Theophile Hyacinthe Laennec rolled up a tube of paper to listen to the chest of an obese woman, the stethoscope has been the most widely used diagnostic instrument in medicine. So ubiquitous is the stethoscope that it has become an icon for the medical profession. The name, stethoscope, comes from the Greek roots, *stethos*, for breast, and *skopein*, to view.

Beginning with Laennec's 928-page treatise linking chest sounds with disease, clinical researchers have developed an extensive library of sound profiles which are indicative of specific cardiac abnormalities. While the lexicon of cardiac auscultation may seem unusual to those unfamiliar with chest sounds, terms developed by Laennec almost two centuries ago still create a mental picture: "mucous rattle," "strong gurgling," "tinkling, like that of a small bell which has just stopped ringing," and "gnat buzzing within a porcelain vase."

From the first two piece, wooden models which were disassembled and carried in Laennec's top hat to today's traditional stethoscopic instruments, there have been only modest developments. Thinner and lighter diaphragms are now in the chestpiece and a separate tube runs to each ear where the ear pieces couple intimately with the ear canal. This close coupling excludes outside noises and maximizes the intensity of the pressure wave incident upon the ear.

Numerous efforts have been made to bring modern electronics to bear on the venerable stethoscope. These fall into four areas:

1. **Chestpiece Transducer:** microphones or similar transducers are substituted for the chestpiece diaphragm of an air-column stethoscope.

2. **Common Mode Rejection:** multiple transducers may be employed to allow the cancellation of sounds which are received simultaneously by both transducers.

3. **Engineered Gain Curves:** amplifiers with built-in filters can emphasize (or de-emphasize) certain frequencies to allow improved sound detection.

4. **Data Display:** display of the signal amplitude versus time on strip chart recorders, portable LCD displays, or computer video display terminals (VTD)

TransMedica has made incremental improvements in all four of these areas:

Chestpiece Transducer

1. A piezoelectric element is employed to convert chest wall motion into electrical impulses. This type of transducer has been selected for its sensitivity (ability to detect very small changes in wall motion), broad frequency response (10 - 1,200 Hz ±3 Hz), and wide dynamic range (60 - 70 dB).

2. A coupling medium has been developed to conduct the chest wall motions directly unto the transducer. This has two very beneficial effects: sounds from the room environment are partially blocked resulting in a 10 - 20 dB improvement in signal-to-noise ratio.

3. While some other designs employ direct contact of the transducer to the chest wall, the conformable coupling of the TransMedica design allows improvements in signal detection by collecting wall motion over a wider area of the chest.

4. Transducers of all types have a narrow range over which they operate in an effective manner. TransMedica has incorporated mass dampening via the transducer housing to provide enough pressure to ensure good coupling without generating excess downward pressure which can degrade the sensitivity of the transducer.

Common Mode Rejection

In the classic reference for auscultation, Guyton, et al. presented a graph of heart sound energy versus the ability of human ears to receive the information. Approximately 10% of the sound energy produced by the human heart is of sufficiently high pressure and frequency to be heard by human ears.

The fact that most heart sounds have sound pressure levels too low to be heard has driven generations of engineers and scientists to try to present these very low amplitude sounds to the eyes and ears of the physician. Most solutions simply use electronic amplification of the heart sounds to put them into the range or human hearing. Physicians have not embraced these solutions because, while the heart sounds are stronger, so too are the noises from the ambient environment. The physician's ability to differentiate heart sounds from room noise has not been improved sufficiently for broad-based adoption of amplified stethoscopes.

Another obvious approach is to dramatically reduce the room noises which compete with heart sounds. Then, when the heart sounds are amplified, the physician will be able to hear sounds which could not be detected in a normal environment. Special sound-proof chambers have been built (from the small and simple to the large and very elaborate) to reject all room noises. This technique, while somewhat effective, has not been accepted because of the physical size of such chambers, their cost, and their lack of portability.

The TransMedica solution has been to reduce the room noises incident upon the transducer by means of a compliant coupling pad and by canceling much of the remaining room noise by rejection of common mode air-conducted ambient sounds:

1. TransMedica has designed a second transducer which detects ambient room noises or interfering bodily sounds at the same time the chestpiece transducer is positioned to collect cardiac or other diagnostic data.

2. Special circuitry in the instrument to reverse the phase of the signals received from the second transducer. When added to the diagnostic transducer's signal, the effect is for signals common to both transducers to be summed together and thereby canceled.

Engineered Gain Curves

In order to process, store and display sounds which are consistent with those heard with air column stethoscopes and traditional electronic stethoscopes, TransMedica has designed its sensor with a gain curve which is relatively flat. This gain curve is represented by the 0 dB Switch Setting Curve of Att[redacted]D.

Data Display

The TransMedica Digital Electronic Stethoscope uses a general purpose digital computer to process, store, and display the sound recordings of the heart. Conventional sound analysis programs have been modified for heart sound data review .

Sound data have three components: amplitude (loudness), frequency, and the time at which the measurement was made. The data display detailed in the Operator's Manual is the Amplitude versus Time (Time Series = Strip Chart).

Electronic Strip Chart Recorder

A strip chart recorder has been commonly used in the past to provide a hard copy record of an electronic stethoscopic examination. The signal is fed into a galvanometer which has a pen at its tip. A motor moves a continuous strip of paper underneath the pen. Large amplitude sounds cause the pen to move to the edges of the paper strip while small amplitude sounds are traced around the strip's center line.

TransMedica uses an electronic analog of the strip chart recorder to perform the equivalent function. Instead of paper, the computer display is indexed one column of pixels to the left each time a new reading is displayed. Screen pixels are darkened to show the path the moving pen would have followed.