DESCRIPTION OF DEVICE

Generic name of device: Breathing Monitor

Accessories for the device:

A disposable PVDF sensor and lead attaching sensor to the device; the sensor is in turn attached to a standard face mask such as used in oxygen therapy etc.

Model name: PIPPA

Model numbers: P001/1, P001/2 and P001/3.

Brief description of device and other devices designed to be used in combination with it:

PIPPA Breathing Monitor is a specially designed electronic unit, which when used with a face mask, a special sensor attached to the mask and connected by a lead to the electronic unit, can count the breaths of a patient wearing the mask. The monitor displays on a screen the number of 'Breaths par Minute (BPM) in units of 1 (0 to 99).

The BPM is calculated on the last four breaths detected. It can also be set to calculate the BPM based upon consecutive breaths. The readings can be taken by pressing a switch and turned of when not required.

An audible alarm is activated when the BPM exceeds preset limits. The prototype models to be used in the proposed clinical investigation are set to trigger when the 6PM exceed 256PM or drops below 6BPM. The alarm is activated if two breaths exceed the limits.

An idle alarm is activated when two consecutive breaths are missed.

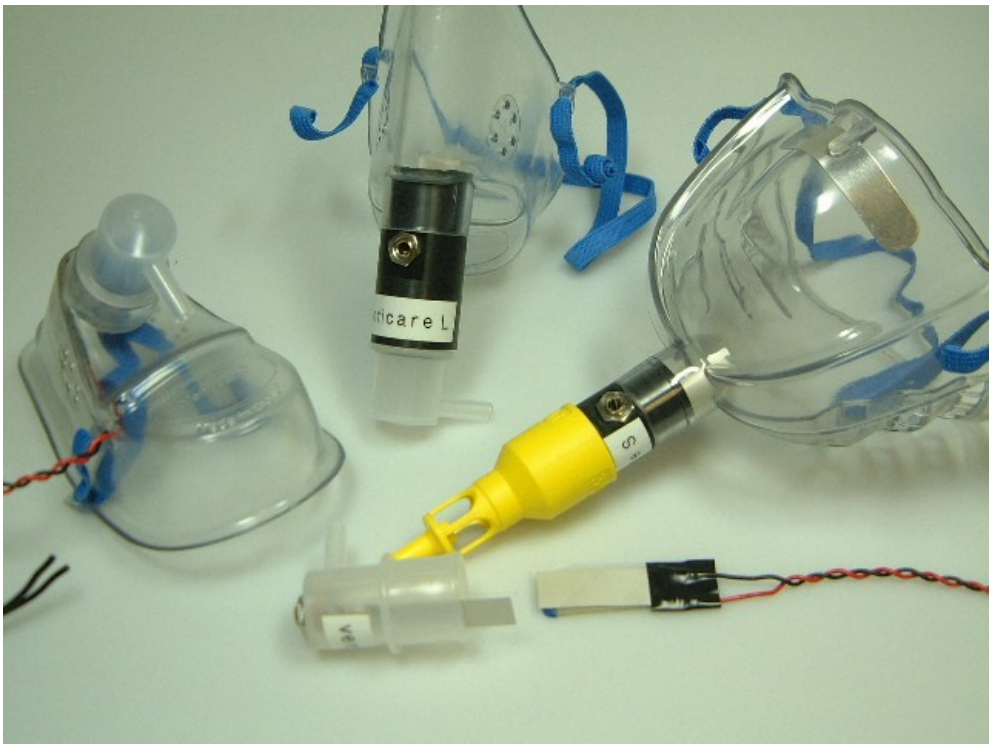
The monitoring unit is powered by a Duracell 9V, 500mA PP3 battery. A low battery alarm is also incorporated into the unit.

ACCESSORIES

The main accessory is a disposable sensor made from polyvinylidene-difluoride (PVDF), which exhibits pyro and piezoelectric properties. In the particular prototypes, the sensors used in the prototypes are manufactured by Measurement Specialties mc, USA. These sensors are used in a variety of applications ranging from consumer products to medical applications. The medical applications include apnea monitors, ambulatory/gait monitors, blood pressure cuff, pulse counter, stethoscope, sleep disorder monitors, respiratory airflow, patient bed monitor, ultrasound applications, handicapped i1 implantables and instrumentation.

The sensor is attached to any standard facemask by a variety of means and is connected to the electronic unit by a double insulated lead.

Examples can be seen in the picture below of some prototype units.



INSTRUCTIONS

Before using the PIPPA Breathing Monitor, it is connected to a facemask with a disposable sensor. The sensor is then attached to the disposable facemask that the patient is likely to be using for oxygen therapy, nebuliser medication, etc.

Operational Instructions for the prototypes:

Power source: The three prototypes are operated with 9volt Duracell batteries

BREATHING DISPLAYS

The Breathing Rate per Minute (BPM) is displayed to the nearest integer. If the first decimal place in the calculated 'BPM is greater than or equal to 0.5, then the BPM is rounded up by 1.

Press the on/off button on the front of the device. The display screen will show the numeral '0' (If it is not connected to a sensor, after 20 seconds an alarm will be set off, and the screen will display two flashing dots at the bottom of the screen. Pressing the second switch marked 'Rate select can turn off the alarm').

The Breathing Rate per Minute (BPM) can be measured in two modes, if a sensor is attached.

1. In the standard (default) mode, the BPM is calculated as 'averaged' on the last four breaths detected.

2. If the 'Rate select' button is pressed, when the monitor is already switched on, a single dot appears on the screen, in addition to the numeral '0'. In this position the 'Instantaneous breathing rate is calculated on the time interval between consecutive breaths and is referred to as IBPM.

TO TOGGLE BETWEEN THE TWO DISPLAY MODES, PRESS THE 'RATE SELECT' BUTTON. IF AN ALARM IS ACTIVE, THIS WILL CANCEL THE ALARM ON THE FIRST PRESS AND WILL NOT TOGGLE THE DISPLAY UNTIL IT IS PRESSED AGAIN.

BREATHING ALARMS

The programmed settings are as follow:

- Maximum breathing rate set to 25 BPM
- Minimum breathing rate set to 6 BPM.

The above limits apply to both modes of operation, i.e. for both counting BPM and IBPM.

An audible alarm (every two seconds) is activated if two consecutive breaths fall outside these limits. For the upper limit, a time interval of less than 4.8 seconds for two breaths will trigger the alarm. For the lower limit, a minimum of 20 seconds will elapse before the alarm is activated.

The alarm may be cancelled by the breathing rate returning to normal 9 allowable 0 rate or by pressing the 'Rate Select' button.

LOW BATTERY ALARM

This alarm is activated when a low battery is detected (typically at a terminal voltage of less than 7.36 volts). The LCD flashes the letters 'bt' on the display and sounds the buzz every 10 seconds for a period of 40 minutes prior to a system shutdown. If the battery alarm sounds on power up, then the battery should be replaced immediately.

The electronic unit is expected to have a life of at least five years.

(A guide on the unit shows what the different screens display).

SCIENTIFIC BACKGROUND SUMMARY

The basic principle of this device has been described by Dennis Dodds, Jonathan Purdy, Chris Moulton in the J. Acci Emerg Med 199: 16,26-28 (copy attached). In essence, it describes the use of a polyvinylidene difluoride (PVDF) sensor, which is able to detect the act of breathing by sensing the difference in temperature between inspired and expired breaths. P Bradley based this work on a B.Sc. Degree Dissertation, under the supervision of Dennis Dodds at the Bolton Institute (formerly Bolton Institute of Higher Education). A copy of the abstract of the thesis follows at the end of this section. A frill copy of the thesis is available for inspection if required

Details

Pyroelectric materials (from the Greek word *pyr* meaning fire) are crystalline substances capable of generating electrical charge in response to heat flow (Application of Piezo/Pyroelectric films in Medical Transducers, Jacob Fraden, J.Clinical Eng **13,** No 3,March-April 1 988).A crystal is considered to be pyroelectric if it exhibits spontaneous, temperature dependant polarization.

However twenty years ago new polyeric materials such as polyvinyl fluoride (PVF) and Polyvinylidene fluoride (PVDF), which are not wholly crystalline, were developed; these are now used to produce piezo- and pyroelectric films.

The PVDF (polyvinylidene difluoride) film transducer exhibits high fidelity throughout a broad range of frequencies, low mechanical and acoustic impedance, high dielectric strength, high volume resistivity, light weight, availability in large area and thin film forms, durability flexibility and resistance to mechanical impact.

Transducer materials convert one form of energy to another. Piezoelectric and Pyroelectric properties of PVDF are used in a variety of applications. It has been found that locating a PVDF transducer close to the airways of a person, it is possible to detect the rate of breathing by comparing the change of temperature between inspired and expired air (See Dennis Dodds et al referred to above)
Suitable electronic circuitry has been developed to measure the intervals between breaths to provide a rate of breathing over a period of time.