Lifebox LB-01 sensor IP disclosure

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Introduction

The present disclosure concerns a pulse oximeter sensor developed by Lifebox and known as a "Lifebox LB-01 sensor". The intent of this document is to publicly disclose, without making claim to, what we believe to be the novel features of the Lifebox LB-01 sensor.

Background

The LB-01 sensor was developed to meet the need in low resource settings for a reusable SpO2 (peripheral capillary oxygen saturation) sensor for 0 to 5 year old patients. Historically this has been done with wrap sensors for neonatal feet, clip sensors for infant toes and other clips designed for pediatric fingers. In the target group of patients the great (big) toe is the preferred site for most of the patients. The greatest challenge in this age group is that the patients move around making the sensor fall off. In particular the existing toe clip sensors fall off easily. The intended use for this sensor is spot checks, and the clips tend to fall off before one can be completed.

Existing pulse oximetry sensors

Criticare 934-10DN sensor, described in US5438986 (expired), discloses a clothespin like design with a pair of rigid plastic shells forming a snake jaw.

US patent number 4685464 of Nellcor was directed to Nellcor's DS100 sensor, and discloses another clothespin like design with a pair of rigid plastic shells connected by a hinge each provided with a respective rigid frame, and hollow flexible pads each attached to a respective one of the rigid frames. The hollow flexible pads are made from silicone rubber. Each hollow flexible pad is formed with a longitudinally extending concave recess respectively for engaging the top and bottom parts of a finger of a patient when the finger is inserted longitudinally into the sensor. A spring is coiled at the hinge and has a pair of end portions each acting on a respective rigid plastic shell to bias the rigid plastic shells rotationally towards each other whereby the flexible hollow pads may grip the patient's finger.

A cable connects to the sensor via one of the rigid plastic shells and at a longitudinal end thereof on the opposite side of the hinge from the hollow flexible pad. Thus the cable extends away from the patient when in use. Each hollow flexible pad supports a respective optical device, one of the optical devices being a light source in the form of an LED and the other being a light detector. The optical devices are supported so as to be opposite each other, whereby when a finger is inserted into the sensor light may pass from the LED, through a portion of the finger, and to the light detector. The optical devices are connected to the cable via wire leads.

Nellcor's DS100A sensor was an improved and cost reduced version of the DS100 and was first marketed in 1991. The design switched the cable exit from being away from the patient to being towards the patient, made the shells more like the Criticare design and changed the hollow silicone finger pad design from a snap in type to a type molded over an aluminum rigid frame secured on the rigid plastic shell. The use of aluminium as the material for the rigid frame enabled the silicone rubber pads to bond to the rigid frames.

Developed Device

The LB-01 integrates many features from existing marketed pulse oximetry sensors. These sensors were all marketed with indications for use on adult fingers only. The key inherited design features are:

1. Clothespin (clothes peg) like overall clip design
2. Pair of rigid plastic shells forming the jaw of the clothespin like design
3. Snake jaw hinge between the rigid plastic shells allowing rotational and lateral movement with a spring provided at the hinge rotationally to bias the shells towards each other on the side of the hinge where a patient body part is to be inserted
4. Hollow silicone pads, one on each of the rigid plastic shells
5. The hollow silicone pads each being molded over a respective rigid frame that is attached to each rigid plastic shell.

The new sensor has the following features to meet the need for application to a 0 to 5 year old.

<u>Longer Body than existing toe or finger sensors</u>

This allows the sensor to grip the foot rather than just the toe, giving it a firmer purchase. The sensor may extend 40 mm, preferably 44mm, or more from the hinge axis to the end of the sensor proximal to the patient. In a preferred embodiment of the sensor, it extends approximately 60mm from the hinge axis to the end of the sensor proximal to the patient.

<u>Shallower rim on sensor shells</u>

The rim of both the upper and lower shells of the sensor is shallower relative to existing designs. This allows the pad to protrude farther, for example 3 mm or more, from the shell towards the opposed pad. With such an increased protrusion, it is not necessary for e.g. a toe to be inserted along the length of the pads, but it is also possible for the sensor to be placed across a foot or on the palm of a hand. By allowing the pad to conform to patient tissue on the sides as well as along the axis of a body part, it provides increased flexibility in the sensor placement. Examples are placement across a neonatal foot or on the palm of an infant hand.

<u>Compliant stops under optical devices</u>

The sensor has compliant stops mounted under the optical devices, although it is also possible to provide a compliant stop under just one of the optical devices. The use of at least one compliant stop has been found to improve performance on wiggling toes compared either to unsupported optics mounted to the hollow silicone pad or rigidly connected to the sensor shell. The compliant stop may be solid or hollow, for example in the form of a hollow tube. The compliant stop extends generally circumferentially with respect to the hinge axis (typically vertically in use), between a base portion of a respective shell and a receiving portion of the hollow pad which receives the optical device. The hollow pad is shaped such that the optical device receiving portion is recessed in the circumferential direction.

Optical devices offset towards hinge

The optical sensors are located along the length of the sensor such that a central optical axis is nearer to an axis of the hinge than it is to the end of the sensor remote from the hinge axis. This means that, in general, a peripheral region of the body part of the patient, such as an infant foot or palm of the hand, inserted into the sensor will align with the optical axis, even if the body part is inserted sideways into the sensor. By aligning a peripheral region with the optical axis, interference with the optical signal by bones can be avoided. In addition, where the sensor has a relatively long body, even if an adult finger is fully inserted longitudinally all the way into the sensor, the position of the optical axis nearer to the hinge means that finger bones will not interfere with the optical signal.

Use of metal frame

Inherited design feature 5 above, namely molding each hollow silicone pad over a respective frame that is attached to each rigid plastic shell, is used because silicone cannot reliably be attached by bonding. In our sensor, we use a metal frame, preferably an aluminium frame. The frame is formed with holes, so that when the silicone is molded over the frame it is forced through the holes making a reliable mechanical connection. In the illustrated embodiment (see below) there are 10 holes in the frame. The frame also has interlocking features that enable it to be held it in place on the rigid plastic shell. Thus it may be fitted into the shell by a snap fit. Alternatively or additionally, the frame may be bonded to the rigid plastic shell.

It will be appreciated that each of the above new features brings its own advantages. Thus we envisage embodiments of the sensor in which only one of the above features is present, embodiments in which one or more of the features is/are present in any combination, as well as the preferred embodiment of the sensor in which all of the features are present. The preferred embodiment also includes all of the inherited design features 1-5 mentioned above.

Utility

Prototypes of the LB-01 were extensively tested. It was found during that testing that the sensor performed well over the intended age range. Additionally, it was found that it also performed well as an adult finger sensor. As a result it can be sold with indication for all ages.

Drawings

A preferred embodiment of the sensor is shown in the drawings, which are briefly described below. Most of the various features of the sensor described above are evident in the drawings and the above description may be used to assist understanding of the drawings. Thus the inherited features 1-5 are all present in the embodiment, including the spring (not shown in the drawings) which biases the shells towards each other and into engagement with a body part of a patient when in use.

As the spring is not shown in the drawings, we will describe it further. The spring coils around the hinge axis and has opposite end portions which protrude along the respective shells in a direction away from the hinge axis on the side thereof proximal to where the patient body part is to be inserted. Thus the spring end portions are biased so that they tend to approach each other. In the preferred embodiment, two such springs are provided, one adjacent to each end of a shaft of the hinge.

The features believed to be new, namely the longer body than existing toe or finger sensors, the shallower rim on sensor cells, the compliant stops under the optical devices, the optical devices being offset towards the hinge, and the use of a metal frame, are also present in the embodiment.

Figure 1 shows a side view of the pulse oximetry sensor;
Figure 2 shows a transverse cross-sectional view through the sensor, taken at a position along its length where the optical devices are provided;
Figure 3 shows a central longitudinal cross-sectional view through the sensor;
Figure 4 shows a perspective view of a hollow flexible pad and the aluminium frame on which it is over molded; and
Figure 5 shows a plan view of the aluminium frame.

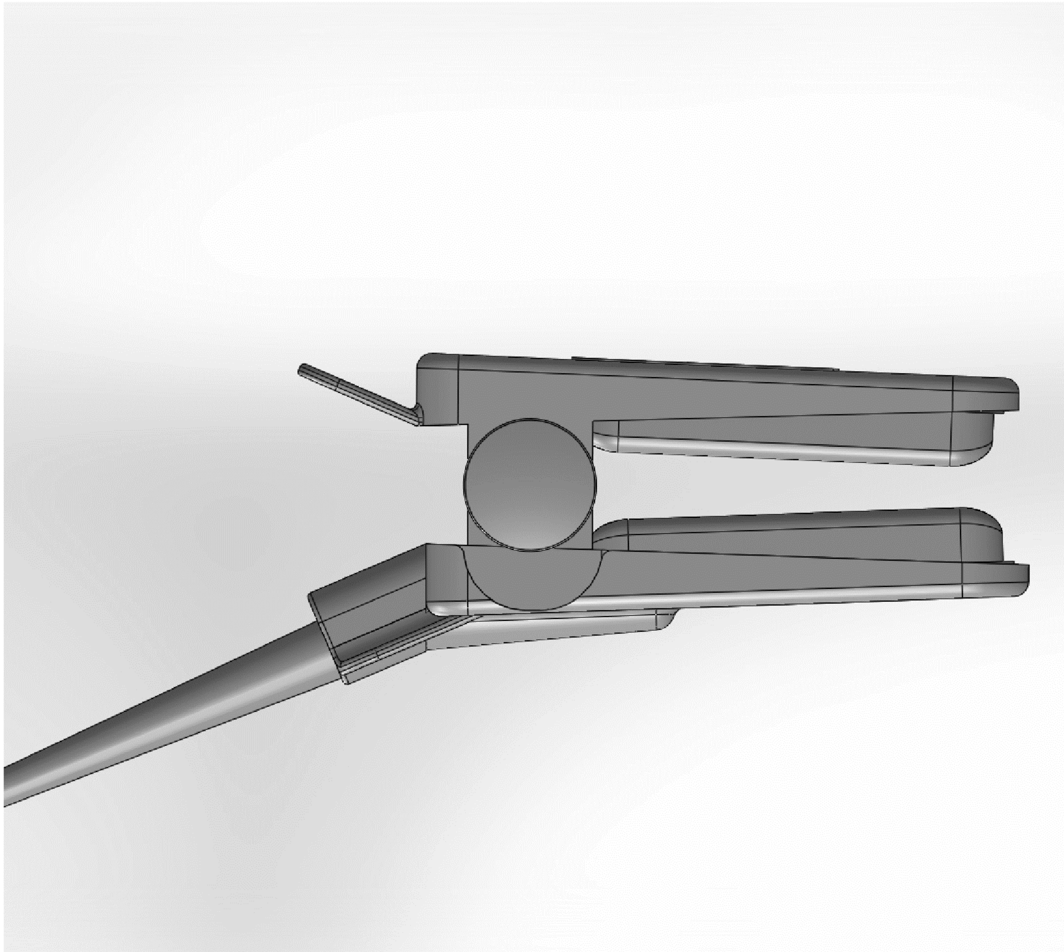

Fig. 1

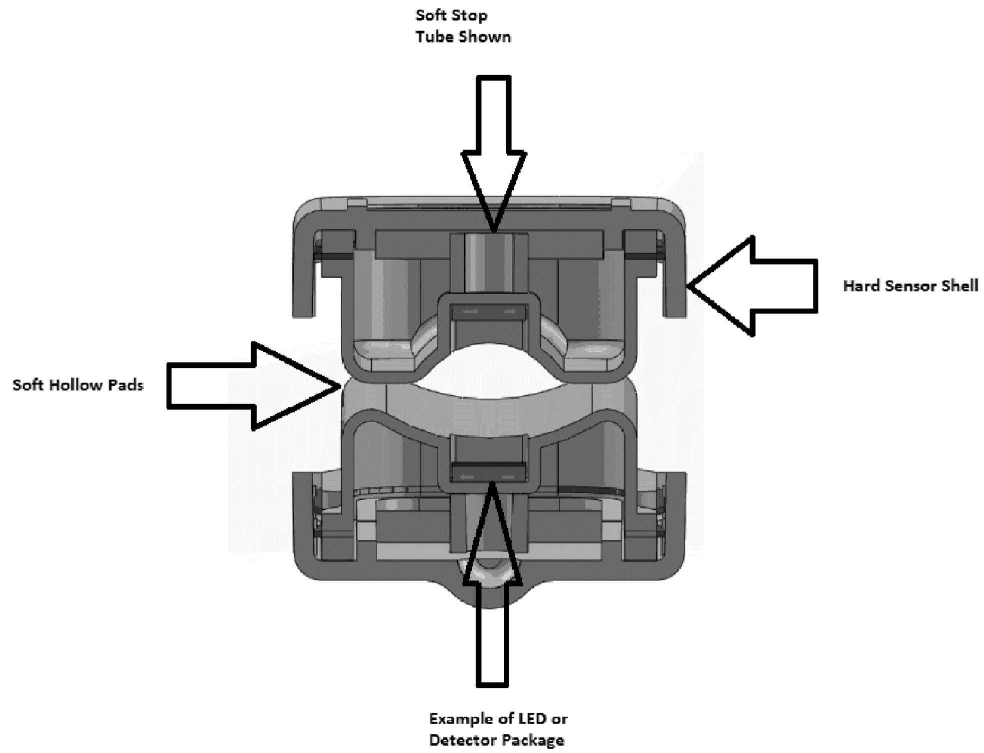
Soft Stop
Tube Shown
Hard Sensor Shell
Soft Hollow Pads
Example of LED or
Detector Package

Fig. 2

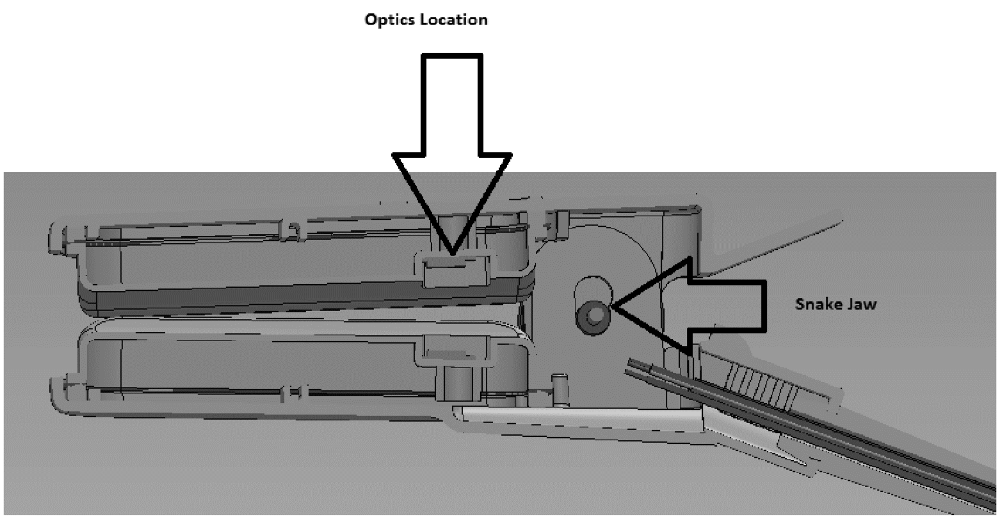
Optics Location
Snake Jaw

Fig. 3

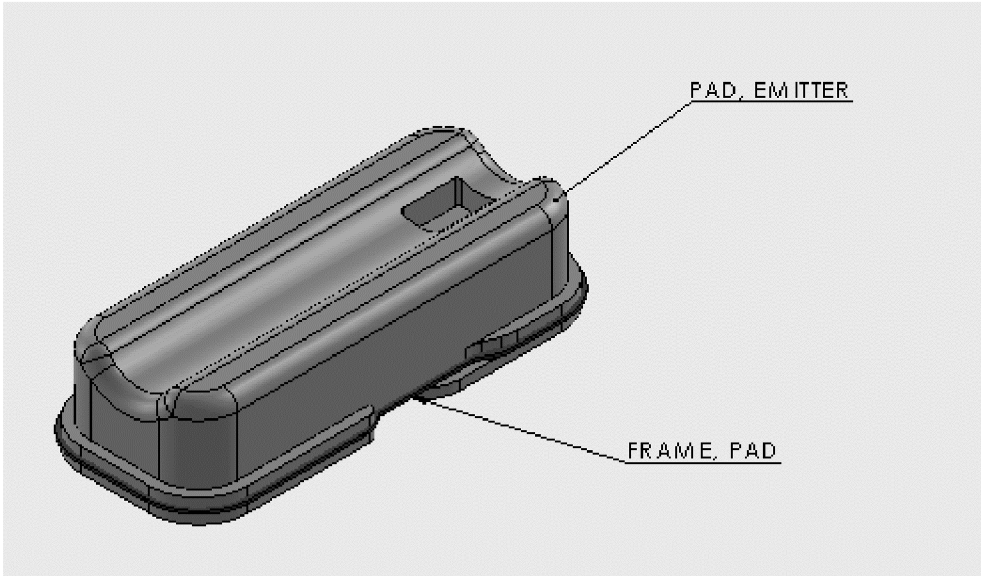

Fig. 4

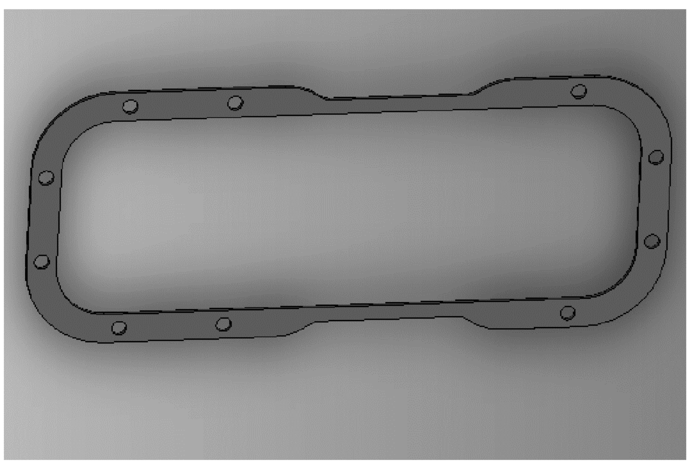

Fig. 5

Note that the frame is embedded, sometimes referred to as over molded, in the silicone.