Burdick

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SUBMITTOR:
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Trade Name: Burdick 200 Oximeter
Common Name: Oximeter
Classification Name: Oximeter

Equivalency:

The Burdick 200 Oximeter is equivalent to the Model 3302 Oximeter manufactured by BCI International.

Description:

The Burdick 200 is a hand held stand alone Pulse Oximeter designed to detect (SpO_2) Oxygen saturation, pulse rate, and pulse strength on any patient from neonates to adults and output the measurements.

The Burdick 200 consists of two units, a hand held pulse oximeter and a table top charger base. Nine probes of various sizes and configurations are available to accommodate the spectrum of body sizes and sites.

Intended Use:

The Burdick 200 Pulse Oximeter provides SpO_2, Pulse Rate, and Pulse Strength measurements. It may be used in the hospital or clinical environment, during emergency land or air transport, or for in home use.

The intended patient population is neonates to adults. The oximeter permits patient monitoring with adjustable alarm limits as well as visual and audible alarm signals.

The Oximeter has three modes of operation: Clinician Mode, Home-use Mode, and Sleep Study Mode.

The Clinician Mode aids the health care professional in monitoring patient activity.

The Home Use Mode permits the home-use caregiver to monitor a patient within the home environment.

The Sleep Study Mode allows the health care professional to record sleep study data which may be later transferred to a PC and analyzed.

Technological Characteristics

The Burdick 200 oximeter and the BCI model 3302 hand held oximeter measure (SpO2) Oxygen saturation, pulse rate, and pulse strength. The oximeter determines SpO2 and pulse rate by passing two wavelengths of light, one red and one infrared through body tissue to a photodetector. The strength of the detected signal resulting from each light source depends on the color and thickness of the body tissue, the probe placement, the intensity of the light source, and the absorption of the arterial and venous blood in the body tissues.

These signals are processed in the oximeter, separating the time invariant parameters from the time variant parameters to identify the pulse rate and calculate oxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

Software accomplishing these measurements and calculations was developed by BCI International for their model 3302 and is used by Burdick Inc. in their model 200 in an unaltered form.

The oximeter contains the following display features: SpO2 Numeric Display, Pulse Rate Numeric Display, Pulse Strength Bar Graph, Probe Light, Batt Light, and Alarm Silenced Light.

The control panel includes the following keys: On, Off/Standby, Alarm Select, Alarm/Alert Silence, Arrow (up), Arrow (down), ID/Clear, Pulse Volume.

The AC adapter/charger base features a receptacle for insertion of the oximeter. The receptacle contains charging contacts, and infrared windows for data communication with the oximeter. The printer I/O and the AC input connectors can be found on the rear panel.

The charger base contains the following indicators: Line Power, Charging, Fully Charged.

Equivalency:

The Burdick 200 Oximeter is equivalent to the BCI International Model 3200 Pulse Oximeter because through contractual agreement Burdick has obtained the rights to manufacture and market the BCI 3302 Oximeter under the Burdick 200 name.

The Burdick 200 Oximeter will be manufactured and tested to the same specifications as the BCI International 3302 Oximeter. Labeling will be altered to reflect the Burdick name, manufacturing location, and model number.

Accessories will be manufactured by and purchased from BCI International, and marketed under their name without any labeling changes. This will be their standard product, currently manufactured.

TESTS

In order to ensure that the slight dimensional and material changes to the enclosure would not compromise the operation of the oximeter, three series of tests were performed on a modified unit.

A functional test was performed on the unit prior to environmental testing to establish that the unit to be tested was operating properly. All test results were within normal established limits.

The oximeter was submitted to an independent laboratory for environmental testing. The laboratory Report indicated that all test results were acceptable, and no negative results were noted.

Following the environmental test an expanded functional test was performed. After review of test results, all were found to be within established limits.