510(k) Summary

Safety and Effectiveness of Neosono XX.

K962853

Safety:

The safety issues for this device are:

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1- *Potential hazard due to power source.*

The Neosono XX uses a 9V transistor battery as a power source. Use of a battery as a power source eliminates opportunity for leakage currents to the utility power supply mains, with resultant leakage currents of zero microamps. For this reason, there is no potential hazard to the patient due to the device power source. Also note the warning against use of wall plug in power adapters at the beginning of the draft user's manual.

2- *Potential hazards due to device failure.*

If the device should cease to function during a procedure, there is no immediate hazard presented to the patient. Should such an event occur, the dentist can fall back to traditional methods of apical foramen determination. Additionally, the device performs a power on self test and monitors the condition of the probe wires and battery on a continuous basis. These tests are:

1- A test for failure of the position measurement circuitry is performed. Failure of this circuitry results in blanking of the file position display digits.

2- A test for open or short circuited probe wires is continuously performed during use. If the connection to the patient is open circuited, the user is notified by means of "bouncing balls" on the depth display digits. If the connection to the patient is short circuited, the user is notified by means of "bouncing bars" on the depth display digits.

3- A circuit for detection of a depleted battery is also included. This circuit is designed to trip at 7V with a 0.1V design tolerance. This results in "Low Battery" being displayed before the voltage regulator input voltage requirements are violated.

4- A square wave is applied to the reamer through a variable attenuator. The attenuator may assume a value bounded by 1.4 kohms and 7 kohms. The worst case condition will be where the attenuator is set at 1.4 kohms with a patient impedance of 900 ohms. This gives a value of 19.7 microamps.This is below the rms current sensation threshold of 20 microamps.

Effectiveness:

The effectiveness issues for this device are:

1- Accuracy and repeatability of the patient impedance measurement.

The core functionality of this device is its ability to accurately determine the capacitance between the canal file and the lip reference electrode. The method employed is the application of a square wave two to the file. A low and a high frequency is then filtered out, their amplitudes are then used with a lookup table in the microprocessor memory. The lookup table supplies suitable display information which is displayed on the liquid crystal display.

Parameters for calibration were determined from extracted teeth and measurements with a vector impedance meter in the labaratory. The threats to this accuracy are variation in the canal environmental conditions, and compromised probe wire connection integrity. These issues are effectively dealt with in the design of this device as follows:

a- The design of the device is such as to accurately measure the position of the reamer in the neighborhood of, and at the apical foramen. This is done with the existing envoirmental conditions in the canal.

b- *Probe wire connection integrity.*

Probe wires, by their nature, are prone to breakage at the point of connection from the wire to the patient. The device performs a boundary test of the measured risetime to detect open or short circuited probe wires. (See the software requirement and software validation procedure for a description of this test). The user is notified of these probe fault conditions by a distinctive display, avoiding the use of the device with faulty probe wires.