

Fisher & Paykel

HEALTHCARE

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K953205

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510(k) Summary of Safety and Effectiveness Information

Model Number / Name: NS272 Peripheral Nerve Stimulator / Locator
Classification Name: Stimulator, Nerve, Peripheral, Electric - 73 KOI
Anesthesiology Devices, 21 CFR §868.2775
Predicate Device: Fisher & Paykel, NS272 Nerve Stimulator / Locator, K924234

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The NS272 is enclosed in a thermoplastic case consisting of four components, held together by clips and screws. Fourteen device control buttons and an LCD display window are located on the front panel. Three connector sockets for current delivery are located on the top end of the unit. Two are 4mm banana-type sockets for the proximal and distal External mode (nerve stimulation) leadwire. One is a 2.5mm miniature audio-type socket for the Internal mode (nerve location) leadwire. The NS272 is internally powered and uses three AA-size batteries, which fit into an enclosure on the back of the unit. This battery compartment cover is configured to allow the unit to be slid into an optional mounting bracket. The NS272 measures 170 × 73 × 43mm, and weighs 0.185kg without batteries (0.255kg with batteries). It contains a single printed circuit board, to which the device buttons, output sockets and display LCD are directly mounted. The standard accessories are patient leadwires of 1.5m in length, with ECG clips for attachment to skin surface electrodes, or alligator clip for attachment to a nerve location needle.

The NS272 output current pulses are square wave, monophasic, constant current and unidirectional. Pulse width is approximately 0.2ms, with maximum available current levels of 160mA External and 10mA Internal. Twitch, Train of Four, Tetanus, Double Burst and Post-Tetanic Count pulse trains are available for External mode, while only Twitch can be used in Internal mode. Repeat pulse patterns of 1 sec Twitch and 12 sec Train of Four are available. A programming mode allows selection of maximum External mode current, External mode current steps, Tetanus frequency and Double Burst pattern options. User-definable programs of available pulse trains and timing can also be stored. Audible and visual indicators of current delivery are used, with a pulse-not-delivered alarm in External mode. The NS272 features a low battery indicator, pulse delivery mute, Post-Tetanic Count five-minute lockout to prevent excessive use of this pulse train, and an automatic 30 minute switch-off.

The intended use of the NS272 is for the application of an electrical current to a patient in External (nerve stimulation) and Internal (nerve location) modes of operation. In External mode this is to test the level of pharmacological effect of anesthetic drugs and gases for neuromuscular blockade monitoring. In Internal


510(k) Summary continued - Fisher & Paykel NS272 Nerve Stimulator / Locator

mode this is for the location of nerves for the administering of anesthetic drugs to accurately achieve neuromuscular blockage. The delivery of constant current stimuli allows accurate comparison of evoked response over time, with minimal effect from changing impedance conditions such as patient electrodes drying.

The general technological characteristics of the modified NS272 are equivalent to the original device. The enclosure materials and design, device functions and controls, power source, main circuit componentry and delivered current output patterns are fundamentally unchanged. Differences between the original and modified NS272 consist of the following modifications. Output circuit clamping components, an External mode high voltage regulator and current controller regulators have been added. Individual components have been added, changed or removed. These changes ensure that current pulses can be delivered correctly and according to specification at all times, across all intended load and current ranges, and taking account of use of alternate components. The output current waveform has also been further improved within specifications. The Internal mode leadsets and output socket have been shrouded in order to fully isolate Internal and External modes of operation of the device, and output sockets have been directly mounted to the device PCB to improve manufacturability. The device specifications for pulse width, maximum load impedances, set current offsets, operating and storage temperature and humidity conditions, and battery life have been respecified with minor modifications to take account of the above electronics changes or for general corrections.

Testing of the modified NS272 has been carried out to establish correct operation and performance of the device. Specific testing relating to particular modifications verifies changes including socket PCB mounting, output clamping and low battery indication. Additional checks for correct functioning of the high voltage regulator and output clamping circuits have been added to the final manufacturing test. General device testing ensures overall electronics modifications do not adversely affect operation, including testing for electromagnetic susceptibility and interference, battery life, standby current used and substitution of alternate components. Performance testing ensures correct functioning of the device under all specification conditions, including tests for delivered current accuracy, correct delivery of Internal and External mode currents, and operation at varying battery levels.

Extensive testing of all deliverable current levels into various test loads ensures that accurate and reliable performance is obtained under all expected conditions of use. Specific testing related to particular modifications made to the NS272 ensure that these changes function as intended, and the performance of the device is within the modified specifications. In general this indicates that the modified NS272 has the same or better safety and effectiveness characteristics as the original device, as the changes return the device to specification or slightly improve performance.

signed: 
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