Orthofix’s BioStim line of bone growth stimulators heal nonunion fractures using pulsed electromagnetic fields (PEMFs). The current method to track BioStim patient compliance is to check whether the device was powered on for the daily treatment duration. In order to more accurately monitor compliance, a reliable Patient Compliance System (PCS) that operates without patient input or knowledge is necessary. By utilizing the data collected from an accelerometer and an IR proximity sensor, the system developed is able to determine if the device is being worn. Attempts to “game” the system were accounted for and mitigated. This system will allow Orthofix to better verify the success rate of the BioStim line and allow prescribing clinicians to verify and track individual patient compliance. The incremental material cost of the PCS is less than $2.00 per unit for production runs of 50,000 units.

**Abstract**

Orthofix’s BioStim line of bone growth stimulators heal nonunion fractures using pulsed electromagnetic fields (PEMFs). The current method to track BioStim patient compliance is to check whether the device was powered on for the daily treatment duration. In order to more accurately monitor compliance, a reliable Patient Compliance System (PCS) that operates without patient input or knowledge is necessary. By utilizing the data collected from an accelerometer and an IR proximity sensor, the system developed is able to determine if the device is being worn. Attempts to “game” the system were accounted for and mitigated. This system will allow Orthofix to better verify the success rate of the BioStim line and allow prescribing clinicians to verify and track individual patient compliance. The incremental material cost of the PCS is less than $2.00 per unit for production runs of 50,000 units.

**Requirements**

- The technology must work in a variety of patient activity levels including but not limited to: sleep, physical exercise, sitting, and standing.
- Technology must not cause patient discomfort.
- Technology must not require complicated patient input.
- Technology must not require human analysis of data to determine compliance.
- Technology must not have obvious workarounds to trick or game the activity tracking/compliance.
- Output of Technology must determine compliance in terms of yes or no when polled by a microcontroller.
- Output must not be visible to patients.
- Technology must fit within the control box or coil assembly of each of the currently available stimulators without a large change to the form factor of either.
- Technology must be capable of interfacing with a microcontroller (STM32 family) using a minimal number of pins (5 max).
- Technology must be compatible with 3.3V logic level.
- Technology must draw no more than 10mA of current while ON and 25µA while OFF.
- Manufacture costs must be less than $20/unit (Assume 50,000 units/year).

**Specifications**

The system designed is composed of an accelerometer and an IR proximity sensor working in concert to detect patient compliance. Raw data is passed through a proprietary and confidential algorithm that determines compliance for each treatment period. Output to the physician is a simple yes/no for each daily treatment period. A more detailed report is also available.

The system developed fits all of the requirements (left) given. The system can be integrated directly onto the control box PCB. The only case modification necessary is the addition of a darkened IR translucent window facing the patient for the inflow of IR proximity data. Since both sensors use the I2C protocol, they may be able to be integrated onto existing data and clock lines, saving open pins on the microcontroller for future additions. With regards to cost, the system can be integrated for roughly $2/unit. The system only uses 806.5 µA of current when active (approximately 8% of our goal) and 2.2 µA of current when off.

The prototype produced (Figure 1) is a standalone detection unit based off the same microcontroller used in BioStim units. Data is sent through serial USB communication to a computer for display or further processing. Power is also provided through USB.

**Testing**

We tested our patient compliance system on Cervical-Stim and Spinal-Stim units using a breadboard setup (shown in demonstration). Because these devices are often prescribed to aid in healing after surgery, it is expected that most patients needing the device will remain inactive during most treatment periods. Testing, therefore, was concentrated on sedentary activities.

**Conclusion**

Our results have shown that the technology designed can successfully detect a patient with high accuracy. While the output of the 30 minute interval detailed report is lacking in accuracy, the final determination of each treatment session is highly accurate in part due to the algorithm. By training the algorithm with actual data, we have applied a low level of machine learning to increase accuracy. This technology should be able to be easily integrated into the final production units and increase patient compliance, ensuring that patients receive the care they need.

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