DyNeuMo Mk-1: A Fully-Implantable, Motion-Adaptive Neurostimulator with Configurable Response Algorithms

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Abstract—There is growing interest in using adaptive neuro-modulation to provide a more personalized therapy experience that might improve patient outcomes. This paper describes the design of the ‘DyNeuMo Mk-1’, a fully-implantable, motion-adaptive research stimulator that titrates stimulation based on the patient’s movement state (e.g. posture, activity, shock, free-fall). The design leverages off-the-shelf consumer technology that provides inertial sensing with low-power, high reliability and modest cost. We used a three-axis accelerometer and its embedded digital motion processor to enable real-time stimulation adaption based on configurable motion parameters. The algorithm configurability and expanded stimulation parameter space allows for a number of applications to be explored in both central and peripheral applications. The implantable system was designed, prototyped and verified using ISO 13485 design controls, including ISO 14971 risk management techniques to ensure patient safety, while enabling novel algorithms. With the design controls in place, first-in-human research trials are now being prepared to explore the utility of automated motion-adaptive algorithms. The design highlights how consumer electronics technology can be leveraged for efficient and reliable medical device development. The implantable system automatically provides activity- and posture-based responsive stimulation which can be configured by the clinician to optimize therapy. Intended applications include adaptive stimulation for movement disorders, synchronizing stimulation with circadian patterns, and reacting to transient inertial events such as shocks for urinary incontinence.

Index Terms—Neural implants, Brain stimulation, Activity recognition, Accelerometers, Adaptive control, Closed loop systems, Design methodology, Risk analysis, Safety management.

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I. INTRODUCTION

The field of adaptive neuromodulation is an active area of development, with particular emphasis on the use of bioelectric signals to inform the control algorithm [1]. For example, the Neuropace RNS is approved in the U.S. for refractory epilepsy [2]. While promising, the ultimate benefit of the responsive stimulation for epilepsy is still debated, and refinement of the algorithmic approach is an active area of study [3]. Likewise, in the field of movement disorders, particularly Parkinson’s disease, adaptive stimulation has shown promise for improving outcomes while lowering energy use [4], [5]. However, the signals recorded from sub-cortical targets are 1) relatively small (1 µV rms), 2) prone to artefacts from stimulation, cardiac signals and motion, and 3) the optimal configuration of algorithms are still debated and might prove complex for programming [6]. In addition, the resolution of small bioelectric signals in the presence of stimulation puts significant constraints on the relationship between sensing and stimulation electrodes, which can severely limit the therapy options [4], [5], [7], [8]; recent work to bypass these constraints potentially compromise the tissue-electrode interface’s safety due to leakage currents and single-fault errors [9].

One alternative to strictly “neural closed-loop” methods is to use wearable sensors to determine an estimation of the patient or symptom state as a feed-forward method to adjust stimulation. The widespread adoption of inertial sensing in consumer wearable electronics has resulted in many features ideal for use in implantable closed-loop neuromodulation systems: 1) low power (order of 10 µW), 2) high reliability and shock immunity, and 3) embedded “digital motion classifiers” that facilitate motion classification [10]. Inertial sensing has already been applied in medical implants to automatically titrate stimulation. Notable examples include activity-based titration of cardiac pacemakers [11], and posture responsive adjustment of stimulation for spinal cord stimulation [12]. Investigational work using the Activac PC+S has also demonstrated the use of inertial sensing in deep brain stimulation (DBS) applications, with wrist-mounted inertial sensors being used to control stimulation in real-time in both essential tremor [13] and Parkinson’s disease [14]. Despite the potential research and therapeutic opportunities allowable by integrating inertial closed-loop functionality into brain neuromodulation devices, there are no such devices broadly available for research.

In this paper, we introduce the Dynamic Neuro Modulator Mark 1 (DyNeuMo Mk-1), a cranial mounted motion-adaptive...
Fig. 1. System block-diagram using the IEC 60601-1-10 physiologic control framework. Blue boxes are derived from user needs, while tan boxes are derived from risk mitigations. Both sources of design inputs inform the system specifications for the DyNeuMo Mk-1. Reproduced with permission from [1].

neurostimulator for use in human investigational studies into inertial-sensing based closed-loop therapies, based on the Picostim system by Bioinduction [15].

Unlike classical DBS devices, implanted in the chest cavity with electrode leads routed through the neck, the DyNeuMo and predicate Picostim systems utilize a cranial mounted design. This approach has several advantages, summarized here from [15]. The surgical procedure is considerably simplified requiring only a single incision, reducing both surgical and infection risk for patients, while also improving the productivity of surgical teams. Avoiding tunnelling of leads through the neck significantly reduces the risk of lead wire breakage or fibrosis around the lead, a cause of stiffness and pain. Overall a cranial mounted device improves patient safety, while also significantly reducing expected treatment costs.

To support first-in-human research, we used ISO 13485–compliant design controls throughout the project. The paper will follow a similar structure to a typical medical device design flow, starting with the assessment of our device requirements motivated by anticipated user needs and risk management. We will then discuss in detail the implementation of our design before demonstrating the system’s functionality through verification testing. Planned future research projects for system validation are presented, as well as a discussion of the advantages and limitations of the implemented approach. The inertial-focused research stimulator will expand the possible research space in human feasibility studies, providing an alternative method for adaptive, patient-specific therapies.

II. DESIGN INPUTS AND REQUIREMENTS

We designed the DyNeuMo Mk-1 to be used as a research system for exploring how we might improve therapies with automated algorithms. The system-level requirements are summarized in Table I.

As a first design requirement, our research tool must preserve the stimulation capabilities of predicate therapy systems, to ensure there is no compromise to clinical care options. This approach is consistent with other state-of-the-art research tools provided for therapy research [16], [17]. The DyNeuMo Mk-1 provides stimulation capability equivalent to predicate deep brain, chronic pain, sacral (incontinence), and gastric stimulators, based on publicly-available manufacturer specifications.

As a general research tool, we aim to support a variety of potential use-cases. Motion-based states of interest include tremor (oscillations), general activity, gait and freezing, absolute posture, falls, and transient shocks. The detection of these motion states can then be applied by researchers exploring improved therapies for postural and gait instability in Parkinson’s disease, transient stress events in mixed incontinence, posture effects in orthostatic hypertension, and titration of stimulation through circadian (sleep-wake) cycles. In addition to automated stimulation titration, inertial sensing also provides diagnostic information on patient activity without an added instrument burden on the user. The sensor also provides an alternative input for the patient to discretely interact with their device through explicit motor inputs, such as tap-activation.

The practical implementation of a motion-adaptive stimulator motivates additional design requirements. To help train and program the classifier, we need a method to gather individual patient data and configure the algorithm classifier based on their specific characteristics. We also need to implement a control method to map motion classification to the desired stimulation state. To minimize the impact on device longevity or avoid increasing recharge burden, the addition of the algorithm must not significantly increase the power consumption compared to baseline therapy, e.g. roughly < 400 µW for Parkinson’s disease bilateral stimulation. Finally, we need a safe verification process to confirm the functional operation of the motion-adaptive algorithm in each patient.
III. Risk Mitigations for Motion Adaptive Algorithms

In parallel with defining user needs for research, we followed the ISO 14971 risk management process to identify and address potential harms to the patients. Particular emphasis was placed on the automated algorithms, and the IEC 60601-1-10 was used as guidance for the design of physiologic control systems. Fig. 1 helps to illustrate the design considerations for closed-loop medical systems using this framework [1].

Using the physiologic control framework, we identified concerns and specified system mitigations. With an automated system, we need to limit stimulation to known-safe levels as the algorithm commands state changes. This “actuation limit” can be achieved by limiting the algorithm’s access to specific pre-configured programs (patterns of stimulation) [18], [19]. The clinician-researcher then effectively defines a boundary on parameter states, with assurance that the algorithm never exceeds these limits. We also need to provide visibility to the users, both subject and clinician, on the immediate algorithm state. This observability was implemented on the patient controller with specific state alerts, including both the state of the algorithm (enabled/disabled) and the active stimulation program. All available states were also verified in software testing. Aligned with this specification, the patient controller also provides a mechanism to enable and disable the adaptive algorithm with a button press. Supporting the deactivation feature and stimulation limits, a pre-selected open-loop “fallback” program is also defined, which the stimulator defaults to upon manual exit of the algorithm [18]. Timing safeguards were also added including ramped transitions in intensity between stimulation programs (Fig. 6) to avoid subject discomfort such as paresthesia [20], and timing interlocks to avoid inadvertent rapid transitions at classification boundaries. As an additional safeguard out of precaution, we specified that the adaptive motion algorithm should be disabled during recharge to prevent changes in the stimulation program and ensure a known stimulation state is maintained throughout the process.
TABLE I
SYSTEM-LEVEL SPECIFICATIONS FOR THE DyNeuMo-MK1 INVESTIGATIONAL RESEARCH SYSTEM

<table>
<thead>
<tr>
<th>User Needs</th>
<th>Description</th>
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<tbody>
<tr>
<td>Predicate Therapy Support</td>
<td>The research system must support existing stimulation parameters for therapy delivery (amplitude, frequency, pulse width)</td>
</tr>
<tr>
<td>Supported Therapy Research</td>
<td>Deep brain stimulation, chronic pain (spinal cord), incontinence and bladder control (sacral, pudendal nerve), gastroparesis (enteric)</td>
</tr>
<tr>
<td>Adaptive Sensing Scheme</td>
<td>Inertial accelerometer (three axis) – with DC accuracy for posture detection and AC capability for activity, tremor, gait, shocks and free-fall – flexibility for configuration to specific therapy needs</td>
</tr>
<tr>
<td>Algorithm Training Support</td>
<td>Ability to stream data for classifier training</td>
</tr>
<tr>
<td>Algorithm Power Allowance</td>
<td>The adaptive algorithm must draw no more than 20% of the nominal therapy power (e.g. 80 µW for deep brain stimulation)</td>
</tr>
<tr>
<td>Algorithm Latency</td>
<td>&lt; 20 ms from event detection to stimulation adjustment</td>
</tr>
<tr>
<td>Algorithm Verification</td>
<td>Minimal-risk verification procedure for the algorithm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Mitigations</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stimulation (Actuation) Limits</td>
<td>Pre-defined limits on the stimulation level to ensure patient safety; this includes transition ramps between stimulation program settings for tolerance (e.g. avoid paresthesia)</td>
</tr>
<tr>
<td>State Monitoring and Alerts</td>
<td>Algorithm state clearly shown on patient interface, ability to enable/disable with a button press; data logger for algorithm transitions for issue resolution</td>
</tr>
<tr>
<td>Fallback Mode</td>
<td>Pre-defined stimulation program for emergency exit from algorithm; disengagement of the automated algorithm during recharge</td>
</tr>
<tr>
<td>Physiological Dynamics</td>
<td>Stimulation timing interlocks to avoid inadvertent rapid transitions at classification boundaries</td>
</tr>
</tbody>
</table>

IV. SYSTEM DESIGN IMPLEMENTATION AND CONFIGURATION PROCESS

The DyNeuMo Mk-1 was implemented using the physiologic control model as the design framework (Fig. 1) [1]. To summarize the overall mental model of the design, our aim is to supplement the selection of stimulation parameters using manual and timer-scheduled adjustments with the addition of motion-adaptive changes. This can be considered an additional response loop that adjusts stimulation based on characteristic motion profiles. Using this abstracted framework, we summarize here the key attributes of the design, and how the user engages the adaptive stimulation functionality. The system block diagram is shown in Fig. 2 details the control and signal routing.

The inertial sensing is provided by an embedded ADXL346, an ultra-low power microelectromechanical system (MEMS) three-axis accelerometer manufactured by Analog Devices [21]. The classifier leverages the digital motion processor (DMP) embedded in the ADXL346. The DMP is configured through the clinician interface through a read/write register field. While this interface requires referring to the register table in the manufacturer-provided documentation [21] to fully utilize, it does provide full accessibility to the DMP, which was deemed desirable for research teams exploring custom algorithms. The sensing axis, combination of axes, thresholds, AC/DC coupling, and timing constraints for rules/threshold-based classification provided by the DMP are all accessible in the register field. To lower the user burden, a set of reference register tables is provided to facilitate DMP configuration using representative use cases for algorithms based on absolute posture, general activity/inactivity, and transient shocks.

The control policy is implemented by allowing the DMP to raise interrupts in the system. For this, DMP event marker signals are attached to digital inputs of the embedded microcontroller, and set as external interrupt sources. In the current design, two unique interrupts can be generated, based on the DMP register configuration (Fig. ref fig 3a). DMP interrupts are then able to select between two pre-configured stimulation programs to apply to the electrodes. The association between the stimulation program and the interrupt source is configured on the clinician’s tablet programmer. In addition to the DMP-driven stimulation programs, the clinician also sets the default fallback program (per risk management) during configuration. The final control policy constraint is to ensure that the stimulation amplitude ramps during program transitions are acceptable to the patient; the ramp rate represents a user-controlled trade-off between side-effects, such as paresthesia and response time [22].

Given the multiple control inputs, we also needed to define the priority of changes being sent to the stimulation controller (Fig. 3b). Based on the analysis of use cases, we chose to use the latest command arising from either the motion classifier,
was chosen to balance time resolution and power constrains. The streaming rate to an external reference accelerometer. As illustrated in Fig. 5, the real-time streaming is provided in Fig. 4 which is compared to a transient event, which falls within the reported acceptable latency for responding to mixed incontinence stress events [23]. The stimulation will stay active until the timing threshold is met; in this case, one second. For improved specificity when required, the functionality of the double tap mechanism is supported through wire-connection, while manual intervention can always override these automated adjustments, including disabling them completely.

Once the motion-adaptive algorithm is configured, the verification of the automated system is supported through wireless telemetry to the patient programmer. When the motion-adaptive algorithm is activated with a button press, the screen indicator shows the current stimulation program in use. As the patient changes their motion state, the clinician-researcher can then verify that the expected stimulation program is activated by monitoring updates telemetered to the patient controller.

We also developed a system for classifier training and verification. The training module included real-time data streaming at 10 Hz through the MICS-band radio, while logging the accelerometer data to a file that can be used to determine register values for a motion-specific classifier. An example of the real-time streaming is provided in Fig. 4 which is compared to an external reference accelerometer. As illustrated in Fig. 5, the training module includes a wearable sensor that acts as a twin of the implant. The digital twin allows for register settings and classifier outcomes to be established before committing to the implant. Note that while streaming, the register table on the Clinician PC (tablet programmer) is also updated to display the implant’s embedded classification state. The streaming rate was chosen to balance time resolution and power constrains.

**V. System Verification**

System verification ensures that the DyNeuMo Mk-1’s motion adaptive algorithms have provided the desired automated stimulation adjustments, while not compromising the existing functionality of the Picostim. Most of the system hardware and software leverages the Picostim predicate, and verification testing protocols for functional areas such as stimulation, telemetry, and biocompatibility. The DyNeuMo Mk-1 firmware and software changes required to implement motion-adaptive stimulation.

We specifically focused on the expected use cases that leverage posture sensitivity, activity sensitivity, and tap/shock activation. Verification protocols demonstrated that the ADXL346 registers could be programmed appropriately for detection of specific inertial states, and that stimulation was then adjusted accordingly. For example, Fig 6 shows a representative posture activation that occurs when a subject transitions from laying down to upright (at time t1). Inertial transition points, timing interlocks, stimulation program mapping, and ramp rates were verified to operate as expected. Note that temporal responsiveness is fully programmable, as an example when a subject is laying down (at time t2), the DMP could wait for several minutes to avoid symptoms while transitioning to sleep; however while standing up it could respond immediately to prevent falls. Other verification examples included activity vs inactivity (e.g. for essential tremor control or gait detection) by testing the AC-coupled accelerometer mode for classification. Finally, we verified tap/shock detection, which could be useful for transient events such as those related to urinary incontinence, or as a mechanical patient input that eliminates their need for interaction using the handheld controller. As illustrated in Fig. 7, the stimulator can respond in under 15 ms to a transient event, which falls within the reported acceptable latency for responding to mixed incontinence stress events [23]. The stimulation will stay active until the timing threshold for inactivity is met; in this case, one second. For improved specificity when required, the functionality of the double tap constraint, which can help prevent false positives, was also verified.

In addition to algorithm functional performance, we also verified other system requirements such as power consumption, patient interface controls, and the human factors for algorithm programming. The power consumption of the MEMS sensor, including classification, is approximately 40µW, or 10% of the nominal therapy for a Parkinson’s or essential tremor patient. Note that this estimate does not include any potential energy savings by turning down stimulation at night.
or during periods of low activity. Other key performance results are summarized in Table II.

VI. SYSTEM VALIDATION THROUGH CLINICAL TRIALS

We consider system validation to be addressed through research protocols targeting specific disease states. To facilitate these experiments, the DyNeuMo Mk-1 is being released as a research tool for the clinical neuroscience community including the design history files required to support investigational device approvals. In-line with our user requirements, we aim to support existing therapies that might benefit from motion-adaptive stimulation; if the algorithm is not successful, it can be disabled and the patient benefits at a minimum from the predicate therapy.

For the initial validation case, we are exploring the treatment of orthostatic hypertension, gait imbalance, and sleep disturbances using deep brain stimulation of the pedunculopontine nucleus [24], [25]. Our choice of this protocol is motivated by the relationship between inertial signal inputs, clinical state, and stimulation parameters that can be explored with motion-adaptive stimulation. Pending promising outcomes from this trial, we can expand out to other disease states where explicit mappings between inertial signals and desired stimulation exist, such as tremor, cervical dystonia, and urinary incontinence [14], [26].
VII. LIMITATIONS OF THE DyNeuMo Mk-1 ADAPTIVE ALGORITHM

The DyNeuMo Mk-1 does have significant limitations worth noting; these are both technical and physiological. Perhaps most importantly, the current embodiment limits the measurement of motion to the device implantation site. In the case of a cranially-mounted system such as the predicate Picostim for deep brain stimulation, the specific measurement of hand tremor is therefore not supported; a more general correlation with general motion is required, which limits the specificity of the adaptive algorithm. An additional specificity error arises from the measurement limitations of a three-axis accelerometer. Specifically, the DMP can be confounded when estimating
TABLE II
TECHNICAL SPECIFICATIONS FOR THE DyNEuMo-Mk1 INVESTIGATIONAL RESEARCH SYSTEM

<table>
<thead>
<tr>
<th>Sensor Characteristics</th>
<th>Inertial sensing</th>
<th>3-axis accelerometer, sensitive to 4 mg activity variations; dynamic range programmable ±2 g to ±16 g; typical sampling rate is 50 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stimulation Characteristics</strong></td>
<td><strong>Channel Access</strong></td>
<td>8 independent electrodes, typ. arrangement is 2 leads × 4 electrodes</td>
</tr>
<tr>
<td></td>
<td><strong>Stimulation overview</strong></td>
<td>2 independent channels, current-controlled, charge-balanced monophasic/symmetric biphasic with programmable interphasic delay</td>
</tr>
<tr>
<td></td>
<td><strong>Multiplexing</strong></td>
<td>Full matrix configuration across electrodes (inc. the case reference)</td>
</tr>
<tr>
<td></td>
<td><strong>Stimulation magnitude</strong></td>
<td>0–15 mA (0.05 mA increments) and 0–450 µs pulse width, fractionalized distribution available for guarded cathodes, etc; programmable and independent ramp rates</td>
</tr>
<tr>
<td></td>
<td><strong>Recharge characteristics</strong></td>
<td>Programmable passive and active recharge, with variable recharge ratio</td>
</tr>
<tr>
<td></td>
<td><strong>Stimulation frequency</strong></td>
<td>1–500 Hz frequency stimulation; can go sub-Hz with cycling enabled; independent frequencies available across stimulation channels</td>
</tr>
<tr>
<td></td>
<td><strong>Stimulation cycling</strong></td>
<td>Adjustable cycle timing for enabling burst stimulation</td>
</tr>
<tr>
<td></td>
<td><strong>Stimulation programs</strong></td>
<td>Up to 8 independent programs can be configured in the IPG and accessed by algorithms or patient controller</td>
</tr>
<tr>
<td><strong>Algorithm Characteristics</strong></td>
<td><strong>Motion Classification</strong></td>
<td>Absolute orientation, activity vs non-activity (parameterized), shocks and free-fall detection</td>
</tr>
<tr>
<td></td>
<td><strong>Stimulation Control policy</strong></td>
<td>Detected classification states mapped to pre-configured stimulation programs with pre-specified transition ramp rate. Two independent stimulation programmes tied to motion states, and a default fall-back.</td>
</tr>
<tr>
<td></td>
<td><strong>Risk mitigations</strong></td>
<td>Algorithm implementation aligns to 60601-1-10 specifications for physiologic control loops (e.g. limits, alerts, data logs, fallback modes)</td>
</tr>
<tr>
<td><strong>Other System Characteristics</strong></td>
<td><strong>Battery capacity, recharge cycle</strong></td>
<td>50 mAh 3.6 V Lithium Ion, minimal fade, &lt; 2 h recharge</td>
</tr>
<tr>
<td></td>
<td><strong>Mechanical Characteristics</strong></td>
<td>Cranial-mount, 7.4 cc titanium package, with 2 leads for 4 contacts/lead, typical bal-seal style modular fixation system</td>
</tr>
<tr>
<td></td>
<td><strong>Telemetry/External Sensor and Stimulation Synchronisation</strong></td>
<td>MICS-band radio, &gt; 1 m distance, with hand-held module</td>
</tr>
<tr>
<td></td>
<td><strong>MRI compatibility (in process)</strong></td>
<td>MRI conditional imaging for 1.5 T and 3 T imagers</td>
</tr>
<tr>
<td></td>
<td><strong>Electrodes</strong></td>
<td>Modular design with ability to customize lead length and electrode spacing; currently supports brain stimulation and peripheral extradural electrodes and cuffs</td>
</tr>
<tr>
<td></td>
<td><strong>Clinician programmer</strong></td>
<td>Standard consumer tablet running Windows 10</td>
</tr>
</tbody>
</table>

posture by the superposition of linear acceleration with the gravitational field. This concern can be addressed somewhat by adjustment of the time and level constraints before generating an interrupt, but this mitigation is a trade-off with transition latency. While a gyroscope might help improve specificity, it also requires significantly more power than most therapies due to the principles of MEMS-based Coriolis sensing. Finally, our use of interrupt source to determine the stimulation program currently limits us to transitions between two stimulation states. If this is found to be severely limiting, we could perform more advanced interrupt masking and explore adaptive DMP register adjustments in the future. As one example of physiological limitations, the time dynamics between stimulation and physiological response need to align with the adaptive algorithm capabilities. For example, if stimulation requires extended time to take effect, then the utility of adaptive stimulation titration might be limited. At this time, we believe that several clinically-meaningful adaptive algorithms can be implemented with the first generation research tool, and we can refine future designs based on relevant clinical experience.
VIII. SUMMARY

There is growing interest in adaptive medical devices, particularly using neuromodulation, to improve therapies by automatically adjusting stimulation based on clinically-relevant physiological features. In response to the worldwide demand for research tools to support clinical studies into adaptive neuromodulation techniques, we have developed a fully-implantable medical device that responds to inertial signals. The advantages of our approach are that it is 1) relatively easy to configure the classifier for clinically-relevant states, 2) relatively inexpensive to manufacture, and 3) highly reliable as a method. The limitations of this approach include limited specificity for detection away from the implant location, and confounds from superimposed motion when posture measurement is the goal. Even with these limitations, inertial sensing could be a practical solution for several unmet needs, which can be validated in first-in-human studies using the DyNeuMo Mk-I research system. It could also serve as a secondary input to improve the performance of alternative methods using bioelectrical signals. As consumer electronics and the internet-of-things continue to evolve, we believe future medical devices will benefit from continued adoption of mainstream technology, which will provide meaningful clinical solutions with favourable economics and reliability.

ACKNOWLEDGMENT

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DISCLOSURES

The University of Oxford has research agreements with Bioinduction Ltd. Tim Denison also has business relationships with Bioinduction for research tool design and deployment.

REFERENCES


