Pain Monitoring Device: PMD-200™
Medasense Biometrics Ltd

The need

Pain represents a major clinical, social and economic problem[1] so it is no surprise that treating pain is at the epicentre of medicine and structures the aim of healthcare professionals. Pain affects hundreds of millions of people and, in Europe, national healthcare and socioeconomic costs of conditions associated with chronic pain run into billions annually and represents 3–10% of gross domestic product[2]. Currently there are no validated objective markers of nociception or pain that can be recommended for clinical use[3] so treatment relies on patients' subjective assessment and clinician interpretation, a particular issue when the patient cannot communicate (e.g. those who are anaesthetised). Postsurgical complications related to inadequate pain management negatively affect the patient's welfare and the hospital performance because of extended lengths of stay and readmissions, both of which increase the cost of care[4]. Medasense's vision is to optimise pain management through accurate and objective assessment of pain at hospitals, clinics and at home.

The solution

Medasense have developed a novel, multi-parametric, patented technology to objectively assess nociception (pain), quantify it and measure the analgesic effect. Due to the multifaceted nature of pain, Medasense's solution focuses on the body's physiological integrated response to pain, rather than individual pain pathways. The device consists of a non-invasive finger probe which continuously records multiple pain related physiological signals – using four sensors namely a photoplethysmograph, galvanic skin response, temperature and accelerometer. From the signals- dozen of pain related physiological parameters and derivatives are extracted and computed (heart rate, heart rate variability, skin conductance level, photoplethysmography pulse wave amplitude, a number of skin conduction fluctuations, skin temperature and more). The PMD200 bedside monitor uses composite artificial intelligence algorithms to analyze dozens of pain-related measurable changes in the physiological parameters and determine the individual's nociception level index (NOL™). This NOL™ is visualized on the PMD200™ monitor using a scale of 0 to 100, where 0 represents no pain and 100, extreme pain. The device is calibrated to the individual's baseline and provides continuous, real time monitoring.
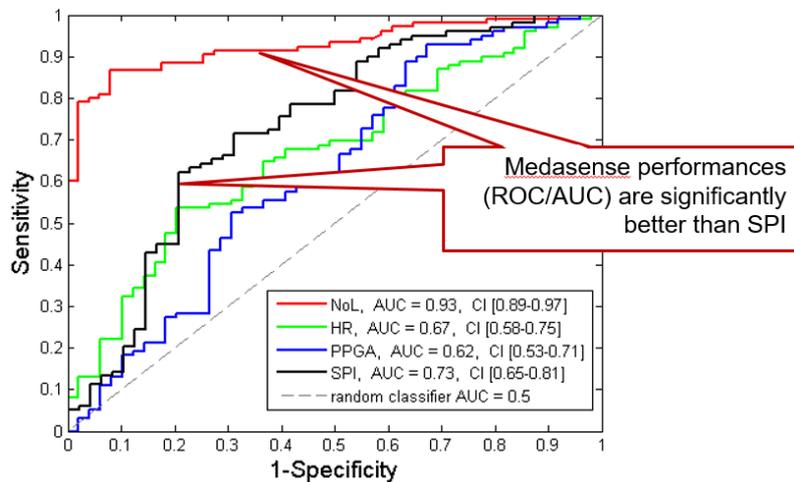
The benefits

NOL™ helps healthcare professionals monitor pain intensity and titrate analgesic medication accordingly during anaesthesia[5,6] with the aim to reduce suffering and minimise adverse events which can be caused by over or under usage of analgesic medications.

The evidence

Over an 8 year research period, 8 studies were conducted in Canada, Europe and Israel, involving more than 500 patients. These patients were a combination of conscious, anaesthetised and those suffering from acute and chronic pain[5-8] and included trials performed on patients undergoing surgery. Key results published and cited in peer reviewed medical journals (Pain, Anesthesiology, The Journal of Clinical Monitoring and Computing) have demonstrated the NOL™ index outperforms currently used parameters and methods.

Results show the technology is able to discriminate between noxious and non-noxious stimuli with high intensity and specificity, and grade the different levels[5,6].

Medasense performances (ROC/AUC) are significantly better than SPI

NoL, AUC = 0.93, CI [0.89-0.97]
HR, AUC = 0.67, CI [0.58-0.75]
PPGA, AUC = 0.62, CI [0.53-0.71]
SPI, AUC = 0.73, CI [0.65-0.81]
random classifier AUC = 0.5

The market

Following the CE approval of the PMD200™ the first stage of rollout will be aimed at institutions which treat anesthetised surgical patients, namely ORs, with further expansion anticipated once other regulatory approvals are received. Expansion of the market by collaborating with leading patient monitoring companies and possibly anaesthesia and infusion equipment suppliers, pharmaceutical companies, research institutes and wearable providers is a possibility. With nearly 234.2 million major surgical procedures worldwide each year[9], the market potential for this device is enormous.

The company

Medasense Biometrics Ltd. is an award-winning company led by experienced industry veterans, professionals in the fields of signal processing and computer engineering, together with key opinion leaders and renowned researchers in the field of pain. In 2015, the company was awarded the 'Most Innovative Medical Device Company' by IATI Biomed and was chosen as the 'Start-up to Watch' in the September issue of the MedTech Strategist Magazine. In 2016 they were named as one of the 'Top 5 Medtech startups' by TechWorm and an Israeli tech company to watch in 2017 by Isreal21c. The Scientific advisory board includes key opinion leaders, well-known researchers and prominent pain specialists from the US, Israel, Europe and Canada. During 2016 Medasense has closed a $8 million Series B financing round which was led by Benslie investment group and joined by existing investors and Baxter Healthcare Ltd.

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