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Mdoloris Announces CE Marking of the Analgesia Nociception Index (ANI®) Module for the Masimo Root® Patient Monitoring and Connectivity Hub

Lille, France – April 29, 2019 - Mdoloris Medical Systems announced today the CE marking of the Mdoloris Analgesia Nociception Index (ANI®) module for the Masimo Root® Patient Monitoring and Connectivity Hub, the result of a Masimo Open Connect® (MOC) partnership between Mdoloris and Masimo. ANI provides an objective, noninvasive, and continuous way to automatically monitor the pain level of patients. The Root platform, with its open architecture and built-in connectivity, is designed to allow third-party technologies, such as ANI, to expand Root's capabilities even beyond the advanced Pulse CO-Oximetry, SedLine® brain function monitoring, and other technologies offered by Masimo itself. With the combination of ANI and Masimo SedLine, Root can now be used to simultaneously monitor depth of sedation and level of pain.

Pain relief is a major concern in developed countries, while pain assessment has historically been subjective, time-consuming due to its manual nature, and intermittent. To address these limitations, Mdoloris developed ANI technology and made it available on Root as a MOC-9® expansion module. ANI quantifies parasympathetic tone and autonomic nervous system activity through analysis of the brief and rapid heart rate variations induced by each respiratory cycle (spontaneous or artificial). Use of the ANI may help clinicians improve pain assessment and through it, patient care and pain management with more objective and precise drug administration.

The ANI is a numerical value between 0 and 100. Studies have shown that for an unconscious patient under general anesthesia, the target values are between 50 and 70.[1-4] An ANI below 50 corresponds to an opioids failure and is predictive of hemodynamic response, while an ANI higher than 70 suggests an opioid overdose. For the conscious patient, ANI reflects acute pain and stress level. The target values are between 50 and 100; an ANI value approaching 100 reflects optimized patient comfort.

"We are delighted to be able to announce that ANI is now cleared for sale in the EU," said Fabien Pagniez, Founder and CEO of Mdoloris Medical Systems. "We consider Masimo to be the most innovative company in the patient monitoring space and we believe Root offers a unique and compelling solution for implementing our ANI technology."

ANI on Masimo Root has not received 510(k) clearance and is not available for sale in the United States.

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About Mdoloris Medical Systems

Mdoloris (www.mdoloris.com), a medical devices manufacturer, was created in June 2010 out of 23 years of academic research performed in Lille University hospital, France. It has an international representation in more than 64 countries and a scientific, technical and medical acknowledgement. Mdoloris has so far developed three products, all able to continuously assess the pain level of patients (the ANI technology for patients older than two years old, the NIPE technology for neonates, and the PTA technology for pets). Its innovative technologies provide clinical added value for clinicians who are not able to communicate with their patients in order to personalize pain medications and avoid known side effects due to over- and under-dosage of such drugs. More than 1,200 devices are now used by anesthesiologists and intensivists wordwide and more than 140,000 patients have benefited from Mdoloris' technologies. Mdoloris's standalone monitor promoting its innovative adult technology has received 510(k) clearance through the HFVI brand in the US under the number K142969. Mdoloris recently closed a nine-million euro fundraising round in order to keep developing new-to-the-world technologies that always keep one target in mind: helping clinicians improve the quality of care.

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