



## **FDA Clears First Medical Device With Internal Game Mode** Monitors Proper Device Use and Enhances Patient Compliance

SAN DIEGO, CA. September 15, 2014 – AVACEN Medical announced today that its AVACEN 100 Class II medical device, received 510 (k) OTC clearance by the U.S. Food and Drug Administration. This clearance allows the AVACEN 100 to be marketed over the Internet for: *the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; and muscular relaxation.*

The AVACEN 100 is a robust medical device incorporating over 3,000 firmware instructions supporting numerous innovations including an internal “Game Mode”. This mode encourages users to complete their 10-30 minute therapy session, and also allows a therapist to monitor for proper device use during self-administered therapy.

Optional Game Mode awards real-time points when the user keeps their hand properly positioned on the hand pad during the therapy session. Accumulated points are shown on the display panel. The better the hand position, the more points earned. If the patient's hand drifts too far off target, an alarm goes off and 10,000 points are lost.

At the end of the therapy session the final score is displayed, along with the previous high score and a random encouragement message which relates to the performance achieved e.g. “*Major league performance! Wow*”.

“We designed this feature for a family member with attention challenges. The goal was to help him remain engaged while completing an unexciting 20 minute therapy session. Later we determined that this was also an ideal way to monitor the unattended use by therapy patients. In ‘normal’ mode, the device automatically turns off at the end of each session. In ‘Game Mode’, the therapist can simply look at the points accumulated to determine if the device was properly used,” said Thomas G. Muehlbauer, Chairman and CEO, AVACEN Medical.

About the AVACEN 100: In March of 2014 the US Patent Office issued Patent No. 8,679,170 to AVACEN covering key aspects of the medical technology platform integrated in the AVACEN 100.

The issued patent includes apparatus claims directed to features of the Heat Therapy apparatus manufactured by AVACEN and method claims directed to specific methods of use, referred to by the company as the *AVACEN Treatment Method*. The patent also covers innovations embodied in the AVACEN 100 system, which is expected to allow multiple therapeutic uses to alleviate symptoms associated with a circulatory, neurological, lymphatic, or endocrinal dysfunction, or any combination thereof.

About AVACEN: AVACEN Medical is dedicated to the innovation and design of safe, easy to use, noninvasive drug free alternatives to treat pain associated with diseases such as arthritis, fibromyalgia and migraines. Founded in 2009, AVACEN is headquartered in San Diego. AVACEN can be contacted at (888) 4-AVACEN or [info@AVACEN.com](mailto:info@AVACEN.com).