Press Releases

New US FDA Clinical Evaluation Proves Non-Contact Thermometers Fail To Meet Accuracy Specifications

Exergen: FDA Study Reveals Misleading Labeling by NCIT Manufacturers Regarding Accuracy

WATERTOWN, Mass., Dec. 9, 2021 /PRNewswire/ -- Since the start of the pandemic, non-contact infrared thermometers (NCITs) have been widely used as a screening method for fever detection in healthcare and public settings, as fever is a leading sign of Covid. Now, a new FDA published study[1] demonstrates their failure to reliably detect fevers when used on adults in accordance with the NCIT instructions, and fail to be within the accuracy specifications as advertised in manufacturers' literature, instructions for use, and other labeling. The study suggests that because of their high probability for producing false negative readings close to the CDC fever threshold, NCITs are an unreliable temperature screening tool. FDA's 510(k) premarket notification database shows that more than 20 NCITs have been cleared by the FDA in the past three years.

The study, which was approved by the FDA Institutional Review Board (IRB), was undertaken to determine the accuracy of NCITs and evaluate their adherence to FDA labeling requirements. It tested six different commercially available NCIT models among a large sample of 1,113 adult subjects, 93% between 18 and 30 years old and 7% older than 30. A total of 60 NCITs were tested, with 10 units per model. The temperatures were compared with those taken with a reference oral thermometer in the monitor mode. The mean difference between the reference thermometer and the NCIT measurements for under- and over-reporting varied widely by model. Depending on the specific device, 48% to 88% of the individual temperature measurements fell outside the labeled accuracy stated by the manufacturers. Notably, these false readings were obtained in an highly controlled environment that carefully managed all possible variables.

"This important study underscores what the medical community has known all along: NCITs are *not* accurate and device manufacturers are being irresponsible when accuracy matters most. It also shines light on NCIT manufacturers' lack of adherence to FDA specifications for accuracy in labeling," said Francesco Pompei, Ph.D., CEO of Exergen Corporation. "Covid has changed our world and we can no longer tolerate the rampant false temperature readings we get from NCITs. As the FDA states in the study: 'To successfully screen and track people with elevated temperature, it is essential that accurate temperature measurements are made, and that the thermometer outputs are correctly interpreted.' We agree with the FDA's assessment. For everyone's safety, NCIT manufacturers should be held responsible by the FDA so that their proven inaccuracy can be clearly seen and addressed."

ABOUT EXERGEN CORPORATION

Exergen manufactures and markets two series of the TemporalScanner thermometer: a professional version for hospitals and clinics, and a consumer version sold in major retailers nationwide. More than two billion temperatures are taken each year with TemporalScanners. Used in thousands of hospitals and clinics across the country as well as in millions of homes, TemporalScanners are the #1 preference of pediatricians, nurses, and mothers. The Exergen TemporalScanner's accuracy is supported by more than 100 peer-reviewed published clinical studies covering all ages from preterm infants to geriatrics and all care areas from hospitals to homes. For additional information, visit www.exergen.com.

[1] Sullivan, S.J.L., Rinaldi, J.E., Hariharan, P. *et al.* Clinical evaluation of non-contact infrared thermometers. *Sci Rep* **11,** 22079 (2021). https://doi.org/10.1038/s41598-021-99300-1

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