

EXERGEN: NEW US FDA STUDY PROVES NON-CONTACT INFRARED THERMOMETERS (NCITs) ARE AN UNRELIABLE TEMPERATURE SCREENING TOOL

FDA study highlights misleading labeling by NCIT manufacturers

WATERTOWN, Mass., Feb. 15, 2022 /PRNewswire/ -- Since the start of the pandemic, non-contact infrared thermometers (NCITs) have become the primary tool used in public temperature screenings, even though extensive scientific research has proven that they do not produce reliable or accurate temperature readings. Now, an important new study¹ published by the FDA adds to that body of scientific data, demonstrating that non-contact thermometers fail to reliably detect fevers. It also proves that they fall outside of the accuracy specifications advertised in manufacturers' instructions and labeling for proper usage. In sharp contrast, the Exergen TemporalScanner's accuracy is supported by more than 100 peer-reviewed published clinical studies.

The study was undertaken because of the NCIT's high probability for producing false negative readings close to the CDC fever threshold. It also sought to evaluate their adherence to FDA labeling requirements and in both cases, the non-contact thermometers failed. The study 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 population heavily weighted to healthier individuals, based on age. With 10 units per model, 60 NCITs were tested. and readings were compared to those taken with a reference oral thermometer.

The mean difference between the reference thermometer and the NCIT measurements for under- and over-reporting varied widely by model. Depending on the device, 48% to 88% of the individual temperature measurements fell outside the labeled accuracy stated by the manufacturers. These false readings were obtained in a highly controlled environment that carefully managed all possible variables that could contribute to a high or low reading, making the results even more significant.

"We agree with the FDA's assessment that non-contact thermometers are inaccurate and fail to meet guidelines for accurate labeling and marketing. We are seeing retailers removing NCITs from their shelves, but all manufacturers should be held accountable by the FDA," said Francesco Pompei, Ph.D., CEO of Exergen Corporation.

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>

SOURCE Exergen

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