

ZYTO Technology

Safe - Accurate - FDA Cleared

The only FDA cleared Wellness Scanner



Millions of Scans successfully performed

0 Adverse Hand Cradle incidents

Food & Drug Administration

Established in 1930
Protecting you from harmful & mislabeled foods, drugs, and devices



ZYTO Hand Cradle – Cleared as a Class II Medical Device

Similar approved devices - Tuning fork, Percussor, Biofeedback device, Echoencephalograph
Computerized cognitive assessment aid, Near Infrared brain hematoma detector, Ataxiagraph, Nystagmograph



Hand Cradle testing

Accurate – Tested and confirmed accurate in measuring galvanic skin response

Safe – Met or exceeded EN60601-1-2 and EN55011 Class B Part 15 requirements



Passed

- ✓ Radiofrequency disturbances and limits test
- ✓ Surge test
- ✓ Magnetic field immunity test
- ✓ Voltage dips and interruptions test
- ✓ Electrostatic discharge test

Non-invasive & Safe for:

- Infants
- Children
- Adults of all ages
- Pregnant women
- Those with pacemakers
- Other possible contraindications



Not affected by:

- Jewelry
- Cell phones
- Other electronic devices



100% FDA Compliant

- ✓ ZYTO Hand Cradle
- ✓ ZYTO Software
- ✓ ZYTO Website
- ✓ Marketing Materials

ZYTO & the FDA - Timeline

2011 – ZYTO Hand Cradle cleared by FDA - 510(k) Clearance
 2015 – Software verbiage modified for compliance
 2016 – Voluntary update (in collaboration with the FDA) to ZYTO Select and Elite software
 ZYTO regularly collaborates with the FDA to maintain 100% compliance with all applicable laws and regulations.

The ZYTO Hand Cradle has been cleared by the FDA for the measurement of galvanic skin response. ZYTO software has not undergone FDA review for effectiveness. ZYTO technologies are not intended to be used in the diagnosis, cure, treatment, mitigation, or prevention of any disease or medical condition, but only provide general wellness information. The diagnosis and treatment of medical conditions should only be undertaken by qualified medical professionals. ZYTO products have not been the subject of controlled clinical trials to establish their effectiveness and their use is not a generally accepted medical practice by the traditional medical establishment. If you have any questions regarding ZYTO technology or our products please contact us at info@zyto.com.

