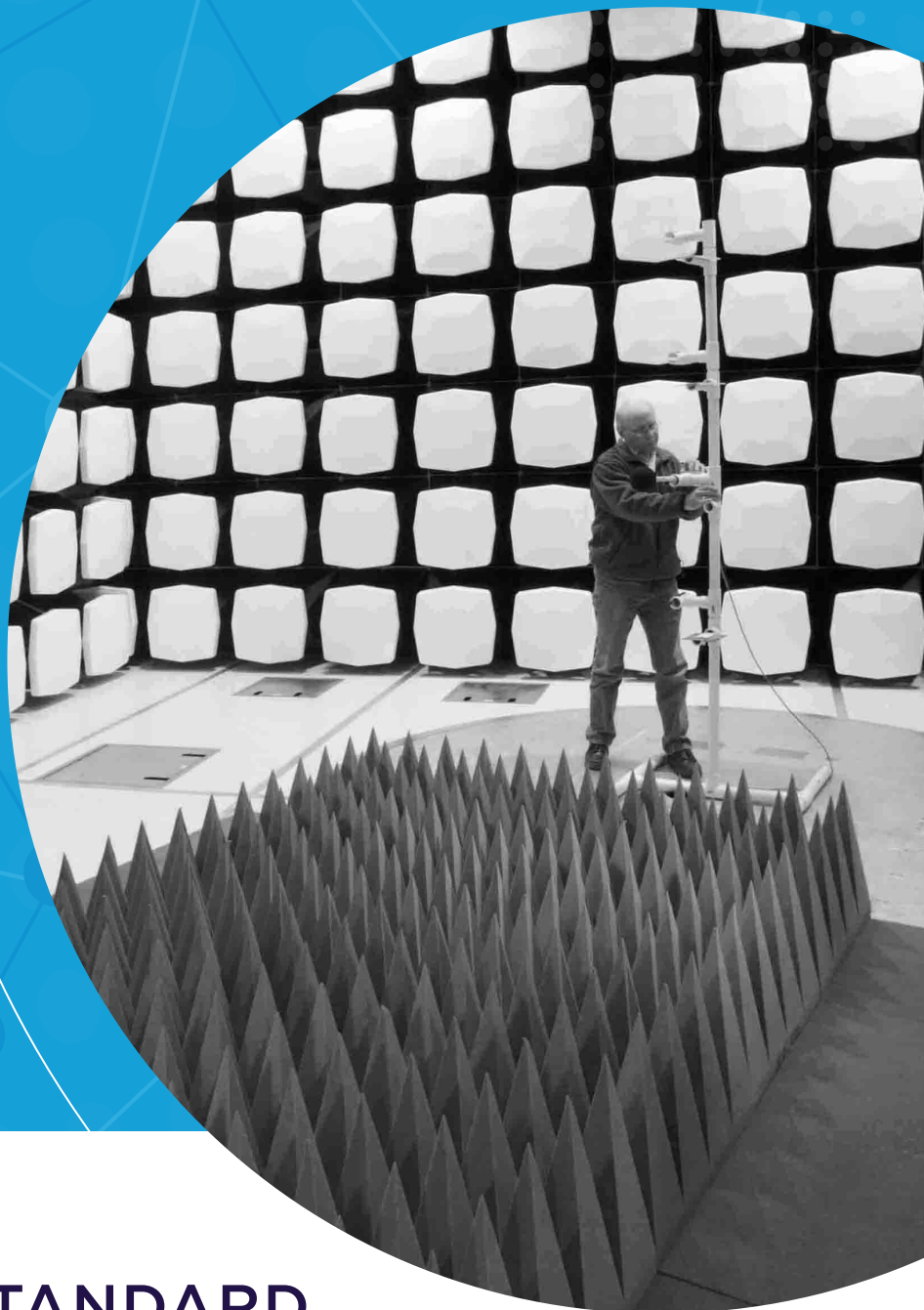
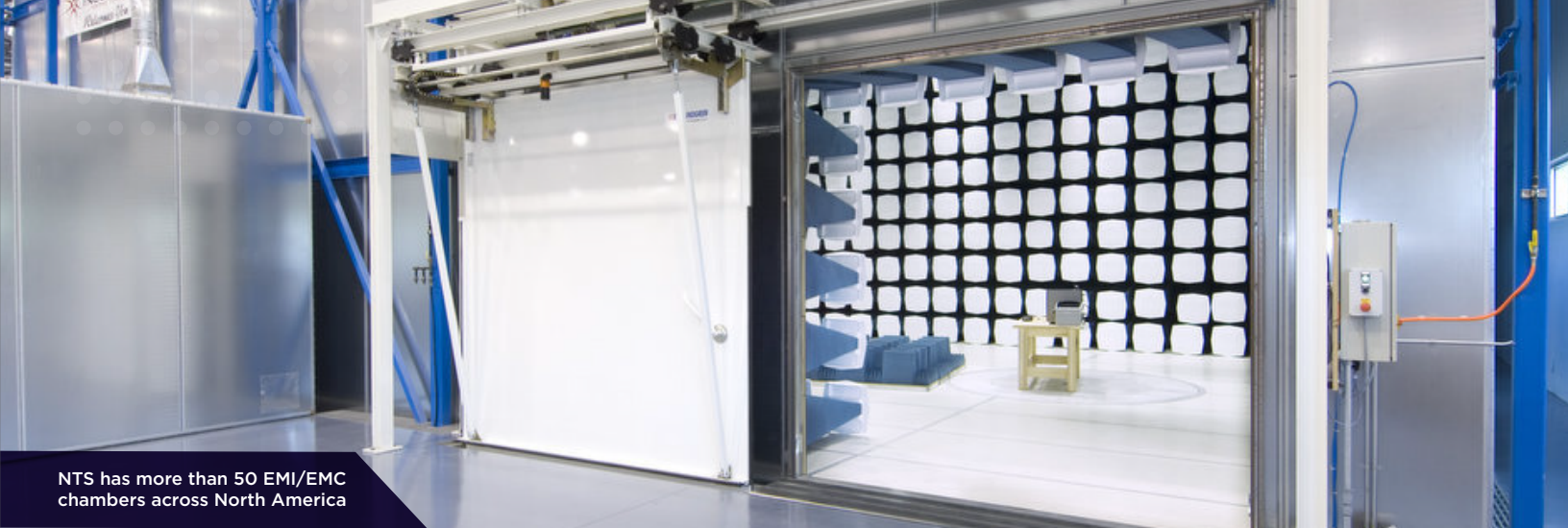


MEDICAL SECTOR

2019 CAPABILITIES



A HIGHER STANDARD
REDEFINING MEDICAL DEVICE TESTING



NTS has more than 50 EMI/EMC chambers across North America

ABOUT NTS MEDICAL DEVICE TEST SERVICES

NTS' laboratories have extensive experience supporting the medical products market. As technology advances and medical equipment becomes more and more sophisticated, the need for testing has increased.

We work with our customers to determine the testing needed to meet FDA, product safety and other certifications and bring their products to market quickly. In some cases, where no testing protocol is established, our engineers assist customers to determine what testing will be the most beneficial to the product development process.

TECHNOLOGY TESTING OF MEDICAL DEVICES

NTS' Advanced Technology division provides a wide range of services associated with the software and hardware technology involved in many of today's medical device products. Certification to specific standards such as USB, FDA coexistence, software compatibility and interoperability, functionality, performance and usability are all routinely conducted. Products tested include monitors, handheld electronic devices, computers and peripherals.

The primary focal areas for the FDA Guidance for medical/wearable devices are wireless coexistence, performance, data integrity, security, and EMC. Our Advanced Technology engineers focus on the identification, documentation and implementation of product design requirements (21 CFR 820.30), the design verification and validation (21 CFR 820.30) and risk management process and procedures.

NTS will prepare a customized test plan, execute the testing, and help with the submission for FDA approval. Certification is the best way to ensure a standard's successful adoption.

RADIO FREQUENCY IDENTIFICATION (RFID) FOR MEDICAL DEVICES

NTS has assisted many customers with their medical device EMC compliance testing. Some examples include:

- Light Therapy Devices
- Surgical Microscopes
- Eye Scanning Analysis Tools
- Muscular Stimulation Devices
- AED Devices
- Glucose Monitors
- Repeater Pumps
- UV Blood Sterillizers
- Medical Waste Disposal Devices
- Electric Wheelchairs
- Large and small surgical systems and devices

ELECTROMAGNETIC COMPATIBILITY FOR MEDICAL DEVICES (EMC)

FDA EMC Recognized Standards:

- IEC 60601-1-1 - Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- ANSI/AAMI/IEC 60601-1-2 - Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- ANSI/RESNA WC-2 - Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems
- IEEE/ANSI STD C63.19 - Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids
- Applicable FCC Standards
 - FCC Part 15 Radio Frequency Devices
 - Part 15 Subpart B: Unintentional Radiators
 - Part 15 Subpart C: Intentional Radiators
 - Part 15 Subpart D: Unlicensed Personal Communications Service Devices
 - Part 15 Subpart E: Unlicensed National Information Infrastructure Devices

ENVIRONMENTAL TESTING OF MEDICAL DEVICES

Some examples of environmental testing we have conducted on medical devices include:

- Altitude, humidity, vibration, susceptibility, drop, ingress, EMC, and vibration of an AED device
- Anechoic chamber testing, shock and load, slow thermal cycle and damp heat testing, vibration, bump and shock on surgical microscopes
- Package testing, random vibration testing, shipping, and altitude conducted on heart pump control units
- RF, ESD, Immunity, Package, Radiated Emissions (RE), Shock, Temp, Drop and Environmental testing for large surgical systems
- Ingress protection (IP) and engineering pre-scan of a Li-ion batteries
- Altitude testing on respiratory ventilators
- Noise testing of blood gas analyzers
- Blowing sand, dust and rain, ingress, shock and vibration of remote (Wi-Fi) patient monitoring systems
- Acoustic noise testing, pull testing, sound testing, temperature, and abrasion testing of breast pumps
- Environmental testing of patient temperature management devices
- Altitude, humidity, vibration, susceptibility, drop, ingress, EMC, and vibration of an AED device
- Enclosure protection of Bluetooth medication trackers
- Shock and vibration of infusion pumps
- Vibration testing of work station carts, cables, microscopes and pumps
- Environmental exposure and durability testing of medication delivery systems such as IV pumps

RADIO FREQUENCY IDENTIFICATION (RFID) FOR MEDICAL DEVICES

Some examples of materials testing we have conducted:

- Root cause failure analysis of medical electronics and non-electronic device field returns
- Component analysis, standard radiography, and computer tomography (CT) of hearing implants
- Cleaning procedure validation of endoscopes
- Cleanliness testing of surgical tools
- Contamination analysis of handheld wireless diagnostic tools
- Mechanical properties (tensile, flexure, compression, hardness, etc.) of non-electronic devices

ABOUT NTS

NTS is the undisputed leader in testing, inspection, and certification. With 1,300 employees and 28 labs in North America, NTS leverages its expertise to serve more than 8,000 customers. NTS thought leaders sit on advisory boards, speak at conferences, and author technical papers. Established in 1961, NTS leverages its rich experience and technical expertise to create best-in-class queue times, on-time reporting, and rigorous testing programs in a variety of areas, including:

NEBS MATERIALS
FAILURE ANALYSIS HYDRAULICS/PNEUMATICS
LIGHTNING PRECISION CLEANING
BALLISTICS ENVIRONMENTAL
MANAGED ENGINEERING SERVICES
EMI/EMC GLOBAL MARKET ACCESS
DYNAMICS



www.nts.com | 800.270.2516 | sales@nts.com

HELPING
CUSTOMERS
DELIVER PRODUCTS
THE WORLD CAN
TRUST