MDEXPO

New England • October 8-10, 2024

DEFIB MAINTENANCE BEST PRACTICES COMPLETING MANUFACTURER BASED PM'S ACCURATELY AND EFFICIENTLY

PRONK TECHNOLOGIES

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OVERVIEW

- Importance of Servicing Defibrillators
- How to find failure and incident information
- Common issues reported to FDA
- Key points to consider when servicing these critical devices
- Demonstration of Defib PM according to manufacturer procedure

PRONK TECHNOLOGIES

SERVICING DEFIBRILLATORS KEY FOCUS

- Life support devices that play critical role in healthcare.
- Devices can be high wear and tear particularly in Emergency Care and field use situations.
- Important to follow manufacturers' procedures and service intervals as the minimum standard of service.
- Important to document the service performed.
- Maintain awareness to manufacturer product updates/notifications.
- Check Defib Event Logs for possible performance issues.

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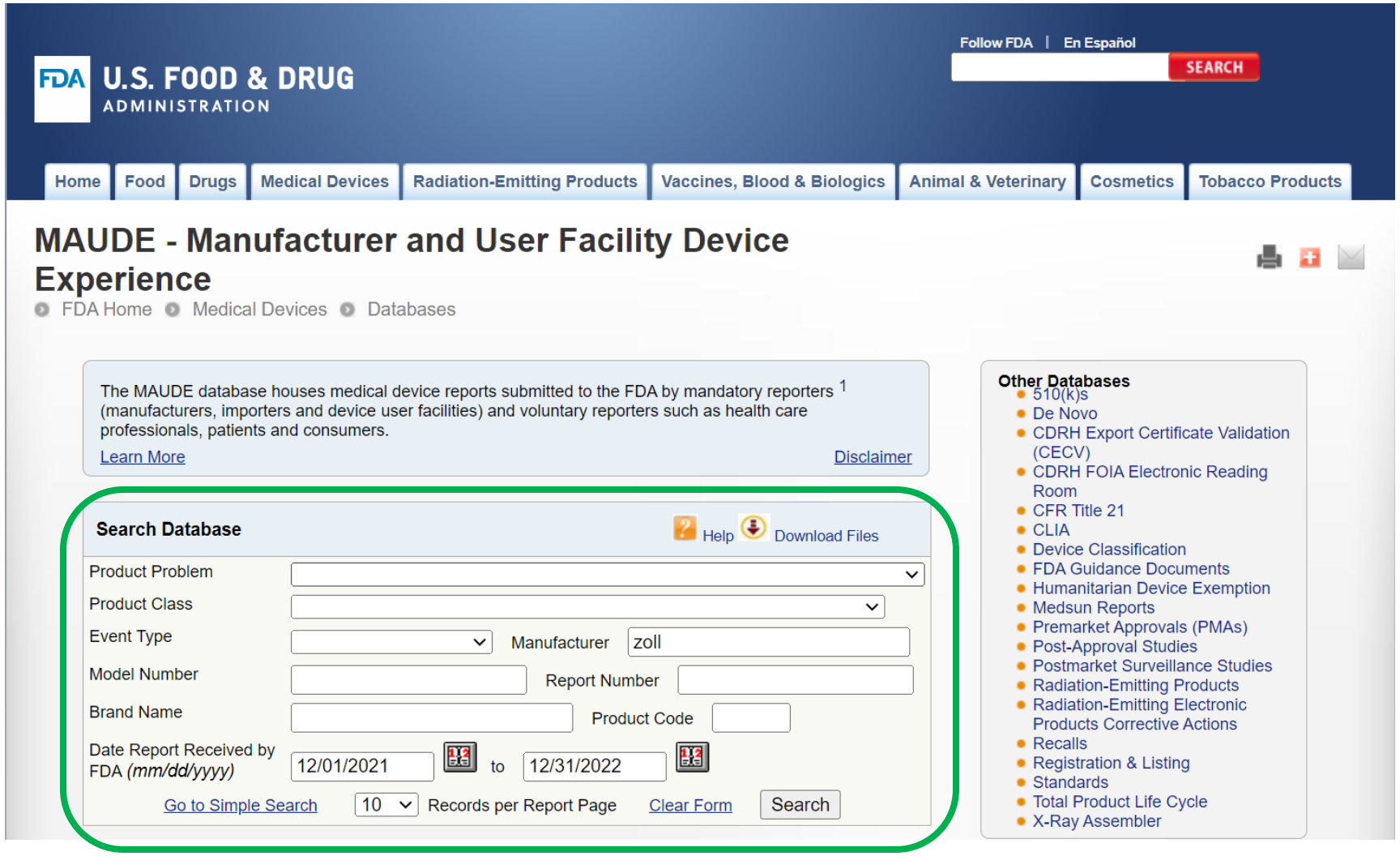
RESOURCES FOR PERFORMANCE AND INCIDENT INFORMATION



https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

RESOURCES FOR SERVICE HISTORY INFORMATION

U.S. FOOD & DRUG ADMINISTRATION

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

MAUDE Adverse Event Report: [redacted] DEFIBRILLATOR/PACEMAKER

FDA Home › Medical Devices › Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

[redacted] **DEFIBRILLATOR/PACEMAKER** Back to Search Results

Model Number [redacted]
Device Problem Failure of Device to Self-Test (2937)
Patient Problem No Clinical Signs, Symptoms or Conditions (4582)
Event Type malfunction
Manufacturer Narrative
[redacted] has not received the device for evaluation and this complaint is still under investigation.

Event Description
Complainant alleged that during biomed testing, the device failed self-test for defib. Complainant indicated that there was no patient involvement in the reported malfunction.

Search Alerts/Recalls

New Search | Submit an Adverse Event Report

Brand Name [redacted]
Type of Device DEFIBRILLATOR/PACEMAKER

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SAMPLE OF ISSUES REPORTED

- Display Blanking issues during use or on power-up
- Device Powering Off unexpectedly
- Energy not delivered
- Unit intermittently powered off. Battery not properly seated.
- Battery pins damaged.
- Did not defibrillate on patient
- Shock button works intermittently. Fails to deliver energy

PRONK TECHNOLOGIES

TEST EQUIPMENT/INFORMATION NEEDED

- Defibrillator/Pacer Analyzer
- Electrical Safety Analyzer
- Patient Simulator
- Stopwatch
- Access to current revision service/maintenance procedures including pass/fail tolerances
- Ability to document test results all test equipment utilized
- Manufacturer specified equipment/fixtures i.e. battery current tester

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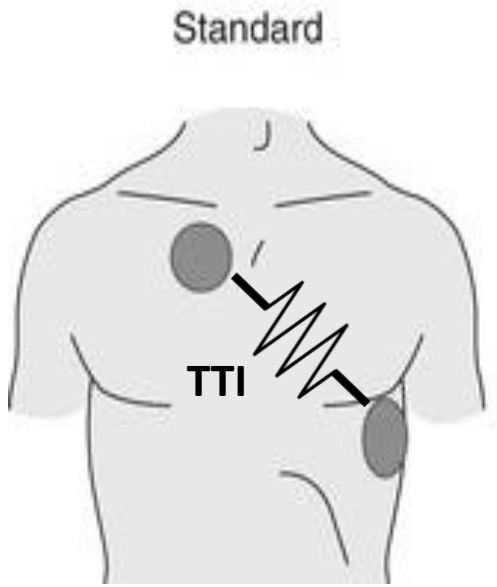
IMPORTANCE OF VISUAL INSPECTIONS

- **Inspect For:**
  - Any physical damage on unit is a good indicator of possibility of performance issues.
  - Check all cabling for damage, including connectors. Should perform a cabling “wiggle” test to verify no intermittent connections.
  - Check battery compartment for contact damage, fit and latch performance

PRONK TECHNOLOGIES

DEFIBRILLATION DISCHARGE (SHOCK) FACTORS

- Patient impedance, Transthoracic impedance (TTI) varies from patient to patient
  - A number of factors impact TTI – age, skin condition, body weight, BMI, hair etc.
- This has an effect on the defibrillation energy (Joules) delivered to the patient. Joules (energy) = Time x Voltage x Current
- Standard requires Defib manufacturers to test across range of impedance in accordance to ANSI/AAMI/IEC 60601-2-4 standards. 25, 50, 75, 100, 125, 150, 175 ohms.



PRONK TECHNOLOGIES

PERFORMING DISCHARGE (SHOCK) TESTING

- Perform testing according to manufacturers test load impedance requirements.
- Common impedance setting for PM is 50 ohms.
- Defib analyzers have as option, external variable load modules for testing across varying impedance to simulate various transthoracic electrical impedance (TTI) of a patient.
    - This can be helpful to ensure Defib meets Shock specifications across wide range of patient impedances.

PRONK TECHNOLOGIES

PERFORMING DISCHARGE (SHOCK) TESTING

- Show chart below and explain sometimes you don't base your tolerances based on the target but what the manufacture states in their manual

CHAPTER 1 MAINTENANCE TESTS

Delivered Energy at 200J Defibrillator Setting into a Range of Loads

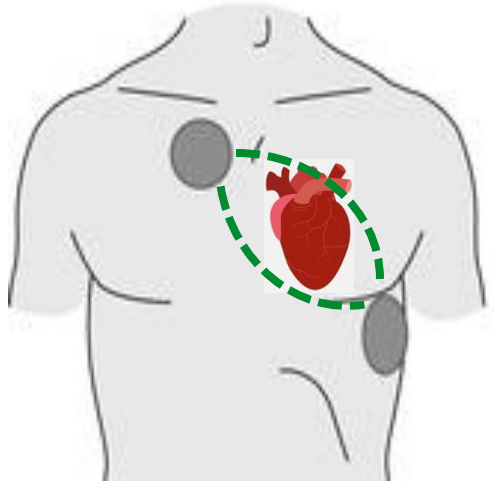
Selected Energy	Load							
	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	Accuracy*
5 J	3 J	5 J	6 J	6 J	6 J	6 J	6 J	±15%
50 J	35 J	54 J	59 J	61 J	62 J	61 J	59 J	±15%
100 J	71 J	109 J	119 J	122 J	125 J	123 J	119 J	±15%
200 J	142 J	230 J	249 J	253 J	269 J	261 J	260 J	±15%

Note: For a complete listing of X Series Delivered Energy at Every Defibrillator Setting into a Range of Loads, see Appendix A in the *X Series Operator's Guide*.

PRONK TECHNOLOGIES

DEFIB TRANSCUTANEOUS PACING (TCP)

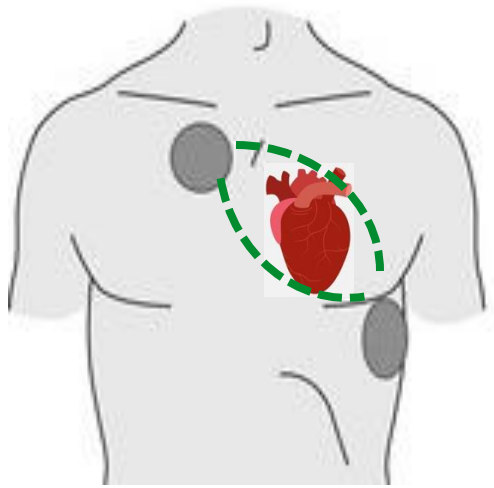
- External pacing is utilized as temporary means to control the heart rate by delivering controlled current pulses between the pacer pads connected to patient.
- Pacing current stimulates heart to contract.
- Current delivered starts at 10mA to “capture” heart but can be much higher depending on patient.
- Fixed or Demand Pacing modes for current and Pulse Per Minute (PPM) rates.
  - Demand: Only paces when HR is out of programmed range.
  - Fixed: Also utilized for performing PM.



PRONK TECHNOLOGIES

PERFORMING DEFIB PACER TESTING

- Perform testing according to manufacturers' test load impedance requirements. It can vary from one brand to the other.
- Important to test at various pacing currents as specified in service manual. This can include varying the rate, Pulses Per Minute (PPM) as well.



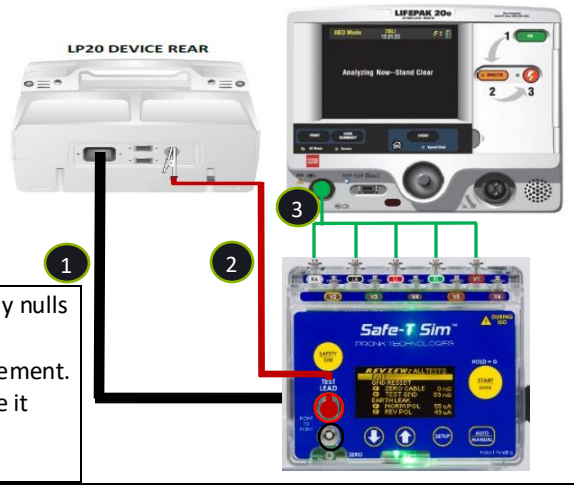
PRONK TECHNOLOGIES

UNDERSTANDING ELECTRICAL SAFETY TESTS

- Tests and electrical safety standard required vary depending on manufacturer.
- Important to understand terminology and pass/fail limits

Example: LIFEPAK 20e
Requires Safety testing per IEC 62353 + IEC 60601 Standards

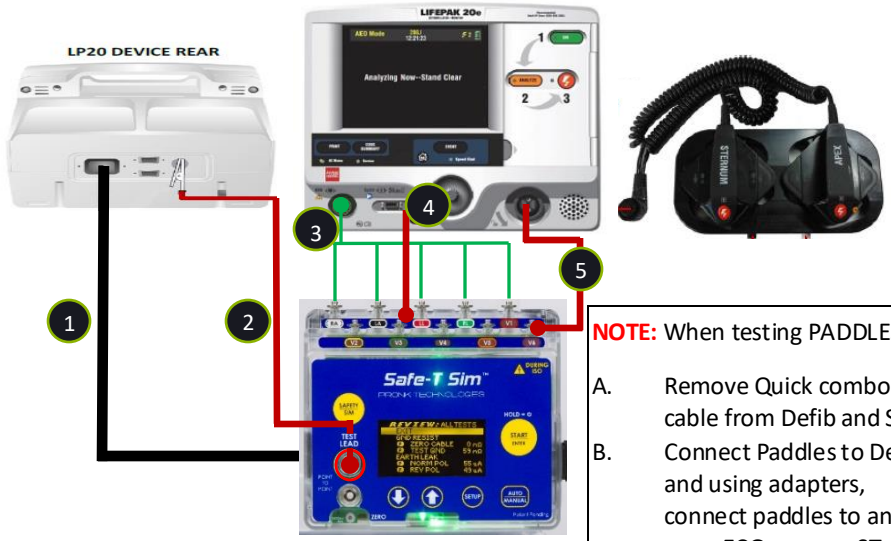
Test #1: Earth Resistance, Earth & Direct Applied Part leakage Tests- ECG
(LifePak 20e PIP Checklist Steps: 12 a, d-e, j-m)
Ground Resistance Limit: 200 mOhms
Earth Leakage Norm. and Rev. Polarity Limit, normal conditions: 2250 µA
Earth Leakage Norm. and Rev. Polarity, Neutral Open Limit: 2625 µA
Lead Leakage ISO (MAP) Norm. and Rev. Polarity, normal conditions Limit: 45 µA



NOTE: ST-1 automatically nulls its Red Test Lead cable resistance from measurement. Not required to measure it manually.

LEGEND
1. *POWER CORD*
2. *PRONK RED TEST LEAD CABLE*
3. *ECG CABLE (3 OR 5 LD.)*
4. *SPO2 LEAKAGE ADAPTER CABLE*
5. *QUICK COMBO THERAPY CABLE*

Test #2: Direct Applied Part leakage Test - Therapy & SpO2
(LifePak 20e PIP Checklist Steps: 12 f- i)
Lead Leakage ISO Norm. and Rev. Polarity, normal conditions Limit: 2625 µA



NOTE: When testing PADDLES:

A. Remove Quick combo cable from Defib and ST-1.

B. Connect Paddles to Defib and using adapters, connect paddles to any open ECG snap on ST-1.

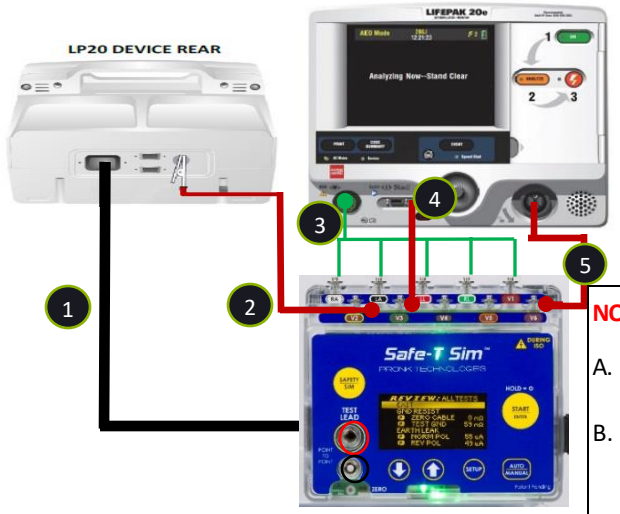
PRONK TECHNOLOGIES

UNDERSTANDING ELECTRICAL SAFETY TESTS

- IEC 62353 utilizes a test not utilized by AAMI/NFPA992012
- Direct Equipment Leakage

Example: LIFEPAK 20e
Requires Safety testing per IEC 62353 + IEC 60601 Standards

Test #3: Direct Equipment leakage Test – Single Fault Condition (SFC)
(LifePak 20e PIP Checklist Steps: 12 b-c)
Lead Leakage to Ground, Norm. and Rev. Polarity, Ground Open Limit: 270 µA
Connect Banana plug side of Red Test lead cable (2) to any ECG snap on ST-1.



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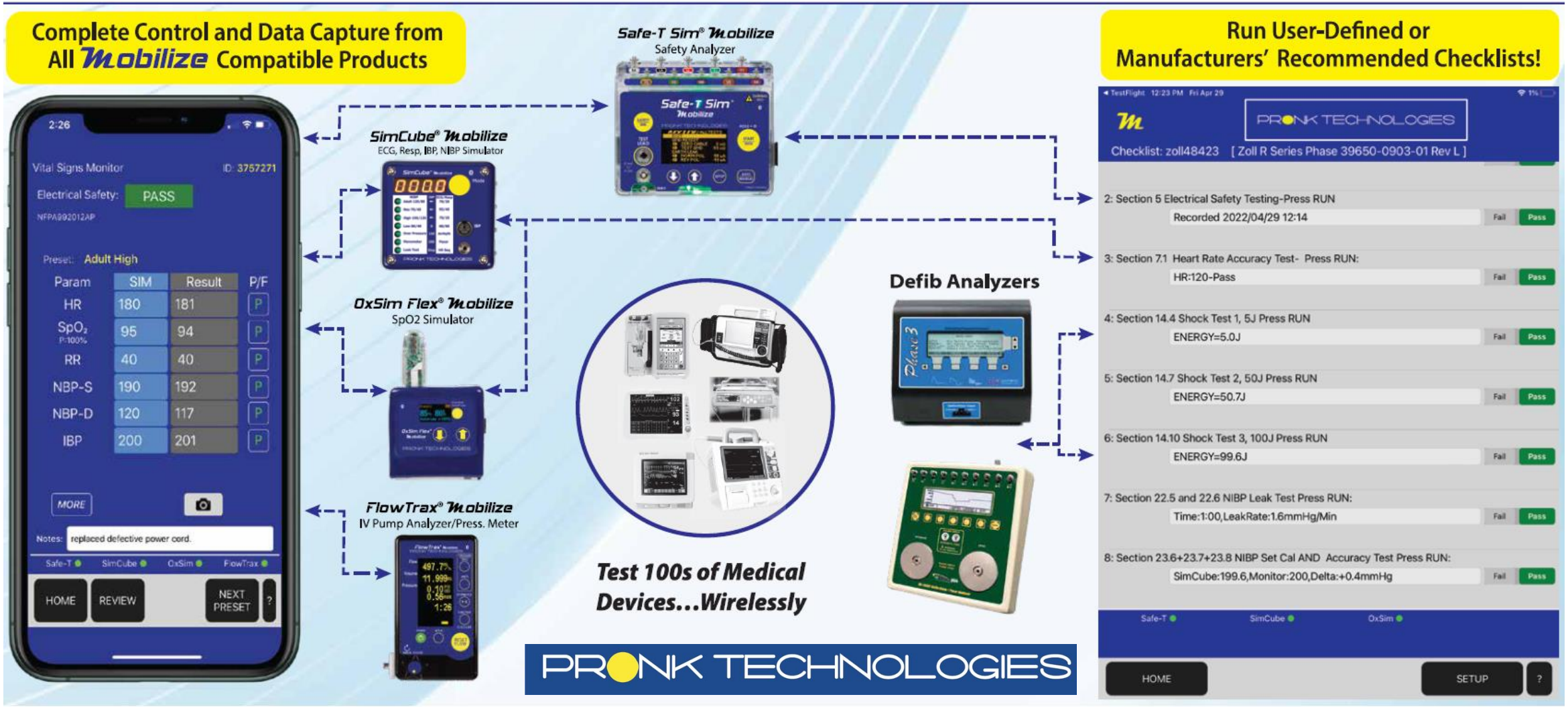
NEW ADVANCES FOR TESTING MEDICAL DEVICES

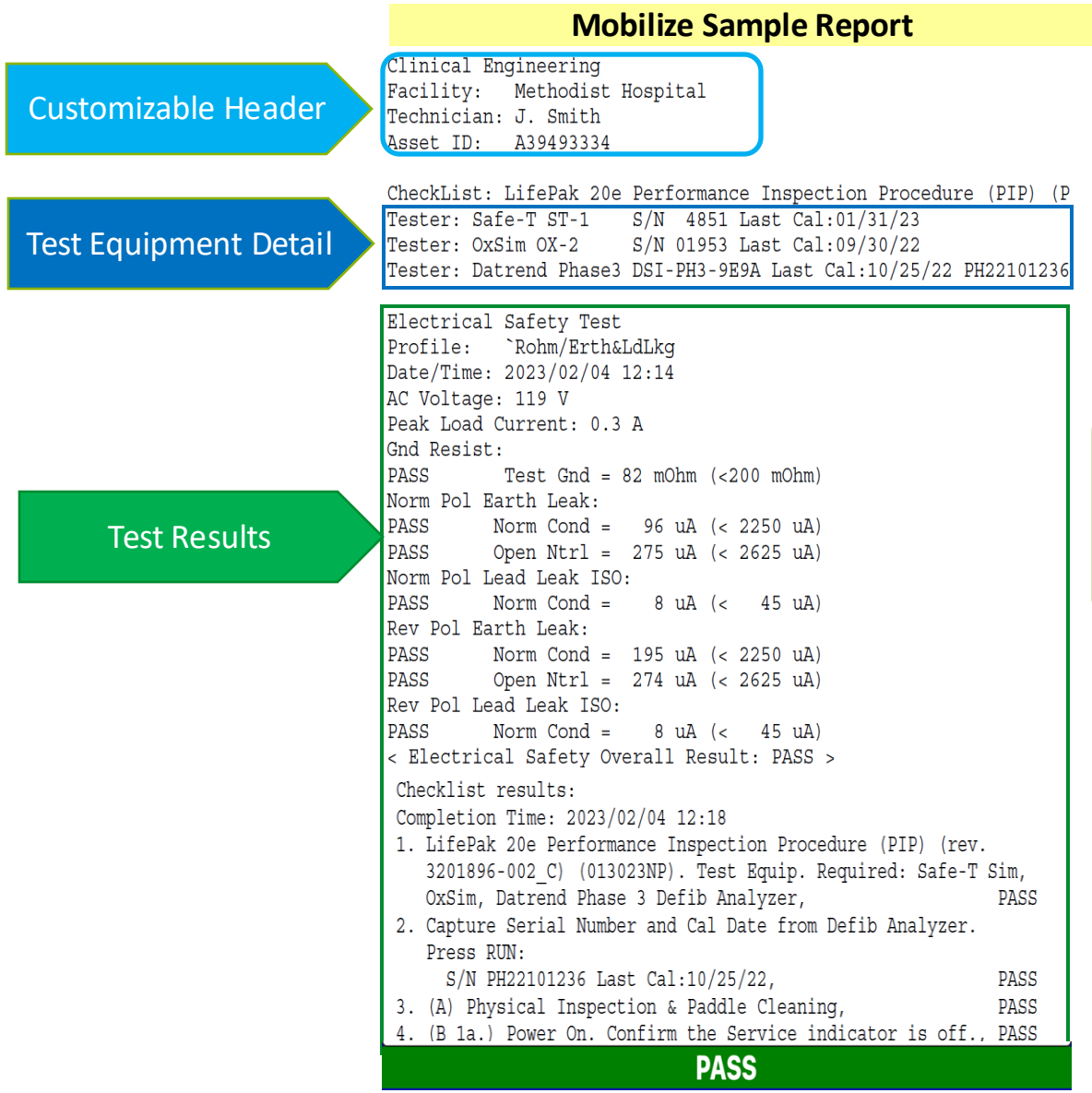


Live Demo

Mobilize

Automatically Generates Electronic Record As you Work

- **Complete Electronic Test Reports**
- **Includes all Test Parameters and Results from Test Protocol/Checklist**
- **Add Notes, Images**
- **PDF, Print, Email, Cloud Drive & CMMS Integration capabilities**

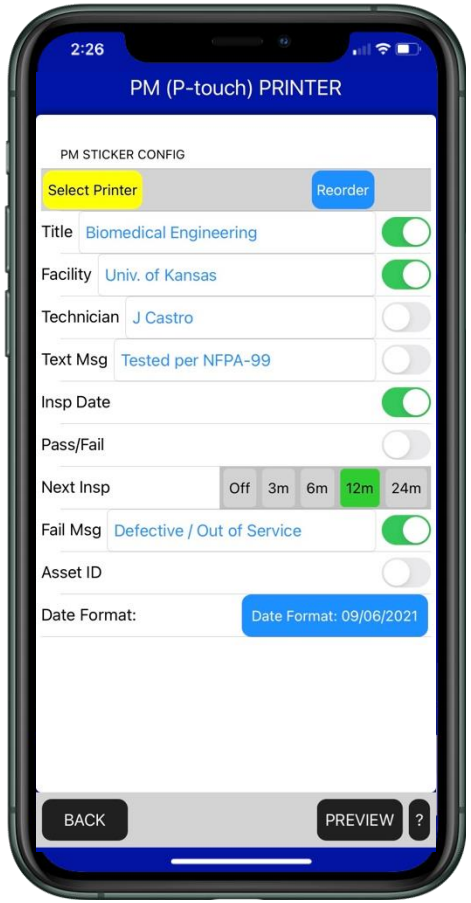


Mobilize Stores up to 1000 Records!

Mobilize

Instant PM Sticker Printing

- Connect Bluetooth Printer to Mobilize and Print Laminated PM Sticker
- Customizable Fields
- Labels Available in Multiple Colors
- Printer Battery operated



Brother P-Touch Cube Plus Printer

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QUESTIONS?

Contact us:

sales@pronktech.com

818-768-5600

www.pronktech.com

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