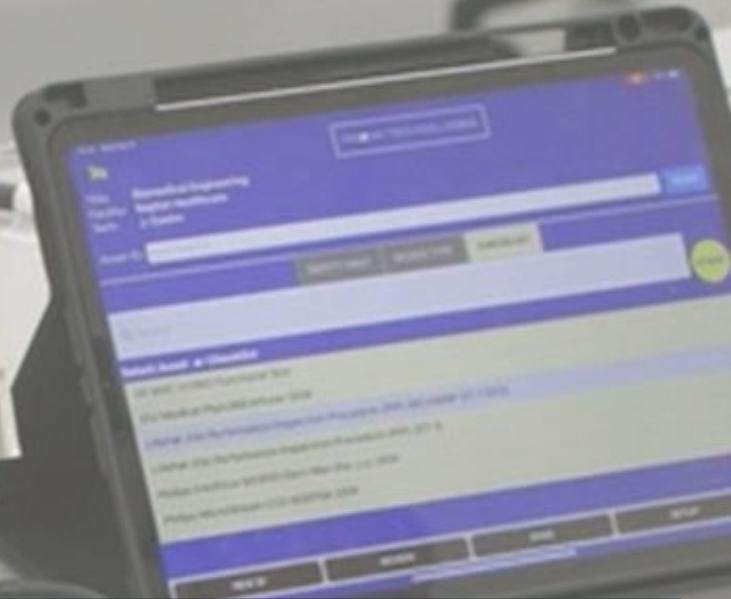




# MD EXPO

New England • October 8-10, 2024



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

**PRONK TECHNOLOGIES**



**MD EXPO**

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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**

# 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.



# RESOURCES FOR PERFORMANCE AND INCIDENT INFORMATION

**FDA U.S. FOOD & DRUG ADMINISTRATION**

Follow FDA | En Español

SEARCH

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

## MAUDE - Manufacturer and User Facility Device Experience

FDA Home Medical Devices Databases

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters<sup>1</sup> (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

[Learn More](#) [Disclaimer](#)

### Search Database

Help Download Files

Product Problem

Product Class

Event Type  Manufacturer

Model Number  Report Number

Brand Name  Product Code

Date Report Received by FDA (mm/dd/yyyy)  to

[Go to Simple Search](#)  Records per Report Page [Clear Form](#)

#### Other Databases

- 510(k)s
- De Novo
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

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

# RESOURCES FOR SERVICE HISTORY INFORMATION

The screenshot shows the FDA MAUDE Adverse Event Report page for a Defibrillator/Pacemaker. The page header includes the FDA logo and navigation tabs for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main title is "MAUDE Adverse Event Report: [redacted] DEFIBRILLATOR/PACEMAKER". Below the title are navigation links for FDA Home, Medical Devices, and Databases. A "CDRH SuperSearch" logo is visible on the left. A navigation menu includes links for 510(k), DeNovo, Registration & Listing, Adverse Events, Recalls, PMA, HDE, Classification, Standards, CFR Title 21, Radiation-Emitting Products, X-Ray Assembler, Medsun Reports, CLIA, and TPLC. The report details include: Model Number [redacted], Device Problem: Failure of Device to Self-Test (2937), Patient Problem: No Clinical Signs, Symptoms or Conditions (4582), Event Type: malfunction, and Manufacturer Narrative: [redacted] has not received the device for evaluation and this complaint is still under investigation. The Event Description section, highlighted with a green border, states: "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." Below the description is a "Search Alerts/Recalls" section and a "New Search | Submit an Adverse Event Report" link. At the bottom, the Brand Name is [redacted] and the Type of Device is DEFIBRILLATOR/PACEMAKER.

# 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



# 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

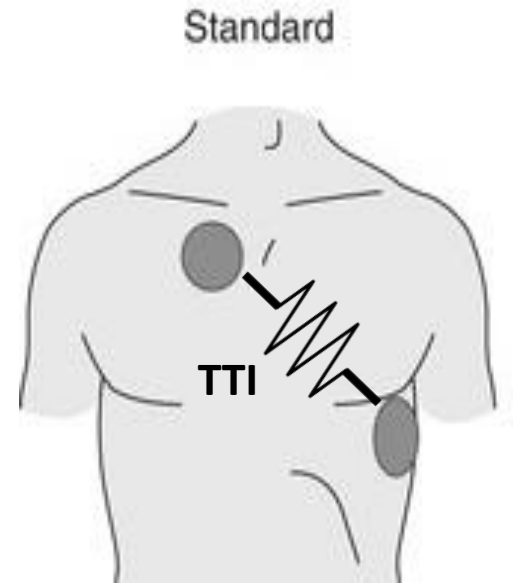
# IMPORTANCE OF VISUAL INSPECTIONS

- **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

# 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.



# 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.



# 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

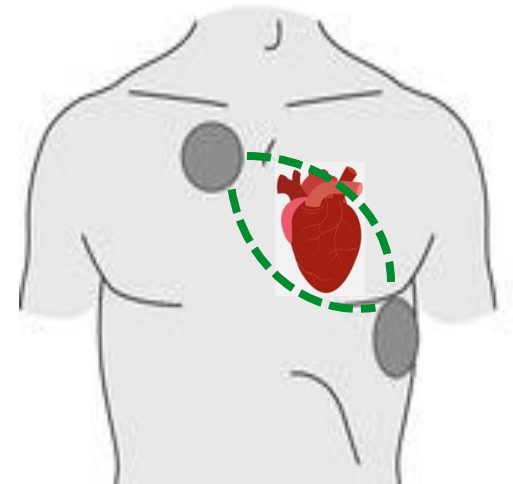
Selected Energy	Load							Accuracy*
	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	
5 J	3 J	5 J	6 J	6 J	6 J	6 J	6 J	±15%
50 J	35 J	54 J	59 J	61 J	62 J	61 J	59 J	±15%
100 J	71 J	109 J	119 J	122 J	125 J	123 J	119 J	±15%
200 J	142 J	230 J	249 J	253 J	269 J	261 J	260 J	±15%

**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*.



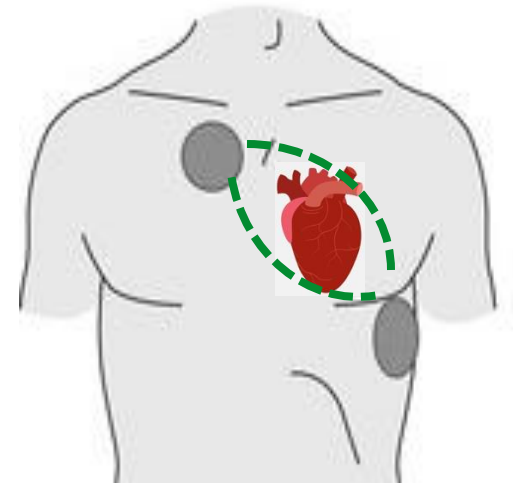
# DEFIB TRANSCUTANEOUS PACING (TCP)

- 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.



# 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.



# 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

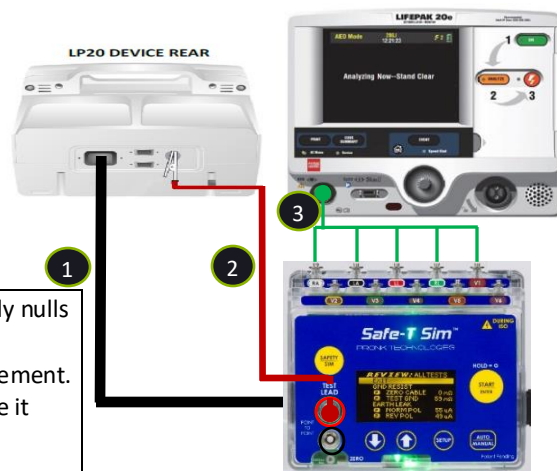
(LifePak 20e PIP Checklist Steps: 12 a, d-e, j-m)

Ground Resistance Limit: 200 mOhms

Earth Leakage Norm. and Rev. Polarity Limit, normal conditions: 2250  $\mu$ A

Earth Leakage Norm. and Rev. Polarity, Neutral Open Limit: 2625  $\mu$ A

Lead Leakage ISO (MAP) Norm. and Rev. Polarity, normal conditions Limit: 45  $\mu$ A



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

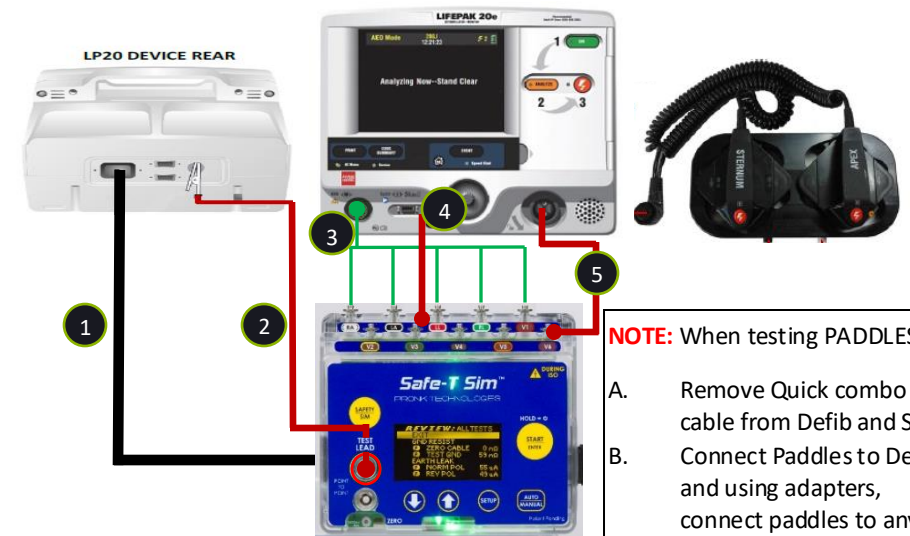
### LEGEND

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  $\mu$ A



**NOTE:** When testing PADDLES:

- Remove Quick combo cable from Defib and ST-1.
- Connect Paddles to Defib and using adapters, connect paddles to any open ECG snap on ST-1.

# UNDERSTANDING ELECTRICAL SAFETY TESTS

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

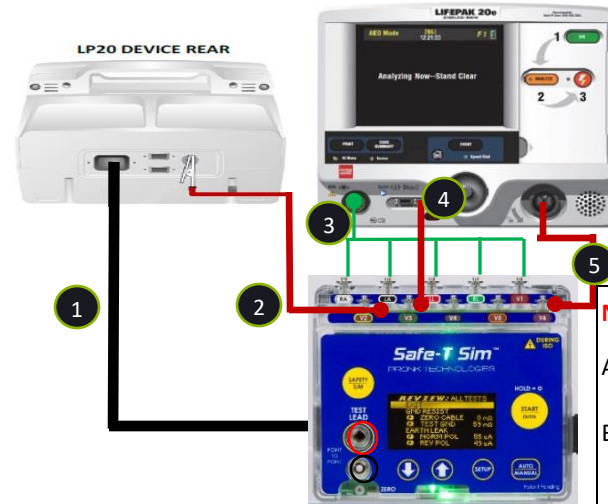
Example: LIFEPAK 20e  
Requires Safety testing per IEC  
62353 + IEC 60601 Standards

## 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  $\mu$ A

Connect Banana plug side of Red Test lead cable (2) to any ECG snap on ST-1.



**NOTE:** When testing PADDLES:

- Remove Quick combo cable from Defib and ST-1.
- Connect Paddles to Defib and using adapters, connect paddles to any open ECG snap on ST-1.

### 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

# NEW ADVANCES FOR TESTING MEDICAL DEVICES

Complete Control and Data Capture from All *Mobilize* Compatible Products



**SimCube<sup>®</sup> Mobilize**  
ECG, Resp, IBP, NBP Simulator



**OxDim Flex<sup>®</sup> Mobilize**  
SpO<sub>2</sub> Simulator



**FlowTrax<sup>®</sup> Mobilize**  
IV Pump Analyzer/Press. Meter



**Safe-T Sim<sup>®</sup> Mobilize**  
Safety Analyzer



Test 100s of Medical Devices...Wirelessly

**Defib Analyzers**



Run User-Defined or Manufacturers' Recommended Checklists!



PRONK TECHNOLOGIES

# Live Demo



## 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

Customizable Header

Clinical Engineering  
Facility: Methodist Hospital  
Technician: J. Smith  
Asset ID: A39493334

Test Equipment Detail

CheckList: LifePak 20e Performance Inspection Procedure (PIP) (P)  
Tester: Safe-T ST-1 S/N 4851 Last Cal:01/31/23  
Tester: OxSim OX-2 S/N 01953 Last Cal:09/30/22  
Tester: Datrend Phase3 DSI-PH3-9E9A Last Cal:10/25/22 PH22101236

Test Results

Electrical Safety Test  
Profile: `Rohm/Erth&LdLkg  
Date/Time: 2023/02/04 12:14  
AC Voltage: 119 V  
Peak Load Current: 0.3 A  
Gnd Resist:  
PASS Test Gnd = 82 mOhm (<200 mOhm)  
Norm Pol Earth Leak:  
PASS Norm Cond = 96 uA (< 2250 uA)  
PASS Open Ntrl = 275 uA (< 2625 uA)  
Norm Pol Lead Leak ISO:  
PASS Norm Cond = 8 uA (< 45 uA)  
Rev Pol Earth Leak:  
PASS Norm Cond = 195 uA (< 2250 uA)  
PASS Open Ntrl = 274 uA (< 2625 uA)  
Rev Pol Lead Leak ISO:  
PASS Norm Cond = 8 uA (< 45 uA)  
< Electrical Safety Overall Result: PASS >  
  
Checklist results:  
Completion Time: 2023/02/04 12:18  
1. LifePak 20e Performance Inspection Procedure (PIP) (rev. 3201896-002 C) (013023NP). Test Equip. Required: Safe-T Sim, OxSim, Datrend Phase 3 Defib Analyzer, PASS  
2. Capture Serial Number and Cal Date from Defib Analyzer.  
Press RUN:  
S/N PH22101236 Last Cal:10/25/22, PASS  
3. (A) Physical Inspection & Paddle Cleaning, PASS  
4. (B 1a.) Power On. Confirm the Service indicator is off.. PASS

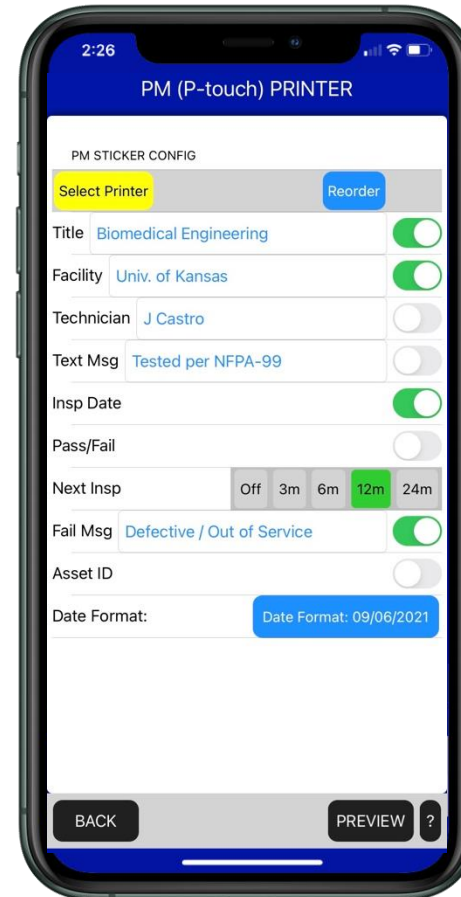
**PASS**

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?

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818-768-5600

[www.pronktech.com](http://www.pronktech.com)

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