



# Overview of MedSun Survey

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**Battery-Powered Medical Devices: Challenges and Opportunities**

**Public Workshop**

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# Medical Product Safety Network “MedSun”

- **Group of 250 hospitals and other healthcare facilities that send reports about issues, concerns and challenges with medical devices and will answer questions about device use.**

# Purpose of the Survey

- **To talk with healthcare providers and other hospital staff to learn about their experiences and challenges**

# Small Sample Surveys

- **Obtain information quickly from the clinical community**
- **Responses are**
  - **Voluntary**
  - **Qualitative - may not represent all device users' experiences**

# Methodology

- **9 telephone interviews with hospital staff conducted**
- **Respondents:**
  - **Biomedical/Clinical Engineers**
  - **Risk Managers**
  - **Nurses**
  - **Purchasing Directors**
- **MedSun hospitals from different regions of the country**

# Focus of Questions

- **Performance**
- **Preventive Maintenance**
- **Labeling & Instructions**
- **Training**
- **Selection and Purchasing Procedures**
- **Suggestions for Improvement**

# Device Performance

- **Devices with most frequent issues:**
  - Large volume infusion pumps
  - Telemetry boxes
  - Pulse oximeters
  - Thermometers
  - Electric beds
  - Monitors
  - Portable/mobile devices

# Types of Battery-Related Issues

<b>Issue/Challenge</b>	<b>Reported/Potential Outcome</b>
Failure to plug in device	Premature depletion; loss of power
Overcharging	Overheating; fire; explosion;
Undercharging	Premature depletion; loss of power
Inaccessible plugs/outlets	Premature depletion; loss of power
Leakage	Fire



# Types of Battery-Related Issues

<b>Issue/Challenge</b>	<b>Reported/Potential Outcome</b>
Swelling	Explosion
Confusion with on/off button	Premature depletion; loss of power
Loose connections	Premature depletion; loss of power
Incorrect replacement	Leakage; increased heat; fire;

# Example

- **Infant isolette temperature setting**
  - Severe weather caused power loss
  - Emergency generator on after 5-6 seconds
  - Memory battery did not back up setting
  - Temperature reverted to manufacturer default setting
  - Isolette became too hot

# Examples

- **Temporary external pacemaker**
  - No indication battery is low or depleting
  - When depleted, staff have 2 to 5 seconds to replace battery
- **MRI conditional monitor**
  - Battery cells can go bad even when device is plugged-in

# Preventive Maintenance (PM)

- **Proactive battery replacement**
  - Based on level of device risk
  - Manufacturer recommendations
  - Hours of usage
  - Ranges from every 6 months to 5 years
- **Service calls for battery issues**
  - Up to 50% of calls
  - Number depends on person responsible and what is needed

# Labeling and Instructions for Battery-Powered Devices

- **Most - clear, adequate**
- **Manuals - often not with the device and may not include when to service or replace battery**
- **Quick guides are helpful but may not include the time needed for battery-charging and may detach from the device**
- **Work pressures, constant transport of patients and devices contribute to devices not plugged-in**

# Training

- **Need consistent and on-going education and training**
- **Provide staff with information about cost implications for replacing batteries**

# Selection and Purchasing

- **Processes and factors similar among hospitals**
- **Based on high risk versus low risk devices**
- **Other factors:**
  - **Cost**
  - **Facility equipment needs**
  - **Quality of battery life**
  - **Technical specifications**

# Suggestions for Improvement

- **Standardization across device types for battery charging, replacement, service intervals, and disposal**
- **Visual indicators**
- **Improved and permanent labeling**



# Suggestions for Improvement

- **Improved technology to eliminate the need for manual battery charging**
- **Access to performance and testing data about device failures**
- **In FDA recall notices, identify the battery and include if battery problem is associated with root cause**



**MedSun Survey Report about  
“Batteries in Medical Devices”  
on FDA’s MedSun Website**

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/action.cfm>



# Thank You