



Batteries in the Home Use Environment

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July 31, 2013



What is considered “Home”?

Any environment other than a professional healthcare facility or clinical laboratory where a device may be used (CDRH’s current definition)



Why Focus on the Home?

- Faster discharges from clinical facilities
- Elderly population
- Individuals with chronic diseases



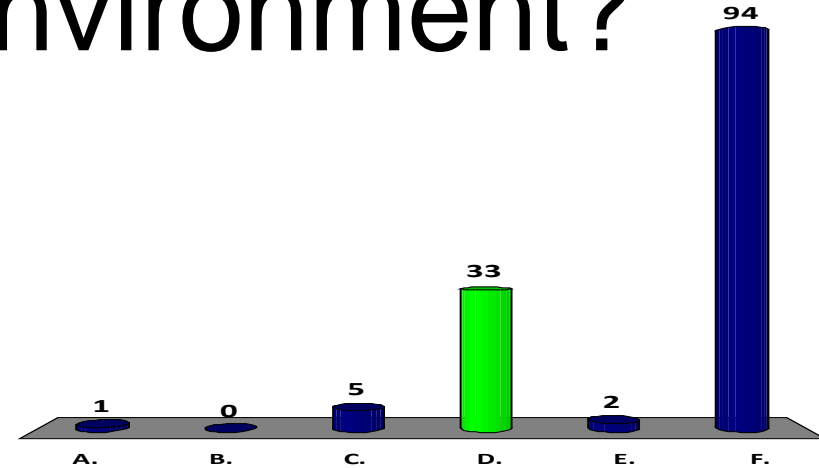
Home Care Facts

- 17,000 home care organizations (9284 Medicare certified)
- 7.6 million individuals in home care
- \$57.6 billion per year
- Growing 20% per year
- 75% receive skilled nursing
- 69% > 65 years old
- 44 million are caregivers of someone >18
- 2/3 are women
- By 2030, 71.5 million over 65
- 1/5 US adults report a disability (47.5 million)

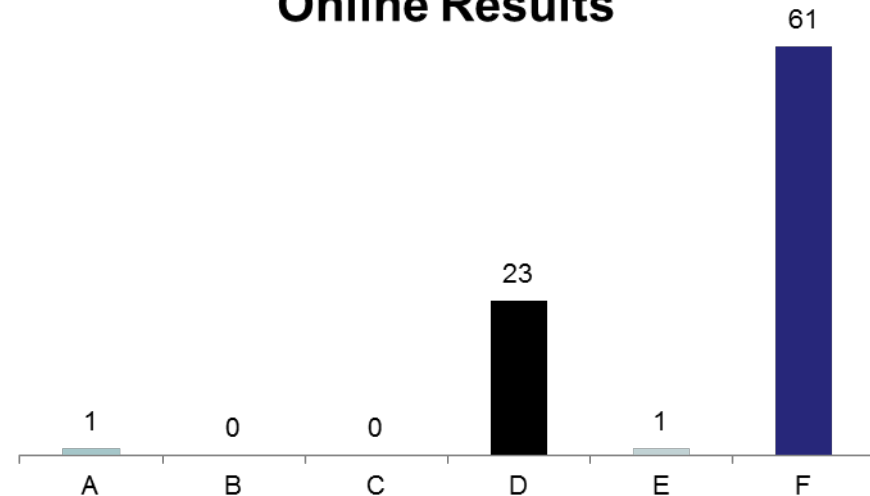


What Device is Currently Not Used in a Home Environment?

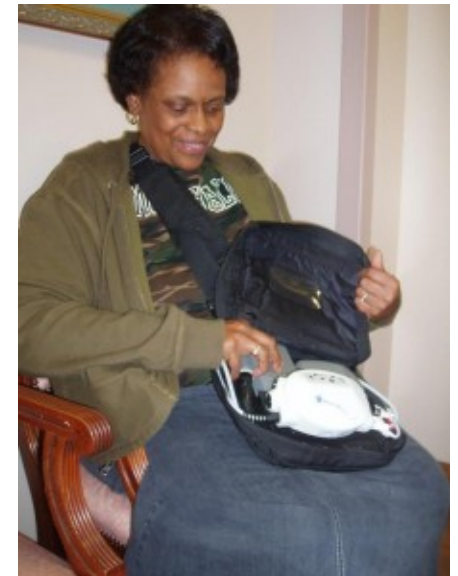
- A. Hemodialysis machine
- B. Ventricular assist device
- C. Phototherapy device
- ✓ D. Lithotripsy
- E. Ventilator
- F. X-ray machine



Online Results



Devices with Batteries in the Home



Home Use Medical Device Initiative 2010

- 1. Establish guidelines for manufacturers of home use devices;**
2. Develop a home use device labeling repository;
3. Partner with home health accrediting bodies to support safe use;
4. Enhance postmarket oversight; and
5. Increase public awareness and education





Guidance

Draft Guidance for Industry and FDA Staff –
Design Considerations for Devices
Intended for Home Use:

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm331675.htm>

Finalizing this year

The Use Environment

- Location
- Temperature
- Dampness and Humidity
- Contaminants
- Atmospheric pressure changes



- Airflow
- Childproofing
- Traveling and International Use
- Fluid Exposure



The User

Physical

Size, mobility, dexterity, coordination, flexibility, strength

Sensory/Perceptual

Vision/hearing abilities, tactile sensitivities, ambient light conditions, alarm visibility

Cognitive

Literacy level, cognitive impairment

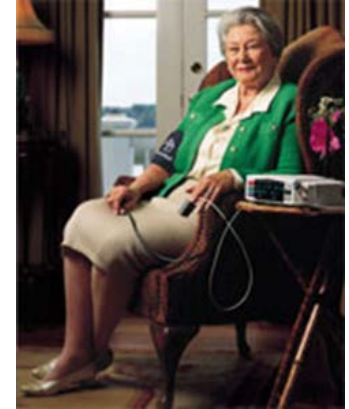
Emotional

Anxiety, fear



The Device

- Lock-out Mechanisms
- Calibration
- Mechanical Strength
- Electromagnetic Compatibility (EMC)
- Wireless Technology
- Alarm Systems



The Device - Electrical Issues

- Supply Mains
 - Interruption of power supply/supply mains
 - Voltage limitations
- Internal electrical power source
 - Typical operation time
 - Recharging
 - Replacing
- Permanently installed devices
 - Protective grounding
- Outlets and Adapters
 - Surge protection
- Power outages
 - Back-up power
 - Emergency contact information
- Battery life



Also consider...

- **Human Factors**

- Validation
- Usability

- **Labeling**

- Simple, easily understood
- User training
- Certification

- **Postmarket**

- Customer service
- Reporting
- Selling and purchasing used Rx devices



Case Study

- ECG
- Lithium-ion battery
- Recharging on kitchen counter
- Popping noises
- Battery on floor
- 15 feet away and in flames
- Son stomped on battery
- No injuries





Resources

- **Reporting adverse events to FDA:**
 - Call 1-800-332-1088
 - Fill online form:
www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
- **Medical Device Reporting: MedWatch**
<http://www.fda.gov/safety/medwatch/howtoreport/downloadforms/ucm149238.htm>
- **FDA Patient Network:** www.patientnetwork.fda.gov
- **FDA's Home Use Devices website:**
www.fda.gov/homeusedevices